PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

United States of America ex rel. Michael K. Drakeford, M.D.,

Plaintiff-Appellee,

v.

TUOMEY HEALTHCARE SYSTEM, INCORPORATED,

Defendant-Appellant,

v.

Womble, Carlyle, Sandridge and Rice Law Firm; Wesmark Ambulatory Surgery Center, LLC; James Arthur Goodson, III, M.D.; Kim Saccone,

Movants.

American Hospital Association,

Amicus Supporting Appellant.

No. 10-1819

Appeal from the United States District Court for the District of South Carolina, at Columbia. Matthew J. Perry, Jr., Senior District Judge. (3:05-cv-02858-MJP)

Argued: January 20, 2012

Decided: March 30, 2012

Before DUNCAN, WYNN, and DIAZ, Circuit Judges.

Vacated and remanded by published opinion. Judge Duncan wrote the opinion, in which Judge Diaz joined. Judge Wynn wrote a separate opinion concurring in the result.

COUNSEL

ARGUED: William Walter Wilkins, NEXSEN PRUET, LLC, Greenville, South Carolina; Arthur Camden Lewis, LEWIS, BABCOCK & GRIFFIN, LLP, Columbia, South Carolina, for Appellant. Tracy Lyle Hilmer, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. ON BRIEF: Kirsten E. Small, NEXSEN PRUET, LLC, Greenville, South Carolina; Mary G. Lewis, W. Jonathan Harling, LEWIS & BABCOCK, LLP, Columbia, South Carolina; Daniel M. Mulholland, III, HORTY, SPRINGER & MATTERN, PC, Pittsburgh, Pennsylvania, for Appellant. Tony West, Assistant Attorney General, Michael D. Granston, Michael S. Raab, Niall M. O'Donnell, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; G. Norman Acker, III, Assistant United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Raleigh, North Carolina, for the United States. Sandra L. W. Miller, WOMBLE CARLYLE SANDRIDGE & RICE, PLLC, Greenville, South Carolina; Kevin Mitchell Barth, BAL-LENGER, BARTH & HOEFER, LLP, Florence, South Carolina, for Michael K. Drakeford, M.D. Melinda R. Hatton, Maureen D. Mudron, AMERICAN HOSPITAL ASSOCIA-TION, Washington, D.C.; Jonathan L. Diesenhaus, Jessica L. Ellsworth, HOGAN LOVELLS US LLP, Washington, D.C., for Amicus Supporting Appellant.

OPINION

DUNCAN, Circuit Judge:

This appeal arises from the district court's order granting final judgment to the United States upon equitable¹ claims of payment by mistake of fact and unjust enrichment against appellant Tuomey Healthcare System, Inc. ("Tuomey") arising out of alleged violations of the Social Security Act, and awarding damages in the amount of \$44,888,651.00, plus preand post-judgment interest.

In the underlying action, the United States alleged that Tuomey entered into compensation arrangements with certain physicians that violated section 1877 of the Social Security Act, commonly known as the Stark Law, 42 U.S.C. § 1395nn. Because the Stark Law does not create its own right of action, the United States sought relief under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33.² The United States further asserted equitable claims premised on the alleged Stark Law violation, including payment under mistake of fact and unjust enrichment. A jury returned a verdict finding that Tuomey did not violate the FCA, but responded affirmatively to a special interrogatory regarding whether it had violated the Stark Law. The district court set aside the jury verdict and ordered a new trial on the FCA claim. It further ordered that, based on the jury verdict, the United States was entitled to judgment on its equitable claims.

¹There is some dispute, discussed below, over whether the claims for payment under mistake of fact and unjust enrichment were legal or equitable in nature. For the reasons we set forth below, we deem the government's claims equitable.

²The United States claimed that Tuomey falsely certified compliance with the Stark Law in connection with claims submitted to the Medicare program, which is actionable under the FCA. *See United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009).

Because we conclude that the district court's judgment in the United States' favor violated Tuomey's Seventh Amendment right to a jury trial, we vacate the judgment and remand for further proceedings. Because we are remanding this case, we also address other issues raised on appeal that are likely to recur upon retrial.

I.

A.

We begin by setting out the statutory framework that forms the basis for the United States' allegations in the underlying proceeding. We first set forth the provisions of the FCA, as relevant to this appeal. We then discuss the pertinent provisions of the Stark Law.

1.

The FCA is a statutory scheme designed to discourage fraud against the federal government. 31 U.S.C. § 3729(a)(i) provides, in relevant part, that "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000 . . . plus 3 times the amount of damages which the Government sustains because of the act of that person." Section 3729(b)(1) defines the term "knowingly" to "mean that a person, with respect to information . . . 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," with the additional provision that "no proof of specific intent to defraud" is required. Section 3729(b)(2) further defines, in relevant part, the term "claim" as "any request or demand, whether under a contract or otherwise, for money or property . . . that . . . is presented to an officer, employee, or agent of the United States."

2.

The Stark Law was enacted to address overutilization of services by physicians who stood to profit from referring patients to facilities or entities in which they had a financial interest. The Stark Law, and regulations promulgated pursuant thereto ("Stark Regulations")³ prohibit a physician who has a "financial relationship" with an entity—such as a hospital—from making a "referral" to that hospital for the furnishing of certain "designated health services" for which payment otherwise may be made by the United States under the Medicare program. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a).⁵ A hospital may not submit for payment a Medicare claim for services rendered pursuant to a prohibited 42 § 1395nn(a)(1)(B); referral. U.S.C. § 411.353(b). The United States may not make payments pursuant to such a claim, and hospitals must reimburse any payments that are mistakenly made by the United States. 42

³The agencies charged with promulgating regulations pursuant to the Stark Law have published three sets of regulations relevant to this appeal: the Phase I rules, 66 Fed. Reg. 856 (2001); the Phase II rules, 69 Fed. Reg. 16,054 (2004); and the Phase III rules, 72 Fed. Reg. 51,012 (2007). Each phase of rulemaking was also accompanied by extensive official agency commentary. *See* 66 Fed. Reg. at 856-952 (2001) (Phase I); 69 Fed. Reg. at 16054-126 (2004) (Phase II); 72 Fed. Reg. at 51012-79 (2007) (Phase III).

⁴The prohibition applies to eleven "designated health care services," including inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6).

⁵The Medicare and Medicaid programs were enacted to pay for the costs of certain healthcare services. The United States Department of Health and Human Services ("HHS") is responsible for the administration and supervision of those programs. The Centers for Medicaid and Medicare Services ("CMS") (previously known as the Health Care Financing Administration ("HCFA")) is an agency of HHS and is directly responsible for the administration of the Medicare program. Under the Medicare program, CMS makes payments retrospectively (after the services are furnished) to healthcare entities, such as hospitals, for inpatient and outpatient services.

U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(c), (d). However, when a physician initiates a service and personally performs it, that action does not constitute a referral under the Stark Law. 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.

The Stark Law and Stark Regulations define a "financial relationship" to include "a compensation arrangement" in which "remuneration" is paid by a hospital to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. §§ 1395nn(a)(2), (h)(1); 42 C.F.R. § 411.354. An indirect financial relationship exists if, inter alia, there is an indirect compensation arrangement between the referring physician and an entity that furnishes services. An indirect compensation arrangement exists if, inter alia, the referring physician receives aggregate compensation that "varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing" services. 42 C.F.R. § 411.354(c)(2)(ii) (emphasis added).6

The Stark Regulations provide that certain enumerated compensation arrangements do not constitute a "financial relationship." 42 C.F.R. § 411.357. Significantly for our purposes, a subset of indirect compensation arrangements do not constitute a financial relationship if the compensation received by the referring physician is (1) equal to the "fair market value for services and items actually provided"; (2)

⁶Such an arrangement further requires an "unbroken chain" between the referring physician and the entity furnishing the services, and the entity must have knowledge or act in reckless disregard of the fact that the physician receives compensation that varies with or takes into account the volume or value of referrals. 42 C.F.R. § 411.354(c)(2). Neither of those elements is contested by the parties on appeal.

⁷The Stark Regulations define "fair market value" as:

[[]T]he value in arm's-length transactions, consistent with the general market value. "General market value" means the price that an asset would bring as the result of bona fide bargaining between

"not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician" for the hospital; and (3) "commercially reasonable." 42 C.F.R. § 411.357(p). Subsection 411.357(p) is known as the "indirect compensation arrangements exception." *See*, *e.g.*, 72 Fed. Reg. at 51,014.

В.

We now turn to the contracts that gave rise to this litigation. Tuomey is a private, nonprofit corporation incorporated in the State of South Carolina. It owns and operates Tuomey Hospital, located in Sumter County, South Carolina. Tuomey Hospital provides inpatient and outpatient health care services. Most of the physicians who provide medical services at Tuomey Hospital are not employed by Tuomey but rather practice medicine through specialty physician groups organized as professional corporations.

In early 2003, the members of Sumter County's gastroenterology specialty group informed Tuomey that they were

well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is . . . the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, . . . [and] has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

42 C.F.R. § 411.351 (emphasis added).

⁸A "commercially reasonable" arrangement is one that "would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician . . . of similar scope and specialty, even if there were no potential [service] referrals" pursuant to the arrangement. 69 Fed. Reg. at 16,093.

considering whether to perform outpatient surgical procedures in-office, rather than at Tuomey Hospital. Other specialty physician groups that performed outpatient procedures at Tuomey Hospital were also considering whether to relocate such procedures. The loss of these outpatient surgical procedures posed a serious financial concern for Tuomey. To dissuade the specialist physicians from performing their outpatient procedures elsewhere, Tuomey sought to enter into agreements with specialist physicians to perform outpatient procedures solely at Tuomey Hospital. Specifically, during 2004 and 2005, Tuomey negotiated with all of the specialist physicians on its medical staff. One of those physicians was appellee Dr. Michael Drakeford, an orthopedic surgeon, with whom negotiations unsuccessfully ended in 2005.

Between January 1, 2005, and November 15, 2006, Tuomey entered into compensation contracts with 19 specialist physicians. All of the contracts included essentially the same terms. Each contract specified that the physician was required to provide outpatient procedures at Tuomey Hospital or at facilities owned or operated by it. Under each contract, Tuomey was solely responsible for billing and collections from patient and third-party payors for outpatient procedures, and the physician expressly reassigned to Tuomey all benefits payable to the physician by third party payors, including Medicare and Medicaid. Tuomey agreed to pay each physician an annual base salary that fluctuated based on Tuomey's net cash collections for the outpatient procedures. Tuomey further agreed to pay each physician a "productivity bonus" equal to 80 percent of the net collections. Moreover, each physician was eligible for an incentive bonus that could total up to 7 percent of the productivity bonus. Each contract had a tenyear term and provided that the physicians would not compete with Tuomey during the term of the contract and for two years thereafter.

Pursuant to the contracts, the physicians performed outpatient procedures at Tuomey facilities. The outpatient procedures generated two billings: a professional fee for the physician for his or her services, also known as the "professional component"; and a facility fee for Tuomey for providing the space, the nurses, the equipment, etc., also known as the "facility component" or "technical component." Subsequent to the performance of the procedures, Tuomey submitted claims requesting reimbursement for both the professional fee and the facility fee to third-party payors, including Medicare and Medicaid. As relevant here, Tuomey presented, or caused to be presented, to Medicare and Medicaid claims for payment of the facility fees generated as a result of outpatient procedures performed pursuant to the contracts. ¹⁰

C.

1.

In October 2005, Drakeford filed an action in the District Court for the District of South Carolina under the qui tam provisions of the FCA, 31 U.S.C. § 3730(b). In September 2007, the United States intervened in Drakeford's qui tam action as to the issue of whether Tuomey submitted false claims as a result of the contracts with the physicians. The government subsequently filed its own complaint. Pertinent to this appeal, the government asserted three causes of action: Count I (False Claims Act, 31 U.S.C. § 3729(a)(1) Presenting Claims to Medicare and Medicaid for Designated Health Services Rendered as a Result of Violations of the Stark Statute); Count IV (payment under mistake of fact); and Count V (unjust enrichment). The province of the Stark Statute).

⁹For clarity, we will refer to it as the "facility component."

¹⁰The number and value of such claims is in dispute.

¹¹31 U.S.C. § 3730(b)(2) provides that the government may elect to intervene and proceed with a § 3730(b) action.

¹²All references to the government's complaint are to the Second Amended Complaint of the United States, filed on November 12, 2008.

¹³The Second Amended Complaint contained six counts. As we understand it, Counts II (Use of False Statements) and III (False Record to

Specifically, Count I alleged that Tuomey knowingly presented, or caused to be presented, false and fraudulent claims for payment or approval to the United States, including those claims for reimbursement for services rendered to patients who were referred by physicians with whom Tuomey had entered into financial relationships—i.e., the contracts—in violation of the Stark Law. Count I further sought the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law.

Count IV alleged that the United States had compensated Tuomey as a result of mistaken understandings of fact. Specifically, it alleged that Tuomey was not entitled to receive payment from the United States for services rendered by any physician who was in a financial relationship prohibited by the Stark Law, and that the United States paid Tuomey for such prohibited claims under the mistaken belief that Tuomey was entitled to receive payment for these claims. Accordingly, the United States claimed that Tuomey was liable to it for the amount of the payments made in error to Tuomey by the United States.

Count V alleged that by obtaining government funds to which it was not entitled, Tuomey was unjustly enriched. The United States claimed that Tuomey was liable to it for such amounts, or the proceeds therefrom, to be determined at trial.

2.

The government's claims under the FCA were tried to a jury in March 2010. At the conclusion of the evidence, the district court instructed the jury that the United States had brought the case

Avoid an Obligation to Refund), which both alleged FCA violations, were subsequently dismissed. Count VI, which alleged an equitable claim of disgorgement, constructive trust, and accounting, does not appear to have been dismissed, but it is not before us on appeal.

asserting that the defendant has committed fraud under the Medicare program. . . . The United States alleges that beginning on or about January 1, 2005, and continuing until the present, Tuomey presented false claims to the United States by submitting claims in violation of the Stark Law when Tuomey knew that the defendant was not entitled to receive payment for the claims.

J.A. 976-77.

The district court further instructed the jury regarding the elements of a Stark Law violation, as well as the elements of an FCA violation. With regard to the Stark Law, the district court instructed the jury to conduct a two-step inquiry to determine whether Tuomey violated the statute. At step one of the inquiry, the jury was to determine whether the contracts are indirect compensation arrangements as defined by the Stark Law and Stark Regulations. For the jury to find in favor of the government, it was required to prove that the physicians received aggregate compensation from Tuomey, and that such compensation varied with or otherwise took into account the volume or value of the physicians' referrals to Tuomey. If the jury answered step one in the affirmative, at step two of the inquiry, it was to determine whether Tuomey had proven by a preponderance of the evidence that the contracts fell within the indirect compensation arrangement exception. The district court further instructed the jury to determine the number and value of the claims for services that the physicians referred pursuant to the contracts, and for which Tuomey received payment from Medicare.

With regard to the FCA claim, the district court instructed the jury:

[T]he United States must establish by a preponderance of the evidence the following: One, that Tuomey presented or caused to be presented to Med-

icare; two, false or fraudulent claims for payment; and three, that Tuomey knew that the claims for payment were false or fraudulent. If you find that the United States has established these elements by a preponderance of the evidence then, of course, you may find a verdict for the United States.

J.A. 989. With respect to the second element of an FCA violation, i.e., whether the claims were false or fraudulent, the district court instructed the jury:

What is false? In this case, the United States alleges that certain of the defendant's claims were false because Tuomey was in violation of the Stark Law. For purposes of this case, a claim is false if it was submitted to Medicare in violation of the Stark Law.

J.A. 990. With respect to the third element of an FCA violation, i.e., whether Tuomey knew the claims for payment were false or fraudulent, the district court instructed the jury:

[F]or purposes of the [FCA], a person knows that a claim is false if a person, one, has actual knowledge of the information, or two, acts in deliberate ignorance of the truth or falsity of the information, or, three, acts in reckless disregard of the truth or falsity of the information. It is not necessary that the United States prove that the defendant intended to submit false claims. . . . In order to find that Tuomey took action knowingly, you . . . would need to find that at least one individual employee or agent of Tuomey knew that Tuomey was submitting claims to Medicare and knew that the claims were false.

J.A. 990-91. The district court further instructed the jury with respect to damages under the FCA:

If you find that the defendant has violated the [FCA], you must then determine the damages sustained by

the United States because of the violations. The measure of the United States' damages under the [FCA] is the amount of money that the United States paid out by reason of the false claims. Defendant's compliance with the Stark Law was a condition of the government's payment decision. If the defendant violated the Stark Law, defendant was not allowed to submit claims for payment to Medicare for services that were referred by the physician whose compensation arrangement violated the Stark Law. And if defendant violated the Stark Law, Medicare was not allowed to pay for any services furnished that were referred by the physicians whose compensation arrangements violated the Stark Law. Therefore, your calculation of damages should be based on what the Medicare program paid to the defendant in violation of the Stark Law. . . . If you find the hospital, Tuomey, liable under the [FCA], then you must determine the number of false claims that the defendant submitted to the United States.

J.A. 992-93.

The district court provided the jury with a verdict form, with respect to which it instructed the jury:

[S]ubsection A, regards the Stark Law. It says, we the jury, find that Tuomey, and there are two choices here, violated the Stark Law or did not violate the Stark Law. . . [S]ubsection B regard[s] the [FCA]. One, we the jury find that Tuomey, again, I've given you two choices, violated the [FCA] or did not violate the [FCA]. . . . Two, if Tuomey violated the [FCA], the total damages under the [FCA], if any, and then you will record on a line that I provided for your use the amount of money you award as damages. . . . Three, if Tuomey violated the [FCA], how

many false claims were submitted by Tuomey, if any?

J.A. 996-97.

On March 29, 2010, the jury reached a verdict. In subsection A of the verdict form, the jury indicated that it found that Tuomey violated the Stark Law. In subsection B of the verdict form, the jury indicated that it found that Tuomey did not violate the FCA. Because the jury found no FCA violation, it indicated no response to either the second or third interrogatories in subsection B, i.e., the amount of damages, if any, and the number of false claims, if any.

3.

Subsequent to the jury's verdict, the parties made several post-verdict motions. Tuomey moved for judgment in its favor on the government's equitable claims, including payment under mistake of fact and unjust enrichment. The United States, in response, moved for judgment in its favor on those claims. The United States further moved for judgment as a matter of law under Federal Rule of Civil Procedure 50 on the FCA claim, or alternatively for a new trial under Federal Rule of Civil Procedure 59 on that claim, based on its assertion that the district court erroneously excluded certain evidence regarding Tuomey's knowledge.

On June 3, 2010, the district court conducted a hearing with respect to those post-verdict motions. The district court stated that it would deny the government's Rule 50 motion, but grant the government's Rule 59 motion. Although the government sought a new trial only on the issue of knowledge under the FCA, the district court declined to grant a new trial solely "on the limited question of knowledge," but instead granted a new trial "on the whole issue of the [FCA]." J.A. 1119-20. The district court nevertheless indicated that it would grant a judgment in the United States' favor on the equitable claims

based on the jury's finding that Tuomey had violated the Stark Law.

On July 13, 2010, the district court issued two orders. In the first, the district court granted the government's motion for a new trial and ordered that it be held "on the whole issue of the United States' cause of action for violation of the [FCA], consistent with the separate order being issued by this Court concerning the [equitable] claims." J.A. 135. In the second order, the district court addressed the United States' motion for judgment in its favor on its equitable claims. It made the following findings of fact: (1) "Pursuant to the jury verdict, Tuomey violated the Stark Law"; (2) Tuomey submitted claims in violation of the Stark Law, and the United States paid those claims in the amount of \$44,888,651.00. J.A. 136. It further made the following conclusions of law: (1) "Under the Stark Law, claims submitted in violation of that Statute and payments made by the government in response to such claims must be repaid to the government"; and (2) "The Supreme Court of the United States has recognized that where the government pays out moneys under a circumstance that is unlawful or is improper that the government has a right to be reimbursed." J.A. 137. Based on these conclusions of law, the district court held in favor of the United States with regard to Counts IV and V. It noted that the FCA allegations remained before the court for retrial.

That same day, the district court entered a judgment indicating that the United States should recover from Tuomey on Counts IV and V of its complaint in the amount of \$44,888,651.00, plus pre- and post-judgment interest. The judgment further indicated that "[t]his action was tried by a jury, with the [district judge] presiding, and the jury has rendered a verdict by answering special interrogatories." 14 Id.

¹⁴The judgment form provided a menu of options. One option stated: "This action was tried by a jury, the Honorable _____ presiding, and the jury has rendered a verdict by answering special interrogatories." J.A. 139.

139. On July 16, 2010, Tuomey noticed appeal from the district court's order granting final judgment to the United States upon Counts IV and V and damages.

II.

On appeal, Tuomey makes several arguments. Most significantly, Tuomey contends that the district court violated its Seventh Amendment rights by basing its judgment with respect to the equitable 15 claims on the jury's interrogatory answer regarding the Stark Law, even though the district court had already set aside the jury's verdict in its entirety. 16 For the reasons set forth below, we agree.

A second option stated: "This action was tried by the Honorable _____ presiding, without a jury presiding, and the above decision was reached." *Id.* A third option stated: "This action was decided by the Honorable." As noted above, the clerk of the district court selected the first of these options. *Id.*

¹⁵Even though, at trial, the government treated Counts IV and V as equitable claims, it argues on appeal that they are legal in nature because they solely seek money damages. For purposes of our analysis, we assume that the government's claims of unjust enrichment and payment by mistake are equitable in nature, despite its seeking money damages. See United States ex rel. Taxpayers Against Fraud v. Singer Co., 889 F.2d 1327, 1330 n.15 (4th Cir. 1989) (noting that remedy of restitution in claims for unjust enrichment and payment under mistake of fact is equitable in nature); see also Duke v. Uniroyal Inc., 928 F.2d 1413, 1424 (4th Cir. 1991) ("[A] money damages award may be a form of equitable relief if it is restitutionary"). Notably, were we to entertain the government's argument that those claims are legal in nature, that would not change our conclusion that Tuomey's Seventh Amendment right to jury trial was violated. If those claims were legal in nature, Tuomey was entitled to a jury trial on them, which it did not receive.

¹⁶Tuomey makes several additional arguments: that the judgment against it is improper because the Stark Law does not apply to the contracts; that because the FCA provides an adequate legal remedy for any harm suffered by the government as a result of a Stark Law violation, the government should have been precluded from seeking the relief it obtained on the equitable claims; and that the district court erred in awarding mone-

We now turn to consideration of Tuomey's Seventh Amendment argument, an issue we review de novo. *See Pandazides v. Va. Bd. of Educ.*, 13 F.3d 823, 827 (4th Cir. 1994). If a denial of the right occurred, we must decide whether the denial constituted harmless error. *Id.* We address each question in turn.

A.

The Seventh Amendment states that: "In Suits at common law . . . the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." U.S. Const. amend. VII; see also Fed. R. Civ. P. 38(a) ("The right of trial by jury as declared by the Seventh Amendment to the Constitution . . . is preserved to the parties inviolate."). We have held that the Seventh Amendment right extends "to all suits, whether at equitable or arising under federal legislation, where legal rights are involved." Pandazides, 13 F.3d at 828.

The Seventh Amendment demands that facts common to legal and equitable claims be adjudicated by a jury. *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 510-11 (1959)¹⁷;

tary relief because the government failed to prove, as it was required to do, the number of referrals and the amounts of any improper payments made to Tuomey. Because we hold that the district court erred in relying upon the jury's interrogatory answer regarding the Stark Law and vacate the district court's judgment on that basis, we need not, and do not, address most of Tuomey's other arguments on appeal. Because Tuomey's contention that the contracts do not come within the purview of the Stark Law is an issue that is likely to arise on remand, however, we address some of Tuomey's arguments in that regard in Part III below. We emphasize that, except as set forth below in Part III, the violation of Tuomey's Seventh Amendment right forms the sole basis for our decision.

¹⁷We note that *Beacon Theatres* left open the possibility that the right to a jury trial of legal issues could be lost through prior determination of equitable claims "under the most imperative circumstances which . . . we cannot now anticipate." 359 U.S. at 510-11. There is no suggestion that such circumstances are present here.

Lytle v. Household Mfg., 494 U.S. 545, 550 (1990) ("When legal and equitable claims are joined in the same action, the right to jury trial on the legal claim, including all issues common to both claims, remains intact.") (quotation marks omitted). When equitable claims rest on facts necessary to determination of legal claims, "the legal claims involved in the action must be determined prior to any final court determination of [the] equitable claims." Dairy Queen, Inc. v. Wood, 369 U.S. 469, 479 (1962). In short, Beacon Theatres and Dairy Queen teach that "a district court may not deprive a litigant of his right to a jury trial by resolving an equitable claim before a jury hears a legal claim raising common issues." Lytle, 494 U.S. at 551; see also Ritter v. Mount St. Mary's Coll., 814 F.2d 986, 990 (4th Cir. 1987) (holding that Beacon Theatres and Dairy Queen "stand for the proposition that, where legal and equitable claims are contained in the same set of facts, the right to jury trial, which the legal claims permit, should predominate, precluding the prior determination of the factual issues by a court sitting in equity").

We now apply the foregoing principles to this case. As already noted, whether there was a financial relationship between Tuomey and the physicians that violated the Stark Law is a factual predicate to liability on the equitable claims. The FCA claim, too, is premised on the existence of such an illegal relationship. As such, the factual issue of whether a financial relationship prohibited by the Stark Law existed is common to the equitable claims and the FCA claim. It follows that the district court was required to submit that issue to the jury before it could resolve the United States' equitable claims.

Here, the district court failed to do precisely that. Although it tried the FCA claim to a jury, and the jury returned a verdict on that claim that indicated that Tuomey had violated the Stark Law but had not violated the FCA, the district court set that verdict aside when it granted the government's motion for a new trial under Rule 59, specifically ordering that the

new trial would encompass the whole FCA claim, including whether Tuomey had violated the Stark Law. ¹⁸ As a result, the jury's interrogatory answer regarding the Stark Law is now a legal nullity. In other words, following the order granting the Rule 59 motion, a jury had yet to determine the common issue necessary to resolution of both the FCA claim and the equitable claims, i.e., whether Tuomey violated the Stark Law. In granting judgment to the United States on the equitable claims, the district court impermissibly resolved that common issue before a jury had adjudicated it. It thereby deprived Tuomey of its right to a jury trial.

B.

Having concluded that the district court denied Tuomey's Seventh Amendment right to a jury trial, we must decide whether the denial constituted harmless error. Error is harmless only if the district court would have granted judgment as a matter of law to the prevailing party, i.e., if "the evidence is such, without weighing the credibility of the witnesses, that there is only one conclusion that reasonable jurors could have reached." *Pandazides*, 13 F.3d at 827 (quoting *Keller v. Prince George's Cnty.*, 827 F.2d 952, 955 (4th Cir. 1987)). Error is not harmless where both sides introduce sufficient conflicting evidence on the relevant questions such that the district court could not have granted a motion for judgment as a matter of law. *Id.* at 833.

Here, both sides introduced conflicting evidence regarding whether Tuomey's contracts with the physicians violated the Stark Law. We find that the record before us is insufficient to assess whether the district court could have granted judgment

¹⁸See, e.g., 66 C.J.S. New Trial § 331 (2011) ("Where a motion for new trial has been sustained, the issues stand as though they had never been tried. The cause is to be tried de novo. The whole case, including the issues of fact at the former trial, is open for hearing and determination.") (footnotes omitted).

as a matter of law. Notably, as we discuss below in Part III, the jury must determine on remand whether the contracts took into account the volume or value of referrals. If it so finds, the jury must further determine whether Tuomey could bear its burden of proof with respect to the indirect compensation arrangement exception. Finally, if the jury finds that the contracts created a financial relationship—as defined by the Stark Law—between Tuomey and the physicians, it must determine the number and value of claims Tuomey presented to Medicare for payment of facility fees resulting from the facility component referrals made by the physicians, and for which it received payment.

III.

Because we are remanding this case, we will briefly address other issues raised on appeal that are likely to recur. With respect to our colleague's objection to this course as expressed in his separate opinion, *see infra* at 27-31, we note that our precedent is clear that we may address issues that are likely to recur on remand. *See Levy v. Lexington County, S.C.*, 589 F.3d 708, 716 (4th Cir. 2009) ("Because we are remanding this case, we will address other issues raised on appeal that are likely to recur."); *see also Elm Grove Coal Co. v. Dir. O.W.C.P.*, 480 F.3d 278, 299 n.20 (4th Cir. 2007) (addressing issue because it was likely to arise on remand); *Gordon v. Schweiker*, 725 F.2d 231, 236 (4th Cir. 1994) ("Since the case must be reconsidered . . . we do provide some guidance as to a matter very likely to arise at the hearing which will occur."). 19

¹⁹Contrary to our colleague's description of this part of our opinion, it is not advisory in nature. "We would issue an advisory opinion were we to pass 'judgment upon issues which remain unfocused because they are not pressed before the Court with that clear concreteness provided when a question emerges precisely framed and necessary for decision from a clash of adversary argument exploring every aspect of a multifaceted situation embracing conflicting and demanding interests." Rux v. Republic of Sudan, 461 F.3d 461, 476 (4th Cir. 2006) (quoting United States v. Fruehauf, 365 U.S. 146, 157 (1961)). No such danger exists here. We have decided the pure questions of law "based on a concrete set of facts in the context of a live controversy between the parties." Id.

Specifically, we address two threshold issues relating to liability under the Stark Law that are purely legal in nature and that the district court will be called upon to address upon retrial. It bears emphasis that the parties presented these issues to us as pure questions of law. First, we address whether the facility component of the services performed by the physicians pursuant to the contracts, for which Tuomey billed a facility fee to Medicare, constituted a "referral" within the meaning of the Stark Law and Stark Regulations. Second, we examine whether, assuming that Tuomey considered the volume or value of *anticipated* facility component referrals in computing the physicians' compensation, the contracts implicate the "volume or value" standard under the Stark Law.

A.

As already noted, the Stark Law and Stark Regulations define a "referral," in relevant part, as the request by a physician for a service for which payment may be made under Medicare, but not including any services performed or provided by the referring physician. 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351. Neither the statute nor the regulation addresses whether a facility component that results from a personally performed service constitutes a referral. In promulgating the final rule on referrals, however, HCFA commented that the personal services exception does not extend to a facility fee a hospital bills for a facility component resulting from a personally performed service:

We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity . . . However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an

inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service.

66 Fed. Reg. at 941.20

Applying the Stark Law and Stark Regulations, as interpreted by the agency,²¹ we conclude that there was a referral

²⁰At least one district court has relied upon this commentary to reject an argument that a physician did not violate the Stark Law because his treatment of his own patients at a hospital was not an unlawful referral under the law. *See United States v. Campbell*, No. 08-CV-1951, 2011 WL 43013, at *7 (D.N.J. Jan. 4, 2011).

²¹Under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), we "are instructed to defer to the reasonable interpretations of expert agencies charged by Congress to fill any gap left, implicitly or explicitly, in the statutes they administer." Nat'l Elec. Mfrs. Ass'n v. U.S. Dep't of Energy, 654 F.3d 496, 504 (4th Cir. 2011) (quotation marks omitted). "Under the first step of Chevron, a reviewing court is to 'employ [] traditional tools of statutory construction' to determine whether Congress addressed 'the precise question at issue.' " Id. (quoting Chevron, 467 at 842, 843 n.9). "If, however, the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. (citations and quotation marks omitted). At this second step of the *Chevron* inquiry, we defer "to the agency's interpretation so long as the construction is a reasonable policy choice for the agency to make. We afford controlling weight to an agency's reasonable interpretation even where we would have, if writing on a clean slate, adopted a different interpretation." Id. at 506 (citations and quotation marks omitted). As already noted, the Stark Law does not specifically address the issue of whether a facility component constitutes a referral. As such, Congress has not directly spoken to the precise question at issue. Under the second step of the *Chevron* inquiry, we note that neither party has challenged the reasonableness of the agency's interpretation, and we find that it is eminently reasonable. It bears note that we extend such deference to the agency's interpretation of its formal regulations because the agency possesses special expertise in interpreting the Stark Law, the interpretation emerged out of notice-and-comment rulemaking, and involved a statute of sufficient complexity that it was fair to assume that Congress understood that the agency would be required to engage in policy making when it administered the statute. See Barnhart v. Walton, 535 U.S. 212, 221-22 (2002).

here, consisting of the facility component of the physicians' personally performed services, and the resulting facility fee billed by Tuomey based upon that component. Thus, the claims for facility fees based on patient referrals were prohibited under the Stark Law if there was a financial relationship within the meaning of the law between the physicians and Tuomey. As such, Tuomey's argument that the physicians were not making referrals—as that term is defined in the Stark Law—pursuant to the contracts fails.

В.

Having concluded that the physicians were making referrals to Tuomey, we now turn to the question of whether the contracts implicate the Stark Law's "volume or value" standard. As already noted, the regulatory definition of "indirect compensation arrangement" requires that the aggregate compensation received by the physician "var[y] with, or take[] into account, the volume or value of referrals or other business generated by the referring physician." 42 C.F.R. § 411.354(c)(2)(ii) (emphasis added). Notably, the government contends that Tuomey's conduct fits within this definition because it included a portion of the value of the anticipated facility component referrals in the physicians' fixed compensation.22 Tuomey argues that the inquiry is whether the physicians' compensation takes into account the volume or value of referrals, not whether the parties considered referrals when deciding whether to enter the contracts in the first place. Thus, the parties disagree about whether anticipated referrals constitute a proper basis for a finding that a physician's compensation takes into account the volume or value of referrals.

²²Although Tuomey has not expressly disputed this factual assertion before us, we proceed on the assumption that whether the physicians' compensation under the contracts took into account the volume or value of anticipated referrals is an open question of fact. As we discuss below, it is a question for the jury to resolve on remand.

In determining whether contracts that are found to have taken into account anticipated referrals implicate the "volume or value" standard, we look to the Stark Law, Stark Regulations, and the official agency commentary. Our analysis of these sources, set forth below, yields the conclusion that compensation arrangements that take into account anticipated referrals do implicate the volume or value standard.

We begin by observing that the official agency commentary explains that "[a]rrangements under which a referring physician receives compensation tied to the volume or value of his or her referrals . . . are the very arrangements at which [the Stark Law] is targeted." 66 Fed. Reg. at 868. We further note that the Stark Regulations and the agency commentary specifically address circumstances in which compensation that takes into account anticipated referrals implicates the "volume or value" standard. The Stark Regulations, for instance, define "fair market value," in pertinent part, as compensation that "has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals." 42 C.F.R. § 411.351 (emphasis added). The official agency commentary to the Phase I rules notes that the Stark Law "establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed," and should not be "inflated to compensate for the physician's ability to generate other revenues." 66 Fed. Reg. at 877. It further notes that "[i]n order to establish a 'bright line' rule, we are applying this interpretation of the volume or value standard uniformly to all provisions under [the Stark Law and Stark Regulations] where the language appears (for example, . . . indirect compensation arrangements)." Id. The commentary further specifies that compensa-

²³Because neither the statute nor the regulations speak to the precise issue of whether anticipated referrals constitute a proper basis for finding that a physician's compensation takes into account the volume or value of referrals, we defer to the agency's interpretation, provided that it is reasonable. *See ante* at 22 n.20.

tion arrangements that take into account the volume or value of *anticipated* referrals implicate the volume or value standard:

Consistent with this interpretation, we have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition for payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the *anticipated* or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires the referrals to certain providers will not vitiate the exception.

Id. (emphasis added).

We conclude from the regulatory definition of fair market value and the applicable agency commentary that compensation based on the volume or value of anticipated referrals implicates the volume or value standard.²⁴ At bottom, the Stark Law and Stark Regulations seek to ensure that hospitals and other health care providers compensate physicians only for the work or services they actually perform, not for their ability to generate other revenues for the provider through referrals. It stands to reason that if a hospital provides fixed compensation to a physician that is not based solely on the value of the services the physician is expected to perform, but

²⁴At least one district court has relied upon the same sources to "conclude that 'anticipated referrals' are a proper consideration under the Stark Act." *U.S. ex. rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 622 (W.D. Pa. 2010).

also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that such compensation by necessity takes into account the volume or value of such referrals. The agency commentary specifically contemplates arrangements such as the contracts that are before us, where a physician is required to refer patients to a particular provider as a condition of compensation. Such arrangements, the commentary indicates, do not violate the Stark Law, *provided that* certain conditions are met, one of which is that the physician's compensation must not take into account the volume or value of *anticipated* referrals.²⁵

Accordingly, the question, which should properly be put to a jury, is whether the contracts, on their face, took into account the value or volume of anticipated referrals. As the Stark Regulations and the agency commentary indicate, compensation arrangements that take into account anticipated referrals do not meet the fair market value standard. Thus, it is for the jury to determine whether the contracts violated the fair market value standard by taking into account anticipated referrals in computing the physicians' compensation.²⁶

²⁵Tuomey argues, based upon a district court decision, that the subjective intent of the parties should not determine whether the volume or value standard is implicated. *United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 693 (W.D. Ky. 2008) ("Where no violation appears on the face of the arrangement, either in the form of above-fair market value compensation or of a provision allowing for increases or decreases in payment based on the number of referrals made, the text and history of the Stark Law's desire to create a 'bright-line' rule would seem to argue against establishing a violation on the basis of intent alone."). We agree with the *Villafane* court that intent alone does not create a violation. However, that does not aid Tuomey if the jury determines that the contracts took into account the volume or value of anticipated referrals.

²⁶For clarification, we emphasize that our holding in Part III is limited to the issues we specifically address. On remand, a jury must determine, in light of our holding, whether the aggregate compensation received by the physicians under the contracts varied with, or took into account, the volume or value of the facility component referrals. If it so finds, a jury must further determine whether the aggregate compensation received by the physicians is nevertheless lawful under 42 C.F.R. § 411.357(p).

IV.

For the foregoing reasons, we vacate the district court's July 13, 2010 judgment, and remand for further proceedings.

VACATED AND REMANDED

WYNN, Circuit Judge, concurring in the result:

Because I agree that the proper disposition of this case is to vacate the district court's judgment against Defendant Tuomey Healthcare System, Inc. and remand for further proceedings, I concur in the result reached by the majority opinion. I write separately because I come to that conclusion on different grounds, and because I am also unable to join in Part III of the majority opinion, which I find to be advisory in nature.

At the outset, I emphasize my substantial agreement with the reasoning so ably articulated by my colleagues in the majority, particularly their observation that "the jury's interrogatory answer regarding the Stark Law is now a legal nullity." *Ante* at 19. Given that the district court set aside the jury's verdict in its entirety, it must follow that the jury's answer to an interrogatory, which was a necessary condition to the jury's verdict, must itself also be a nullity. Notwithstanding that ruling, however, in its order entering judgment against Defendant, the district court found as fact that "[p]ursuant to the jury verdict, Tuomey violated the Stark Law." J.A. 136.1

Indeed, the sole basis for the district court's judgment against Defendant on the equitable claims was the jury's finding of a Stark Law violation.² As such, irrespective of the

¹Citations to the joint appendix are abbreviated as "J.A."

²I note, too, that I wholeheartedly agree with the majority that the district court's error here was not harmless, not least because, in addition to

Seventh Amendment, the judgment, which was predicated entirely on what is now a "legal nullity," simply cannot stand. Given this unremarkable proposition—that a judgment must be vacated if premised on a jury finding that has been set aside and is no longer valid—I see no reason to resort to constitutional analysis to support our holding. See, e.g., Norfolk So. Ry. Co. v. City of Alexandria, 608 F.3d 150, 156-57 (4th Cir. 2010) ("[T]he principle of constitutional avoidance . . . requires the federal courts to strive to avoid rendering constitutional rulings unless absolutely necessary."); Ashwander v. Tenn. Valley Auth., 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) ("It is not the habit of the court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case." (internal quotation marks and citation omitted)).

In addition, I cannot join Part III of the majority opinion, which, in my view, amounts to an advisory opinion on the issues of "whether the facility component of the services performed by the physicians pursuant to the contracts . . . constituted a 'referral' within the meaning of the Stark Law and Stark Regulations," as well as "whether . . . the contracts implicate the 'volume or value' standard under the Stark Law." *Ante* at 21; *see United States v. Blair*, 661 F.3d 755, 773 (4th Cir. 2011) ("[R]endering advisory opinions on cases not before us is not the office of this court.").

Under the district court's order for a new trial on the entire Government's False Claims Act (FCA) claim against Defendant and the majority's holding here, no legal issues remain

the significant disputed factual issues identified by the majority, the verdict sheet also provided no detail about the number or nature of the alleged violation(s). Despite the lack of any indication that the jury found each and every referral in question to be a violation of the Stark Law, the district court nevertheless awarded repayment for all services performed under the contracts at issue. Without more particularized findings by the jury concerning the specific violations, the district court's estimation of damages cannot be described as "harmless."

for us to resolve prior to further proceedings. We have fully disposed of the matters before this Court, and the conclusions set forth in Part III are thus unnecessary either to the disposition or to the retrial of this case. Accordingly, there is no need to delve into these questions now and potentially usurp the proper role and province of the jury and district court.

To be sure, the three cases cited in the majority opinion for the proposition that an appellate court may properly "address other issues raised on appeal that are likely to recur," *ante* at 20-21, are distinguishable in two critical ways from the situation presented here: (1) each identified and rectified actual, specific errors of law committed by the district court or lower authority; and (2) each involved bench trials, not juries. *See Levy v. Lexington Cnty., S.C.,* 589 F.3d 708, 716 (4th Cir. 2009); *Elm Grove Coal Co. v. Dir. O.W.C.P.,* 480 F.3d 278, 299 n.20 (4th Cir. 2007); *Gordon v. Schweiker,* 725 F.2d 231, 236 (4th Cir. 1994).

By contrast, here, Part III does not identify any specific errors committed by the district court during the first trial; instead, it decides issues before they have been squarely presented to this Court, particularly given that the analysis takes place in the context of what the majority has recognized as a "legal nullity." Not only does the majority fail to point to any actual error in the analysis of the original trial judge in this case (who is now deceased), but we also have no indication that the new trial judge requires this Court's cold record guidance on these issues. Cf. Levy, 589 F.3d at 716 (finding that trial judge had applied the wrong analysis and, since the matter was remanded to that same judge for retrial, determining that the issues were likely to recur); Elm Grove, 480 F.3d at 299 (finding that two Administrative Law Judges ("ALJs") and the Benefits Review Board ("BRB") had made or upheld an erroneous discovery ruling and, since the relevant decision was vacated and the matter was remanded to the BRB and ALJs for proceedings to begin anew, determining that the same discovery issue was likely to arise again on remand); Gordon, 725 F.2d at 236-37 (remanding for reconsideration by the Secretary of Health and Human Services, not retrial in the district court, because the Secretary's arguments on appeal gave this Court a basis to believe that the issues would likely recur upon the Secretary's reconsideration).

Moreover, the majority opinion's own analysis strongly suggests that the issue of whether referrals took place is actually a mixed question of law and fact, which is properly left to the province of the jury. Further, the conclusion that "compensation based on the volume or value of anticipated referrals implicates the volume or value standard," *ante* at 25, does not provide additional guidance to the district court on remand. Rather, it interprets the relevant statute and regulations in a vacuum, without the defining parameters of an actual case or controversy—the hallmarks of an advisory opinion.

The majority opinion asserts that Part III "is not advisory in nature" because the issues decided are "'based on a concrete set of facts in the context of a live controversy between the parties." Ante at 20 n.19 (quoting Rux v. Republic of Sudan, 461 F.3d 461, 476 (4th Cir. 2006) (internal quotation marks and citation omitted)). Of course, such a statement is generally true of all of the issues in any case before an appellate court—yet prudence and judicial restraint require that we address *only* those questions necessary to the disposition of an appeal, lest we overstep our role. See Rux, 461 F.3d at 476 (quoting United States v. Fruehauf, 365 U.S. 146, 157 (1961), to support the proposition that an opinion is advisory if it passes "judgment upon issues" not "necessary for decision"). Here, Part III of the majority opinion purports to resolve issues not yet passed upon by a jury or a trial judge and thus not yet focused for this Court's consideration.3

³I believe the majority's own direction that the lower court "put to [the] *jury* [the question of] whether the contracts, *on their face*, took into account the value or volume of anticipated referrals," *ante* at 26 (emphases

Because I would vacate the district court's judgment against Defendant based on the "legal nullity" identified by the majority, rather than on Seventh Amendment grounds, and I see no need to pass upon legal issues no longer before this Court as a result of that same legal nullity, I respectfully concur in the result only.

added), perfectly illustrates this point. The meaning of "the contracts, on their face" is most assuredly a question of law appropriately resolved by a court, not a question of fact to be submitted to a jury. See, e.g., Frahm v. United States, 492 F.3d 258, 262 (4th Cir. 2007) ("The interpretation of a contract is a question of law[.]"); Burgin v. OPM, 120 F.3d 494, 497-98 (4th Cir. 1997) ("[T]he essential question is one of the interpretation of the contract's language, a question of law clearly within the competence of courts."); Scarborough v. Ridgeway, 726 F.2d 132, 135 (4th Cir. 1984) (same).

The undesirable and unintended consequences on the judicial process of such erroneous appellate mandates—which in this case will undoubtedly have a significant impact on the organization of the proceedings on remand—are, of course, exactly what the rules against advisory opinions seek to avoid.