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December 30, 2019

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Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1720-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Supplement to Comments on Proposed Regulations

to the Physician Self-Referral Law

File Code CMS-1720-P

To the Centers for Medicare & Medicaid Services:

On December 18, 2019, Horty, Springer & Mattern, P.C. submitted a comment letter in response to the Proposed Regulations to the Physician Self-Referral Law (also known as the "Stark Law") that were published by CMS in the October 17, 2019 Federal Register and the Preamble thereto (the "Proposed Regulations") (the "HSM Comment Letter"). The HSM Comment Letter stated a number of reasons why we believe the Proposed Regulations are a significant positive development.

In the HSM Comment Letter, we made several references to *U.S. ex rel. Bookwalter v. University of Pittsburgh Medical Center*, 938 F.3d 397 (3d Cir. 2019), which was issued on September 17, 2019 (hereinafter *Bookwalter I*). We are now writing to CMS to inform CMS that, on December 20, 2019, Bookwalter I has been vacated, reissued and a rehearing has been granted by the Third Circuit Court of Appeals. *U.S. ex rel. Bookwalter v. Univ. of Pittsburgh Med. Ctr.*, No. 18-1693 (3d Cir. 2019) (hereinafter *Bookwalter II*).

Enclosed with this Supplemental Comment Letter, please find the Order by the Third Circuit granting a rehearing, stating that *Bookwalter I* has been vacated and identifying the pages in *Bookwalter I* that have been revised by the Third Circuit in several key respects. Also enclosed with this Supplemental Comment Letter please find the opinion of the Third Circuit that was issued

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on December 20, 2019, as well as a blacklined copy that shows the differences between Bookwalter I and Bookwalter II.

This Supplemental Comment Letter will now identify the pages in the HSM Comment Letter that will be affected by *Bookwalter II* and the effect of *Bookwalter II* on the comments included with the HSM Comment Letter.

(1) Essential Elements of a Violation of the Stark Law

Bookwalter II did not change the Third Circuit's analysis of a prima facie case under the Stark Law and will still require the defendants to raise compliance with an exception as an affirmative defense. However, the citations found on Pages 2-3 of the HSM Comment Letter are now found on Pages 4-5 of Bookwalter II.

(2) References to Medicare and Medicaid as "Bottom Billers"

The Third Circuit has continued to describe the Medicare and Medicaid Programs as "well known bottom-billers" but the reference is now on Page 8 of *Bookwalter II*.

(3) References to U.S. ex rel. Drakeford v. Tuomey

The Third Circuit has also deleted all references to *U.S. ex rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776 (D.S.C. 2013) and 792 F.3d 364 (4th Cir. 2015) whenever they have appeared in *Bookwalter I.* Specifically, *Bookwalter II* has deleted the following statement from *Bookwalter I:* "We agree with the Fourth Circuit's logic." 938 F.3d at 411.

As we stated in the HSM Comment Letter, CMS is to be commended for addressing the Third Circuit Court of Appeals' incorrect interpretation of "split billing" arrangements in *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009) and the incorrect analysis of the Stark Law by the Fourth Circuit in *U.S. ex rel. Drakeford v. Tuomey Healthcare. See* 84 Fed. Reg. 55,766, 55,795; 80 Fed. Reg. 70,887, 71,321 (Nov. 16, 2015); 80 Fed. Reg. 70,886, 71,321 (Nov. 16, 2015). CMS should take this opportunity to analyze the Stark Law so that other courts do not follow the Fourth Circuit's incorrect analysis in *Tuomey*.

(4) Concurring Opinion Has Been Withdrawn

Due to the changes in the majority's opinion in *Bookwalter II*, Judge Ambro has withdrawn his concurring opinion.

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(5) Further Clarification Needed to the Volume or Value Standard

While *Bookwalter II* has corrected much of the Third Circuit's incorrect analysis of the Stark Law, the following quote clearly shows that the court is still struggling with how to interpret the Stark Law's volume or value standard:

The parties disagree about what it means for compensation to vary with referrals. Appellants argue that varies with requires only correlation. And compensation correlates with referrals here, they argue, because surgeons racked up more Work Units and earned more money by generating more referrals. So the surgeons' aggregate compensation allegedly varied with their referrals. Appellees, by contrast, deny that a correlation suffices. Rather, they insist that the law requires some form of causation. (Bookwalter II at Page 6.)

Bookwalter II, No. 18-1693 at 6.

(6) Need for Guidance Greater Than Ever

The mere fact that the Third Circuit had to vacate and reissue its opinion within months shows that even the federal courts are confused as to how to properly interpret the Stark Law. We continue to urge CMS, that when issuing the final regulations, CMS should provide clear and unambiguous guidance on the key terms of the Stark Law similar to CMS's analysis in the Proposed Regulations.

(7) Conclusion

We regret any confusion that may have arisen due to our citations to *Bookwalter I* and respectfully request that CMS refer to the Bookwalter II decision when considering any of the comments that we included in the HSM Comment Letter.

Sincerely,

Henry Casale

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HC/las

Enclosures

4814-3742-2256, v. 1

2019 WL 7019394 Only the Westlaw citation is currently available. United States Court of Appeals, Third Circuit.

UNITED STATES OF AMERICA, ex rel. J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA

UPMC; UNIVERSITY OF PITTSBURGH PHYSICIANS, d/b/a UPP DEPARTMENT OF NEUROSURGERY

J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA, Appellants

No. 18-1693

Argued: January 10, 2019

Filed: December 20, 2019

On Appeal from the United States District Court for the Western District of Pennsylvania

(D.C. No. 2:12-cv-00145)

District Judge: Honorable Cathy Bissoon

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Before: AMBRO, BIBAS, and FUENTES, Circuit Judges

BIBAS, Circuit Judge.

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OPINION OF THE COURT

Healthcare spending is a huge chunk of the federal budget. Medicare and Medicaid cost roughly a trillion dollars per year. And with trillions of dollars comes the temptation for fraud.

Fraud is a particular danger because doctors and hospitals can make lots of money for one another. When doctors refer patients to hospitals for services, the hospitals make money. There is nothing inherently wrong with that. But when hospitals pay their doctors based on the number or value of their referrals, the doctors have incentives to refer more. The potential for abuse is obvious and requires scrutiny.

The Stark Act and the False Claims Act work together to ensure this scrutiny and safeguard taxpayer funds against abuse. The Stark Act forbids hospitals to bill Medicare for certain services when the hospital has a financial relationship with the doctor who asked for those services, unless an exception applies. And the False Claims Act gives the government and relators a cause of action with which to sue those who violate the Stark Act.

Here, the relators allege that the defendants have for years been billing Medicare for services referred by their neurosurgeons in violation of the Stark Act. The District Court found that the relators had failed to state a plausible claim and dismissed their suit.

This appeal revolves around two questions: First, do the relators offer enough facts to plausibly allege that the surgeons' pay varies with, or takes into account, their referrals? Second, who bears the burden of pleading Stark Act exceptions under the False Claims Act?

*2 The answer to the first question is yes. The relators' complaint alleges enough facts to make out their claim. The relators make a plausible case that the surgeons' pay is so high that it must take their referrals into account. All these facts are smoke; and where there is smoke, there might be fire.

The answer to the second question is the defendants. The Stark Act's exceptions work like affirmative defenses in litigation. The burden of pleading these affirmative defenses lies with the defendant. This is true even under the False Claims Act. And even if that burden lay with the relators, their pleadings meet that burden here.

We hold that the complaint states plausible violations of both the Stark Act and the False Claims Act. So we will reverse.

I. BACKGROUND

A. Factual Background

1. The University of Pittsburgh medical system. On this motion to dismiss, we take as true the facts alleged in the second amended complaint: The University of Pittsburgh Medical Center is a multi-billion-dollar nonprofit healthcare enterprise. The Medical Center is the parent organization of a whole system of healthcare subsidiaries, including twenty hospitals. The Medical Center is the sole member (owner) of each hospital.

More than 2,700 doctors, including dozens of neurosurgeons, work at these hospitals. The doctors are employed not by the hospitals, but by other Medical

Center subsidiaries. Three of these subsidiaries matter here: University of Pittsburgh Physicians; UPMC Community Medicine, Inc.; and Tri-State Neurological Associates-UPMC, Inc.

These three subsidiaries employed many of the neurosurgeons who worked at the Medical Center's hospitals during the years at issue, from 2006 on. Pittsburgh Physicians' Neurosurgery Department employed most of the surgeons at issue. Tri-State employed two, and Community Medicine employed one. The Medical Center owns all three subsidiaries. In short, the Medical Center owns both the hospitals and the companies that employ the surgeons who work in the hospitals.

2. The neurosurgeons' compensation structure. The surgeons who worked for the three subsidiaries here all had simi-lar employment contracts. Each surgeon had a base salary and an annual Work-Unit quota. Work Units (or wRVUs) measure the value of a doctor's personal services. Every medical service is worth a certain number of Work Units. The longer and more complex the service, the more Work Units it is worth. Work Units are one component of Relative Value Units (RVUs). RVUs are the basic units that Medicare uses to measure how much a medical procedure is worth.

The surgeons were rewarded or punished based on how many Work Units they generated. If a surgeon failed to meet his yearly quota, his employer could lower his future base salary. But if he exceeded his quota, he earned a \$45 bonus for every extra Work Unit.

3. The neurosurgeons' alleged fraud and its effects on salaries and revenues. This compensation structure gave the surgeons an incentive to maximize their Work Units. And the incentive seems to have worked. The surgeons reported doing more, and more complex, procedures. So the number of Work Units billed by the Neurosurgery Department more than dou-bled between 2006 and 2009.

Much of this increase allegedly stemmed from fraud. The relators accuse the surgeons of artificially boosting their Work Units: The surgeons said they acted as assistants on surgeries when they did not. They said they acted as teaching physicians when they did not. They billed for parts of surgeries that never happened. They did surgeries that were medically unnecessary or needlessly complex. And they did these things, say the relators, "[w]ith the full knowledge and endorsement of the Medical Center. App. 184 ¶190.

*3 Fraud can be profitable. And here it allegedly was.

With these practices, the surgeons racked up lots of Work Units and made lots of money. Most reported total Work Units that put them in the top 10% of neurosurgeons nationwide. And some received total pay that put them among the best-paid 10% of neurosurgeons in the country.

The surgeons' efforts proved profitable for the Medical Center too. The Medical Center made money off the surgeons' work on some of the referrals. And to boot, healthcare provid-ers bill Medicare for more than just the surgeons' own Work Units. Whenever a surgeon did a procedure at one of the hospitals, the Medical Center also got to bill "for the attendant hospital and ancillary services." App. 166 ¶ 104. This part of the bill could be four to ten times larger than the cost of the surgeon's own services. So when the surgeons billed more, the Medical Center made more. "Indeed, in 2009," the Neurosurgery Department "was the single highest grossing neurosurgi-cal department in the United States, with Medicare charges alone of \$58.6 million." App. 163-64 ¶ 91.

B. Procedural History

The relators first filed suit in 2012. They alleged that the Medical Center, Pittsburgh Physicians, and a bevy of neurosurgeons had submitted false claims for physician services and for hospital services to Medicare and Medicaid. Four years later, the United States intervened as to the claims for physician services. The government settled those claims for about \$2.5 million. It declined to intervene as to the claims for hospital services, but it let the relators maintain that part of the action in its stead.

After the government intervened, the District Court dismissed the first amended complaint without prejudice for failure to state a claim. The relators then filed their current complaint, asserting three causes of action against the Medical Center and Pittsburgh Physicians under the False Claims Act:

- (1) one count of submitting false claims,
- (2) one count of knowingly making false records or state-ments, and
- (3) one count of knowingly making false records or state-ments material to an obligation to pay money to the United States.

The District Court again dismissed for failure to state a

claim, this time with prejudice. The relators now appeal.

II. STANDARDS OF REVIEW AND PLEADING

We review a district court's dismissal for failure to state a claim de novo.

Vorchheimer v. Philadelphian Owners
Ass'n, 903 F.3d 100, 105 (3d Cir. 2018). Our job is to gauge whether the complaint states a plausible claim to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

Plausible does not mean possi-ble. If the allegations are "merely consistent with" misconduct, then they state no claim.

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007). There must be something in the complaint to suggest that the defendant's alleged conduct is illegal.

Id. at 557.

But plausible does not mean probable either. Our job is not to dismiss claims that we think will fail in the end. See <u>id. at 556</u>. Instead, we ask only if we have "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of" each element. Id.

This is the baseline pleading standard for all civil actions. Fed. R. Civ. P. 8; Iqbal, 556 U.S. at 684. But the relators allege claims for fraud. So they must also meet Rule 9(b)'s heightened pleading requirement. United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 306–07 (3d Cir. 2016). That rule says that a party alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

III. THE STARK ACT AND THE FALSE CLAIMS ACT

A. The Stark Act

*4 The Stark Act and its regulations broadly bar Medicare claims for many services referred by doctors who have a financial interest in the healthcare provider. But the statute creates dozens of exceptions and authorizes the Department of Health and Human Services to make even

more exceptions for financial relationships that "do[] not pose a risk of program or pa-tient abuse." 42 U.S.C. § 1395nn(b)(4).

1. Forbidden conduct. The Stark Act opens with a broad ban. It forbids submitting Medicare claims for "designated health services" provided under a "referral" made by a doctor with whom the entity has a "financial relationship." [1] Id. § 1395nn(a)(1). Understanding this ban requires exploring these three quoted terms, each of which has statutory and reg-ulatory definitions.

The Stark Act lists several categories of designated health services, including inpatient hospital services. Id. § 1395nn(h)(6)(K). And inpatient hospital services include bed and board, interns' and residents' services, nursing, drugs, sup-plies, transportation, and overhead. 42 C.F.R. §§ 409.10(a), 411.351.

A referral is a doctor's request for a designated health service. 42 U.S.C. § 1395nn(h)(5)(A); 42 C.F.R. § 411.351. That definition is broad, but it has an important exception: services that a doctor performs personally do not count. 42 C.F.R. § 411.351. That makes sense; ordinarily, one cannot refer something to oneself. And the exception's boundaries also fol-low: it does not cover services by a doctor's associates or em-ployees, or services incidental to the doctor's own services. Id.; Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II): Interim Final Rule, 69 Fed. Reg. 16054, 16063 (Mar. 26, 2004).

Finally, financial relationships come in two forms: (1) ownership or investment interests and (2) compensation arrangements. 42 U.S.C. § 1395nn(a)(2). This case turns on the latter. The statute defines compensation arrangement to mean "any arrangement involving any remuneration between" a doctor and a healthcare provider. Id. § 1395nn(h)(1)(A). And remuneration "includes any remuneration, directly or indirectly, in cash or in kind."

Id. § 1395nn(h)(1)(B).

2. Exceptions. On its face, the Stark Act's ban sweeps in lots of common situations. To separate the wheat from the in-nocuous chaff, Congress and the Department of Health and Human Services have created many exceptions. Here, the Medical Center argues that exceptions for four types of compensation arrangements could apply here: bona fide employment; personal services; fair-market-value compensation; and indirect compensation. See id. §

1395nn(e)(2), (e)(3); 42 C.F.R. § 411.357(*l*), (p).

All four exceptions have two elements in common. First, the doctor's compensation must not "take[] into account (directly or indirectly) the volume or value of the doctor's referrals.

42 U.S.C. § 1395nn(e)(2)(B)(ii); accord

id. § 1395nn(e)(3)(A)(v); 42 C.F.R. § 411.357(I)(3), (p)(1)(i). Second, the doctor's compensation must not exceed fair market value.

U.S.C. § 1395nn(e)(2)(B)(i), (e)(3)(A)(v); 42

C.F.R. § 411.357(I)(3), (p)(1)(i).

In litigation, these exceptions are affirmative defenses. So once a plaintiff proves a prima facie violation of the Stark Act, the burden shifts to the defendant to prove that an exception applies.

<u>United States ex rel. Kosenske v. Carlisle HMA, Inc.</u>, 554 F.3d 88, 95 (3d Cir. 2009).

*5 3. No built-in cause of action. The Stark Act forbids the government to pay claims that violate the Act. 42 U.S.C. § 1395nn(g)(1). It demands restitution from those who receive payments on illegal claims. 1 Id. § 1395nn(g)(2). And it creates civil penalties for submitting improper claims or taking part in schemes to violate the Act. 1d. § 1395nn(g)(3), (4). But it gives no one a right to sue. 1 United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 374 n.4 (4th Cir. 2015).

So the Stark Act never appears in court alone. Instead, it always come in through another statute that creates a cause of action—typically, the False Claims Act.

B. The False Claims Act

Under the False Claims Act, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is civilly liable to the United States.

31 U.S.C. § 3729(a)(1)(A). A Medicare claim that violates the Stark Act is a false claim under the False Claims Act.

Kosenske, 554 F.3d at 94. The False Claims Act also makes liable anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to" a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(B), (G).

IV. THE RELATORS PLEAD STARK ACT VIOLATIONS

A prima facie Stark Act violation has three elements: (1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for the referred services. See United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 241 (3d Cir. 2004). This combination of factors suggests potential abuse of Medicare. When they are all present, we let plaintiffs go to discovery.

Here, no one denies that the defendants made Medicare claims for designated health services. The issue is whether the complaint sufficiently alleges referrals and a compensation arrangement. We hold that it does. The alleged Medicare abuse is plausible and deserves more scrutiny.

A. The surgeons referred designated health services to the hospitals

The relators allege that "[e]very time [the neurosurgeons] performed a surgery or other procedure at the UPMC Hospi-tals, [they] made a referral for the associated hospital claims." App. 193 ¶234. They are right that these claims are referrals.

As mentioned, the law defines referrals broadly. A referral is a doctor's request for any designated health service that is covered by Medicare and provided by someone else. 42 C.F.R. § 411.351. Designated health services include bed and board, some hospital overhead, nursing services, and much more. 42 C.F.R. § 409.10(a). And the relators plead that as the surgeons performed more procedures, those procedures required (and the hospital provided and "increased billings for[)] the attendant hospital and ancillary services including ... hospital and nursing charges." App. 166 ¶104 (emphasis added). So the plaintiffs plead that the surgeons referred designated health services to the hospitals.

Treating these services as referrals makes sense. The Stark Act's first step is to flag all potentially abusive arrangements. And doctors who generate profits for a hospital may be tempted to abuse their power, raising

hospital bills as well as their own pay. These financial arrangements thus deserve a closer look. And they will get a closer look only if we call these arrangements what they are: doctors referring services to hospitals.

*6 The Department of Health and Human Services agrees. In Phase I of its Stark Act rulemaking, it considered this point. It determined that "any hospital service, technical component, or facility fee billed by [a] hospital in connection with [a doctor's] personally performed service" counts as a referral. Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856, 941 (Jan. 4, 2001). This is true even "in the case of an inpatient surgery" where the doctor performs the surgery. Id.

Then, in Phase II of its rulemaking, the agency revisited the question and considered narrower definitions. For instance, many commenters suggested excluding "services that are performed 'incident to' a physician's personally performed services or that are performed by a physician's employee" from the definition of a referral. 69 Fed. Reg. at 16063.

But the agency reasonably rejected these suggestions. A narrower view, it reasoned, would all but swallow at least one statutory exception. *Id.* And it explained that the availability of that and other exceptions did enough to protect innocent conduct. *Id.* "[T]his interpretation is consistent with the statute as a whole," which begins by casting a broad net to scrutinize all potential abuse. *Id.*

B. The relators' complaint alleges an indirect compensation arrangement

A referral is ripe for abuse only when the doctor who made it has a financial relationship with the provider. Only then can a doctor profit from his own referral. The financial relationship here is a compensation arrangement.

Compensation arrangements can be either direct or indirect. is 42 C.F.R. § 411.354(c). The hospitals did not pay the surgeons directly. So if there is any compensation arrangement here, it is indirect. That requires three elements: First, there must be "an unbroken chain ... of persons or entities that have financial relationships" connecting the referring doctor with the provider of the referred services.

1d. § 411.354(c)(2)(i). Second, the

referring doctor must get "aggregate compensation ... that varies with, or takes into account, the volume or value of referrals."

Id. § 411.354(c)(2)(ii). And third, the service provider must know, recklessly disregard, or deliberately ignore that the doctor's compensation "varies with, or takes into account, the volume or value of referrals."

Id. § 411.354(c)(2)(iii). (The parties do not challenge any of the regulations at issue, so we likewise assume that they are valid.) The complaint plausibly pleads enough facts to satisfy each element.

- 1. An unbroken chain of entities with financial relationships connects the surgeons with the hospitals. An unbroken chain of financial relationships links the surgeons to the hospitals. First, the Medical Center owns each hospital. Second, the Medical Center also owns three entities: Pittsburgh Physicians, Community Medicine, and Tri-State. Third, each of these three entities employs and pays at least one of the surgeons. That adds up to an unbroken chain of financial relationships. Neither party disputes this.
- 2. The surgeons' suspiciously high compensation suggests that it took into account the volume and value of their referrals. Next, the relators allege that the surgeons' aggregate compensation varied with, and took into account, their referrals.

The parties disagree about what it means for compensation to vary with referrals. Appellants argue that varies with requires only correlation. And compensation correlates with referrals here, they argue, because surgeons racked up more Work Units and earned more money by generating more referrals. So the surgeons' aggregate compensation allegedly varied with their referrals. Appellees, by contrast, deny that a correlation suffices. Rather, they insist that the law requires some form of causation.

*7 We need not resolve the meaning of varies with here. Re-gardless, the complaint plausibly alleges that the surgeons' compensation takes into account the volume or value of their referrals. Under the Stark Act and its regulations, compensation takes into account referrals if there is a causal relationship between the two. And here, the surgeons' suspiciously high compensation suggests causation.

Compensation for personal services above the fair market value of those services can suggest that the compensation is really for referrals. This is just common sense. Healthcare pro-viders would not want to lose money by paying doctors more than they bring in. They would do so only if they expected to make up the difference another

way. And that way could be through the doctors' referrals.

This may not be obvious on the face of the statute and regulations. The Stark Act often treats fair market value as a con-cept distinct from taking into account the volume or value of referrals. For example, these two concepts are separate elements of many Stark Act exceptions. E.g.,

42 U.S.C. § 1395nn(e)(2) (bona fide employment), (e)(3) (personal service); 42 C.F.R. § 411.357(I) (fair-market-value compensation), (p) (indirect compensation). And the definition of an *indirect compensation arrangement* includes taking referrals into account, but not fair market value. 42 C.F.R. § 411.354(c)(2)(ii).

But the Act's different treatment of these concepts does not sever them. To start, just because a statute has two elements does not mean that one can never be evidence of the other. Theft requires taking another's property with intent. Those are two elements, but the fact of taking property can be circum-stantial evidence of intent.

So too here. Perhaps not all payments above fair market value are evidence of taking into account the doctor's referrals. But common sense says that marked overpayments are a red flag. Anyone would wonder why the hospital would pay so much if it was not taking into account the doctor's referrals for other services. And we do no violence to the statutory text by seeking an answer to that question.

The agency confronted this question directly. It remarked that even "fixed aggregate compensation can form the basis for a prohibited ... indirect compensation arrangement" if it "is *inflated* to reflect the volume or value of a physician's referrals." 69 Fed. Reg. at 16059 (emphasis added). The same is true of "unit-of-service-based compensation arrangements," like the one here. *Id.* Excessive compensation is thus a sign that a surgeon's pay in fact takes referrals into account.

So aggregate compensation that far exceeds fair market value is smoke. It suggests that the compensation takes referrals into account. And the relators here plead five facts that, viewed together, make plausible claims that the surgeons' pay far exceeded their fair market value. First, some surgeons' pay exceeded their collections. Second, many surgeons' pay exceeded the 90th percentile of neurosurgeons nationwide. Third, many generated Work Units far above industry norms. Fourth, the surgeons' bonus per Work Unit exceeded what the defendants collected on most of those Work Units. And finally, the government alleged in its settlement agreement that the

Medical Center had fraudulently inflated the surgeons' Work Units. That much smoke makes fire plausible.

*8 a. Pay exceeding collections. Paying a worker more than he brings in is suspicious. And the complaint alleges that at least three surgeons (Drs. Bejjani, Spiro, and El-Kadi) were paid more than the Medical Center collected for their services. The complaint also alleges that the Medical Center credits surgeons with 100 percent of the Work Units that they generate, even if it cannot collect on all of them. So at least three surgeons (maybe more) were paid more than they bring in.

b. Pay exceeding the 90th percentile. The relators allege that "[c]ompensation exceeding the 90th percentile is widely viewed in the industry as a 'red flag' indicating that it is in excess of fair market value." App. 191 ¶223. The defendants do not deny this.

Several surgeons were paid more than the 90th percentile. For example, the relators point to the compensation of Drs. Abla, Spiro, Kassam, and Bejjani between 2008 and 2011. Apart from Dr. Spiro in 2008, each of these surgeons was paid more than even the highest estimate of the 90th percentile for all U.S. neurosurgeons in all four years. And depending on which estimate of the 90th percentile you use, they were some-times paid two or three times more than the 90th percentile. Dr. Bejjani's 2011 bonus alone exceeded the 90th percentile of total compensation in some surveys.

c. Extreme Work Units. The relators also allege facts from which we can reasonably infer that the surgeons generated far more Work Units than normal. Many neurosurgeons "were routinely generating [Work Units] exceeding by an enormous margin the 90th percentile as reflected in widely-accepted market surveys." App. 171 ¶126. Even if we look only at the highest industry estimates, all but one of the surgeons reported Work Units above the 90th percentile in 2006 and 2007. In 2008 and 2009, eight of the twelve named surgeons exceeded the highest estimate of the 90th percentile. A few even seemed "super human," racking up two to three times the 90th percentile. App. 169 ¶ 117.

In short, most of the surgeons generated Work Units at or above the 90th percentile. Some of their numbers were unbe-lievably high. And because their pay depends in large part on their Work Units, it is fair to infer that most of their pay was also at or above the 90th percentile.

d. Bonuses exceeding the Medicare reimbursement rate. Once a surgeon had enough Work Units to earn bonus pay, the bonus per Work Unit was more than Medicare

would pay for each one. The surgeons' bonus per Work Unit was \$45. But the Medicare reimbursement rate was only about \$35. So once surgeons became eligible for bonuses, the defendants took an immediate loss on every Work Unit submitted to Medicare.

On its own, this would not show that the surgeons were overpaid. Medicare and Medicaid are well known as bottom-billers. They pay less than private insurers. Though the defendants lost some money on Medicare Work Units, perhaps they made it back with Work Units billed to other insurers.

But the relators also allege that "the majority of all claims submitted by the [defendants] ... were submitted to federal health insurance programs such as Medicare and Medicaid." App. 193 ¶233. We cannot assume that private payments suf-fice to make up the difference. Doing so would disregard our job at this stage: to draw reasonable inferences in favor of the plaintiffs.

In short, the defendants took an immediate financial hit on Work Units for a majority of their claims. This is yet another sign that the surgeons' pay took referrals into account.

*9 The defendants disagree. They argue that the surgeons earn high salaries because of bona fide bargaining with their employers. Their salaries supposedly represent the market's de-mand for their surgical skill and experience.

This argument fails for two reasons. First, the complaint says nothing about the surgeons' skill and experience or the Pittsburgh market for surgeons. On this motion to dismiss, we cannot go beyond the well-pleaded facts in the complaint.

Second, a bare claim of bona fide bargaining is not enough. The Stark Act recognizes that related parties often negotiate agreements "to disguise the payment of non-fair-market-value compensation." Kosenske, 554 F.3d at 97. We trust that bona fide bargaining leads to fair market value only when neither party is "in a position to generate business for the other." Id.; 42 C.F.R. § 411.351 (defining "fair market value" and "general market value"). But that is not true here. The surgeons and the Medical Center can generate business for each other. So we cannot assume that any bargaining was bona fide or that the resulting pay was at fair market value.

e. The possibility of fraud. Finally, the surgeons' high pay may have been based on fudging the numbers. Not only were their individual Work Units "significantly out of line with industry benchmarks," but the Neurosurgery Department as a whole realized astounding "annual growth rates of work [Units] ... of 20.3%, 57.1% and 20.0%" in 2007, 2008, and 2009. App. 171 ¶¶127–28. Two of the surgeons more than dou-bled their output in just a few years. The relators allege that the defendants got this growth by "artificially inflat[ing] the number of [Work Units] in a number of ways." App. 171 ¶130.

Alleging this fraud, the relators' first complaint included claims "relating to physician services submitted by" the defendants along with the "hospital claims" currently before us. App. 189 ¶217 (emphases in original) The government chose to intervene as to the former claims, settling them with the defendants for almost \$2.5 million.

The relators' current complaint quotes that settlement agreement. In it, the government accused the surgeons of many fraudulent practices: They claimed to have acted as assistants when they did not. They claimed to have done more extensive surgeries than they did. And they chose the wrong codes for surgeries. So "claims submitted for these physician services re-sulted in more reimbursement than would have been paid" oth-erwise. App. 188–89 ¶216.

We are careful not to overstate the point. This settlement is not an admission of guilt. It proves no wrongdoing. But at the 12(b)(6) stage, we are looking only for plausible claims, not proof of wrongs. And the government's choice to intervene after years of investigation and its allegations in the settlement are cause for suspicion.

The question is not whether a doctor was able to use an otherwise-valid compensation scheme as a vehicle for fraudulent billing. Not every fraudulent Medicare bill made at a hospital will give rise to a Stark Act violation. Here, however, where the compensation scheme produced results bordering on the absurd, relators plausibly assert that the system may have been designed with that outcome in mind.

*10 The relators allege five sets of facts that suggest that the surgeons' pay far exceeded fair market value: pay exceeding collections, pay above the 90th percentile, extreme Work Units, bonuses above the Medicare reimbursement rate, and the settlement. That is plenty of smoke. We need not decide whether any of these allegations alone would satisfy the relators' pleading burden. Together, they plausibly suggest that the surgeons' pay took their referrals into account. Thus, the relators have pleaded more than enough facts to suggest an indirect compensation arrangement.

3. The hospitals knew that the surgeons' compensation

took their referrals into account. The final element of an indirect compensation arrangement is scienter. To show scienter, the relators' pleadings must allege that the hospitals that provided the referred services either (1) knew, (2) deliberately ignored, or (3) recklessly disregarded that the surgeons got "aggregate compensation that varie[d] with, or t[ook] into account, the volume or value of referrals."

42 C.F.R. § 411.354(c)(2)(iii). They allege this too.

To begin, the Medical Center controls all the hospitals and the surgeons' direct employers. It owns each hospital. And it owns Pittsburgh Physicians, Community Medicine, and Tri-State. So the Medical Center "has unfettered authority with respect to most members of the [medical system] and significant authority (including with respect to financial and tax mat-ters) with respect to the remaining members." App. 146-47 ¶19 (quoting a Medical Center tax filing).

Further, many officers and board members of these entities overlapped. For example, one person simultaneously served as an executive vice president of the Medical Center as well as the president and a board member of Pittsburgh Physicians. And he signed surgeons' pay agreements for Pittsburgh Physicians. The relators identify nine others who served on the board of both the Medical Center and another entity in the medical system. Authority was so centralized that a single person signed a settlement agreement on behalf of all the defendants that were part of the medical system. And with common con-trol comes common knowledge.

The common knowledge included both the surgeons' pay and their referrals. The Medical Center took part in forming, approving, and implementing the surgeons' pay packages. So it knew their structure. The Medical Center also had a central coding and billing department that handled billing for its subsidiaries. So it knew about the surgeons' referrals.

With both sets of data in front of it, we can plausibly infer that the Medical Center knew the surgeons' compensation took their referrals into account. And as the Medical Center knew that, so did the hospitals. They had all the data right in front of them. They knew that the surgeons' pay and Work Units were out of line with industry survey data. Even if they did not actually know that the surgeons' pay and work levels were suspiciously high, they at least deliberately ignored or recklessly disregarded that fact. Thus, the complaint alleges that both the Medical Center and hospitals had scienter.

This means that the relators have successfully pleaded the third and final element of a Stark Act violation: scienter. But they must plead one more thing to survive a motion to dismiss. We must now consider whether the relators have pleaded a plausible prima facie case under the False Claims Act.

V. THE RELATORS PLEAD FALSE CLAIMS ACT VIOLATIONS

The relators plead their Stark Act claims as violations of the False Claims Act. So their pleadings must satisfy all the elements of the False Claims Act. They do. And they satisfy Rule 9(b)'s heightened pleading standard. Last, we hold that the Stark Act's exceptions are not additional elements of a prima facie case. But even if they were, the relators have plausibly pleaded that no exception applies here.

A. The pleadings satisfy all three elements of the False Claims Act

*11 To make out a prima facie case, the relators must plead three elements: "'(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.' "

Schmidt, 386 F.3d at 242 (quoting Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182 (3d Cir. 2001)). They have alleged enough facts to plead all three elements.

First, by submitting claims to Medicare and other federal health programs, the defendants presented claims for payment to the government.

Second, the relators allege that these claims were false. A Medicare claim that violates the Stark Act is a false claim.

**Kosenske*, 554 F.3d at 94*. And we have already explained at length why the Medicare claims here plausibly violated the Stark Act.

Third, the relators' allegations plead scienter. Just like the Stark Act, the False Claims Act requires that the

defendants know, deliberately ignore, or recklessly disregard the falsity of their claim.

31 U.S.C. § 3729(b)(1)(A). But it does not require a specific intent to defraud.

14 § 3729(b)(1)(B).

The claims are false because they allegedly violated the Stark Act. The question is whether the defendants at least recklessly disregarded that possibility. The defendants had a centralized billing department and were familiar with the Stark Act itself, so they knew that they submitted Medicare claims for referred designated health services. That leaves only whether the defendants knew that the hospitals and surgeons had an indirect compensation agreement.

The complaint alleges that the defendants at least recklessly disregarded that possibility. They knew their own corporate structure. We have already explained how they knew or recklessly disregarded that the surgeons' pay varied with their referrals. And we have also explained how they knew or recklessly disregarded that their surgeons' pay far exceeded fair market value and thus plausibly took referrals into account. So the relators have pleaded a prima facie claim under the False Claims Act.

B. The pleadings satisfy Rule 9(b)

The relators' complaint also satisfies <u>Rule 9(b)</u>'s particularity requirement. To do so, the allegations must go well beyond <u>Rule 8</u>'s threshold of plausibility. A mere plausible inference of illegality is not enough. Instead, "a relator must 'estab-lish a "strong inference" that the false claims were submitted.' "<u>United States ex rel. Silver v. Omnicare, Inc.</u>, 903 F.3d 78, 92 (3d Cir. 2018) (quoting

Foglia v. Renal Ventures Mgmt., 754 F.3d 153, 158 (3d Cir. 2014)).

Rule 9(b)'s particularity requirement requires a plaintiff to allege "'all of the essential factual background that would ac-company the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.' " Majestic Blue Fisheries, 812 F.3d at 307 (quoting In re Rock-efeller Ctr. Props., Inc. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002)). The complaint gives us all these necessary details:

- Who? The defendants: the Medical Center and Pittsburgh Physicians.
- · What? The defendants submitted or caused to be

submitted false Medicare claims.

- When? From 2006 until now.
- Where? The Medicare claims were submitted from the Medical Center's centralized billing facility, while the referred services were provided at the Medical Center's twenty hospitals.
- *12 How? When the Medical Center submitted a claim, it certified compliance with the Stark Act. The complaint makes all the allegations discussed above. We will not repeat them. But they detail exactly how these claims violated the Stark Act.

Rule 9(b) does not require the relators to plead anything more, such as the date, time, place, or content of every single allegedly false Medicare claim. The falsity here comes not from a particular misrepresentation, but from a set of circumstances that, if true, makes a whole set of claims at least prima facie false. It is enough to allege those circumstances with particularity. Doing so "inject[s] precision or some measure of substantiation into [the] fraud allegation" and "place[s] the defendant on notice of the precise misconduct with which [it is] charged."

Alpizar-Fallas v. Favero, 908 F.3d 910, 919 (3d Cir. 2018) (quoting Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007)) (last alteration in original; internal quotation marks omitted).

And the relators have done so. The second amended complaint runs 57 pages (plus exhibits) and comprises 257 num-bered paragraphs. Dozens of these paragraphs go into great detail about specific physicians' Work Units and pay levels. The complaint compares those figures at length with industry benchmarks, medians, and 90th percentiles. It alleges specific ways that surgeons padded their bills, by for instance falsely reporting unperformed work assisting other surgeons or phys-ically supervising residents and interns. The complaint also quotes the government's settlement agreement, alleging specific ways that surgeons had been padding their bills. The sum total of these allegations tells a detailed story about how the defendants designed a system to reward surgeons for creating and submitting false claims. See Omnicare, 903 F.3d at 91-92 (quoting Foglia, 754 F.3d at 158). And that is particular enough to satisfy Rule 9(b).

C. Pleading Stark Act exceptions under the False

Claims Act

One final issue is how the Stark Act interacts with the False Claims Act. The defendants argue that the False Claims Act's elements of falsity and knowledge turn the Stark Act's exceptions into prima facie elements of the False Claims Act. On their reading, the relators would have to plead that no exception applies here.

We reject that argument. The defendants retain the burden of pleading Stark Act exceptions even under the False Claims Act. And even if the relators bore that burden, they have met it here.

1. The burden of pleading Stark Act exceptions stays with the defendant under the False Claims Act. The defendants argue that the False Claims Act's knowledge and falsity elements turn the Start Act's exceptions into prima facie elements. Their logic is simple and cogent: The False 31 U.S.C. § Claims Act penalizes only false claims. 3729(a)(1). False claims include claims submitted in violation of the Stark Act. See: Kosenske, 554 F.3d at 94. But if an exception to the Stark Act applies, then the claim is not false. And if the defendant thinks that an exception applies, then the defendant does not know that the claim is false. So, according to the defendants, to plead a False Claims Act claim based on Stark Act violations, a relator must plead that no Stark Act exception applies and that the defendant knows that none applies. Otherwise, the relator pleads neither falsity nor knowledge.

*13 Though this argument has force, we reject it. Our precedent compels this result. Like this case, Kosenske was a False Claims Act case based on Stark Act violations. Id. It placed the burden of proving a Stark Act exception on the defendant. Id. at 95; accord

Tuomey, 792 F.3d at 374. And we see no reason to split up the burdens of pleading and persuasion. It is thus the defendants' burden to plead a Stark Act exception, not the relators' burden to plead that none exists.

2. Even if the relators bore this pleading burden, they have met it. In any event, the relators here plausibly plead that no Stark Act exception applies. The parties identify four that could apply here: exceptions for bona fide employment, personal services, fair-market-value pay, and indirect compensation. All four exceptions require

that the surgeons' compensation not exceed fair market value and not take into account the volume or value of referrals.

We have already explained how the relators plausibly plead that the surgeons were paid more than fair market value. And that itself suggests that their pay may take into account their referrals' volume or value. So the relators plausibly plead that no Stark Act exception applies.

VI. CONCLUSION

Evaluating a motion to dismiss is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." <u>Igbal</u>, 556 U.S. at 679. Our experience and common sense tell us that the relators state a plausible claim that the Medical Center and Pittsburgh Physicians have violated the Stark Act and the False Claims Act.

The facts they plead, if true, satisfy every element of those statutes: A chain of financial relationships linked the hospitals to the surgeons. The surgeons referred many designated health services to the hospitals, generating ancillary hospital services and facility fees. It is plausible that their pay takes into account the volume of those referrals. The hospitals made Medicare claims for those referrals. And the defendants allegedly knew all this.

With all this smoke, a fire is plausible. So this case deserves to go to discovery. Once the discovery is in, it may turn out that there is no fire. We do not prejudge the merits. But this is exactly the kind of situation on which the Stark and False Claims Acts seek to shed light. We will thus reverse the District Court's dismissal and remand for further proceedings.

All Citations

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UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 18-1693

UNITED STATES OF AMERICA ex rel.
J. WILLIAM BOOKWALTER, III, M.D.;
ROBERT J. SCLABASSI, M.D.; ANNA MITINA

٧.

UPMC; UNIVERSITY OF PITTSBURGH PHYSICIANS, d/b/a UPP DEPARTMENT OF NEUROSURGERY

J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA, Appellants

(W.D. Pa. No. 2:12-cv-00145)

SUR PETITION FOR REHEARING

Present:

SMITH, <u>Chief Judge</u>, and McKEE, AMBRO, CHAGARES, JORDAN, HARDIMAN, GREENAWAY, JR., SHWARTZ, KRAUSE, RESTREPO, BIBAS, MATEY, PHIPPS, and FUENTES,* <u>Circuit Judges</u>

The petition for rehearing filed by Appellees in the above-captioned case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, it is hereby **ORDERED** that the petition for rehearing is **GRANTED IN PART**. A majority of the judges who participated in the decision of the Court having voted for rehearing, the petition for rehearing by

^{*} Judge FUENTES's vote is limited to panel rehearing only.

the panel is **GRANTED**. The opinion and judgment filed September 17, 2019, are hereby **VACATED**. A subsequent opinion and judgment are herewith issued.

The majority has made changes to the language that appeared at pages 3–4, 6, 11, 15, 27–30, 32–33, 35–37, and 39–40 of the original opinion. Most of the material that appeared at pages 18–25 of the original opinion has been deleted. Judge AMBRO's opinion concurring in the judgment has been withdrawn.

A majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the Court en banc is **DENIED**.

By the Court,

s/ Stephanos Bibas Circuit Judge

Dated: December 20, 2019

NMR/cc:

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 18-1693

UNITED STATES OF AMERICA, ex rel. J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA

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UPMC; UNIVERSITY OF PITTSBURGH PHYSICIANS, d/b/a UPP DEPARTMENT OF NEUROSURGERY

J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA, Appellants

On Appeal from the United States District Court for the Western District of Pennsylvania (D.C. No. 2:12-cv-00145)
District Judge: Honorable Cathy Bissoon

Argued-: January 10,

2019

Before: AMBRO, BIBAS, and FUENTES, Circuit Judges-

(Filed: September 17 December 20, 2019)

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OPINION OF THE COURT

BIBAS, Circuit Judge.

Healthcare spending is a huge chunk of the federal budget. Medicare and Medicaid cost roughly a trillion dollars per year. And with trillions of dollars comes the temptation for fraud.

Fraud is a particular danger because doctors and hospitals can make lots of money for one another. When doctors refer patients to hospitals for services, the hospitals make money. There is nothing inherently wrong with that. But when hospitals pay their doctors based on the number or value of their referrals, the doctors have incentives to refer more. The potential for abuse is obvious and requires scrutiny.

The Stark Act and the False Claims Act work together to ensure this scrutiny and safeguard taxpayer funds against abuse. The Stark Act forbids hospitals to bill Medicare for certain services when the hospital has a financial relationship with the doctor who asked for those services, unless an exception applies. And the False Claims Act gives the government and relators a cause of action with which to sue those who violate the Stark Act.

Here, the relators allege that the defendants have for years been billing Medicare for services referred by their neurosurgeons in violation of the Stark Act. The District Court found that the relators had failed to state a plausible claim and dismissed their suit.

This appeal revolves around two questions: First, do the relators offer enough facts to plausibly allege that the surgeons' pay varies with, or takes into account, their referrals? Second, who bears the burden of pleading Stark Act exceptions under the False Claims Act?

The answer to the first question is yes. The relators' complaint alleges enough facts to make out their claim. The surgeons' contracts make it very likely that their pay varies with their referrals. And the relators also make a plausible case that the surgeons' pay is so high that it must take their referrals into account. All these facts are smoke; and where there is smoke, there might be fire.

The answer to the second question is the defendants. The Stark Act's exceptions work like affirmative defenses in litigation. The burden of pleading these affirmative defenses lies with the defendant. This is true even under the False Claims Act. And even if that burden lay with the relators, their pleadings meet that burden here.

We hold that the complaint states plausible violations of both the Stark Act and the False Claims Act. So we will reverse.

I. BACKGROUND

A. Factual Background

1. The University of Pittsburgh medical system. On this motion to dismiss, we take as true the facts alleged in the second amended complaint: The University of Pittsburgh Medical Center is a multi-billion-dollar nonprofit healthcare enterprise. The Medical Center is the parent organization of a whole system of healthcare subsidiaries, including twenty hospitals. The Medical Center is the sole member (owner) of each hospital.

More than 2,700 doctors, including dozens of neurosurgeons, work at these hospitals. The doctors are employed not by the hospitals, but by other Medical Center subsidiaries. Three of these subsidiaries matter here: University of Pittsburgh Physicians; UPMC Community Medicine, Inc.; and Tri-State Neurological Associates-UPMC, Inc.

These three subsidiaries employed many of the neurosurgeons who worked at the Medical Center's hospitals during the years at issue, from 2006 on. Pittsburgh Physicians' Neurosurgery Department employed most of the surgeons at issue. Tri-State employed two, and Community Medicine employed one. The Medical Center owns all three subsidiaries. In short, the Medical Center owns both the hospitals and the companies that employ the surgeons who work in the hospitals.

2. The neurosurgeons' compensation structure. The surgeons who worked for the three subsidiaries here all had similar employment contracts. Each surgeon had a base salary and an annual Work-Unit quota. Work Units (or wRVUs) measure the value of a doctor's personal services. Every medical service

is worth a certain number of Work Units. The longer and more complex the service, the more Work Units it is worth. Work Units are one component of Relative Value Units (RVUs). RVUs are the basic units that Medicare uses to measure how much a medical procedure is worth.

The surgeons were rewarded or punished based on how many Work Units they generated. If a surgeon failed to meet his yearly quota, his employer could lower his future base salary. But if he exceeded his quota, he earned a \$45 bonus for every extra Work Unit.

3. The neurosurgeons' alleged fraud and its effects on salaries and revenues. This compensation structure gave the surgeons an incentive to maximize their Work Units. And the incentive seems to have worked. The surgeons reported doing more, and more complex, procedures. So the number of Work Units billed by the Neurosurgery Department more than doubled between 2006 and 2009.

Much of this increase allegedly stemmed from fraud. The relators accuse the surgeons of artificially boosting their Work Units: The surgeons said they acted as assistants on surgeries when they did not. They said they acted as teaching physicians when they did not. They billed for parts of surgeries that never happened. They did surgeries that were medically unnecessary or needlessly complex. And they did these things, say the relators, "[w]ith the full knowledge and endorsement of" the Medical Center. App. 184 ¶190.

Fraud can be profitable. And here it allegedly was. With these practices, the surgeons racked up lots of Work Units and

made lots of money. Most reported total Work Units that put them in the top 10% of neurosurgeons nationwide. And some received total pay that put them among the best-paid 10% of neurosurgeons in the country.

The surgeons' efforts proved profitable for the Medical Center too. The Medical Center made money off the surgeons' work on some of the referrals. And to boot, healthcare providers bill Medicare for more than just the surgeons' own Work Units. Whenever a surgeon did a procedure at one of the hospitals, the Medical Center also got to bill "for the attendant hospital and ancillary services." App. 166 ¶ 104. This part of the bill could be four to ten times larger than the cost of the surgeon's own services. So when the surgeons billed more, the Medical Center made more. "Indeed, in 2009," the Neurosurgery Department "was the single highest grossing neurosurgical department in the United States, with Medicare charges alone of \$58.6 million." App. 163–64 ¶91.

B. Procedural History

The relators first filed suit in 2012. They alleged that the Medical Center, Pittsburgh Physicians, and a bevy of neurosurgeons had submitted false claims for physician services and for hospital services to Medicare and Medicaid. Four years later, the United States intervened as to the claims for physician services. The government settled those claims for about \$2.5 million. It declined to intervene as to the claims for hospital services, but it let the relators maintain that part of the action in its stead.

After the government intervened, the District Court dismissed the first amended complaint without prejudice for failure to state a claim. The relators then filed their current complaint, asserting three causes of action against the Medical Center and Pittsburgh Physicians under the False Claims Act:

- (1) one count of submitting false claims,
- (2) one count of knowingly making false records or statements, and
- (3) one count of knowingly making false records or statements material to an obligation to pay money to the United States.

The District Court again dismissed for failure to state a claim, this time with prejudice. The relators now appeal.

II. STANDARDS OF REVIEW AND PLEADING

We review a district court's dismissal for failure to state a claim de novo. *Vorchheimer v. Philadelphian Owners Ass'n*, 903 F.3d 100, 105 (3d Cir. 2018). Our job is to gauge whether the complaint states a plausible claim to relief. *Ashcroft v. Iq-bal*, 556 U.S. 662, 678 (2009). *Plausible* does not mean *possible*. If the allegations are "merely consistent with" misconduct, then they state no claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). There must be something in the complaint to suggest that the defendant's alleged conduct is illegal. *Id.* at 557.

But *plausible* does not mean *probable* either. Our job is not to dismiss claims that we think will fail in the end. *See id.* at

556. Instead, we ask only if we have "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of" each element. *Id*.

This is the baseline pleading standard for all civil actions. Fed. R. Civ. P. 8; *Iqbal*, 556 U.S. at 684. But the relators allege claims for fraud. So they must also meet Rule 9(b)'s heightened pleading requirement. *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 306–07 (3d Cir. 2016). That rule says that a party alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

III. THE STARK ACT AND THE FALSE CLAIMS ACT

A. The Stark Act

The Stark Act protects the public fise from Medicare and Medicaid fraud. The Act and its regulations broadly bar Medicare Medicare claims for many services referred by doctors who have a financial financial interest in the healthcare provider. But the statute erecates dozens of exceptions and authorizes the Department of Health and Human Services to make even more exceptions for financial financial relationships that "do[] not pose a risk of program or patient patient abuse." 42 U.S.C. §1395nn(b)(4).

1. Forbidden conduct. The Stark Act opens with a broad ban. It forbids submitting Medicare claims for "designated health services" provided under a "referral" made by a doctor with whom the entity has a "financial relationship." Id. §1395nn(a)(1). Understanding this ban requires exploring these three quoted terms, each of which has statutory and regulatory definitions.

The Stark Act lists several categories of designated health services, including inpatient hospital services. Id. §1395nn(h)(6)(K). And inpatient hospital services include bed and board, interns' and residents' services, nursing, drugs, supplies, transportation, and overhead. 42 C.F.R. §§409.10(a), 411.351.

A referral is a doctor's request for a designated health service. 42 U.S.C. §1395nn(h)(5)(A); 42 C.F.R. §411.351. That definition is broad, but it has an important exception: services that a doctor performs personally do not count. 42 C.F.R. §411.351. That makes sense; ordinarily, one cannot refer something to oneself. And the exception's boundaries also follow: it does not cover services by a doctor's associates or employees, or services incidental to the doctor's own services. Id.; Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II); Interim Final Rule, 69 Fed. Reg. 16054, 16063 (Mar. 26, 2004).

Finally, financial relationships come in two forms:

- (1) ownership or investment interests and (2) compensation arrangements. 42 U.S.C. §1395nn(a)(2). This case turns on the latter. The statute defines *compensation arrangement* to mean "any arrangement involving any remuneration between" a doctor and a healthcare provider. *Id.* §1395nn(h)(1)(A). And *remuneration* "includes any remuneration, directly or indirectly, in cash or in kind." *Id.* §1395nn(h)(1)(B).
- 2. Exceptions. On its face, the Stark Act's ban sweeps in lots of common situations. To separate the fraudulent—wheat from the innocuous—in-nocuous—chaff, Congress and the Department of Health and

Human Services have created many exceptions. Here, the Medical Center argues that exceptions for four types of compensation compensation arrangements could apply here: bona fide ememploy- ploymentment; personal services; fair-market-value compensation; and indirect compensation. See id. §1395nn(e)(2), (e)(3); 42 C.F.R. §411.357(I), (p).

All four exceptions have two elements in common. First, the doctor's compensation must not "take[] into account (directly or indirectly) the volume or value of the doctor's referralsreferrals. 42 U.S.C. §1395nn(e)(2)(B)(ii); accordid.

§1395nn(e)(3)(A)(v); 42 C.F.R. §411.357(*l*)(3), (p)(1)(i). Second, the doctor's compensation must not exceed *fair market value*. 42 U.S.C. §1395nn(e)(2)(B)(i), (e)(3)(A)(v); 42 C.F.R. §411.357(*l*)(3), (p)(1)(i).

In litigation, these exceptions are affirmative defenses. So once a plaintiff proves a prima facie violation of the Stark Act, the burden shifts to the defendant to prove that an exception applies. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009).

3. No built-in cause of action. The Stark Act forbids the government to pay claims that violate the Act. 42 U.S.C. §1395nn(g)(1). It demands restitution from those who receive payments on illegal claims. *Id.* §1395nn(g)(2). And it creates civil penalties for submitting improper claims or taking part in schemes to violate the Act. *Id.* §1395nn(g)(3), (4). But it gives no one a right to sue. *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 374 n.4 (4th Cir. 2015).

So the Stark Act never appears in court alone. Instead, it always come in through another statute that creates a cause of action—typically, the False Claims Act.

B. The False Claims Act

Under the False Claims Act, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is civilly liable to the United States. 31 U.S.C. §3729(a)(1)(A). A Medicare claim that violates the Stark Act is a false claim under the False Claims Act. Kosenske, 554 F.3d at 94. The False Claims Act also makes liable anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to" a false or fraudulent claim. 31 U.S.C. §3729(a)(1)(B), (G).

IV. THE RELATORS PLEAD STARK ACT VIOLATIONS

A prima facie Stark Act violation has three elements: (1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for the referred services. See United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 241 (3d Cir. 2004). This combination of factors suggests potential abuse of Medicare. When they are all present, we let plaintiffs go to discovery.

Here, no one denies that the defendants made Medicare claims for designated health services. The issue is whether the complaint sufficiently alleges referrals and a compensation arrangement. We hold that it does. The alleged Medicare abuse is plausible and deserves more scrutiny.

A. The surgeons referred designated health services to the hospitals

The relators allege that "[e]very time [the neurosurgeons] performed a surgery or other procedure at the UPMC Hospitals, [they] made a referral for the associated hospital claims." App. 193 ¶234. They are right that these claims are referrals.

As mentioned, the law defines referrals broadly. A referral is a doctor's request for any designated health service that is covered by Medicare and provided by someone else. 42 C.F.R. §411.351. Designated health services include bed and board, some hospital overhead, nursing services, and much more. 42 C.F.R. §409.10(a). And the relators plead that as the surgeons performed more procedures, those procedures required (and the hospital provided and "increased billings for[)] the attendant hospital and ancillary services including ... hospital and nursing charges." App. 166 ¶104 (emphasis added). So the plaintiffs plead that the surgeons referred designated health services to the hospitals.

Treating these services as referrals makes sense. The Stark Act's first step is to flag all potentially abusive arrangements. And doctors who generate profits for a hospital may be tempted to abuse their power, raising hospital bills as well as their own pay. These financial arrangements thus deserve a closer look. And they will get a closer look only if we call these arrangements what they are: doctors referring services to hospitals.

The Department of Health and Human Services agrees. In Phase I of its Stark Act rulemaking, it considered this point. It determined that "any hospital service, technical component, or facility fee billed by [a] hospital in connection with [a doctor's] personally performed service" counts as a referral. *Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships*, 66 Fed. Reg. 856, 941 (Jan. 4, 2001). This is true even "in the case of an inpatient surgery" where the doctor performs the surgery. *Id.*

Then, in Phase II of its rulemaking, the agency revisited the question and considered narrower definitions. For instance, many commenters suggested excluding "services that are performed 'incident to' a physician's personally performed services or that are performed by a physician's employee" from the definition of a referral. 69 Fed. Reg. at 16063.

But the agency reasonably rejected these suggestions. A narrower view, it reasoned, would all but swallow at least one statutory exception. *Id.* And it explained that the availability of that and other exceptions did enough to protect innocent conduct. *Id.* "[T]his interpretation is consistent with the statute as a whole," which begins by casting a broad net to scrutinize all potential abuse. *Id.*

B. The relators' complaint alleges an indirect compensation arrangement

A referral is ripe for abuse only when the doctor who made it has a financial relationship with the provider. Only then can a doctor profit from his own referral. The financial relationship here is a compensation arrangement.

Compensation arrangements can be either direct or indirect. 42 C.F.R. §411.354(c). The hospitals did not pay the surgeons directly. So if there is any compensation arrangement here, it is indirect. That requires three elements: First, there must be "an unbroken chain ... of persons or entities that have financial relationships" connecting the referring doctor with the provider of the referred services. Id. §411.354(c)(2)(i). Second, the referring doctor must get "aggregate compensation ... that varies with, or takes into account, the volume or value of referrals." Id. §411.354(c)(2)(ii). And third, the service provider must know, recklessly disregard, or deliberately ignore that the doctor's compensation "varies with, or takes into account, the volume or value of referrals." Id. §411.354(c)(2)(iii). (The parties do not challenge any of the regulations at issue, so we likewise assume that they are valid.) The complaint plausibly pleads enough facts to satisfy each element.

- 1. An unbroken chain of entities with financial relationships connects the surgeons with the hospitals. An unbroken chain of financial relationships links the surgeons to the hospitals. First, the Medical Center owns each hospital. Second, the Medical Center also owns three entities: Pittsburgh Physicians, Community Medicine, and Tri-State. Third, each of these three entities employs and pays at least one of the surgeons. That adds up to an unbroken chain of financial relationships. Neither party disputes this.
- 2. The surgeons' compensation varies with, or takes into account, The surgeons' suspiciously high compensation suggests that it took into account the volume and value of their referrals. Next, the re-lators-relators allege that the surgeons' aggregate compensation compensation varied with, and took into account, their referrals. Under the Stark Act and its regulations, compensation varies with referrals if the two are correlated. And compensation takes into account referrals if there is a causal relationship between the two. The structure of the surgeons' contracts is enough to plead correlation. And

the surgeons' suspiciously high compensation suggests causation their referrals.

The parties disagree about what it means for compensation to vary with referrals. Appellants argue that varies with re-quires only correlation. And compensation correlates with re-ferrals here, they argue, because surgeons racked up more Work Units and earned more money by generating more referrals. So the surgeons' aggregate compensation allegedly varied with their referrals. Appellees, by contrast, deny that a correlation suffices. Rather, they insist that the law requires some form of causation.

The relators must show either correlation or causation between compensation and referrals. To start, we have to tease out the difference between varies with and takes into account. Section 411.354(c)(2)(ii) uses both phrases. But in other places, like the exceptions, the Stark Act and its regulations use only takes into account, not varies with 42 U.S.C.

§1395nn(e)(2)(B)(ii), (e)(3)(A)(v); 42 C.F.R. §411.357(l)(3), (p)(1)(i). So varies with must mean something different from takes into account.

Here is the most natural reading of both phrases: Takes into account means actual causation. The doctor's pay must be based on or designed to reflect the volume or value of his referrals. But varies with means correlation. If compensation tends to rise and fall as the volume or value of referrals rises and falls, then the two vary with each other. This reading gives each phrase independent meaning. And it makes the scope of

indirect-compensation-arrangements-broader than the scope of the exceptions.

This makes sense. Correlation does not guarantee causation, but it is evidence of causation. So the agency reasonably decided to include as indirect compensation arrangements those where pay varies with referrals. 69 Fed. Reg. at 16059. That way, such arrangements get a closer look. Then, the defendant gets a chance to show that the correlation is mere coincidence, not causation. If it does, then the compensation arrangement can fit within a Stark Act exception. *Id*.

Our concurring colleague adopts a less natural reading. Instead of treating varies with as a broader phrase-meaning correlation, he reads takes into account as broader. Conc. Op. 4. 6. And he limits this broader phrase to causal relationships, whether explicit or "implicit (that is, unstated)." Id. So his reading of the causation requirement makes varies with (express causation) a subset of takes into account (express or implied causation). But the Stark Act's text and structure are to the contrary.

Textually, the concurrence is right that, read in isolation, varies with sometimes implies causation. Varies with can mean correlation, however, and often does. Mathematicians sometimes use A-varies with B causally, to mean that A is a function of B. But statisticians often say that A varies with B if A correlates with B. Thus, a correlation coefficient expresses the covariance between two variables. Timothy C. Urdan, Statistics in Plain English 79–80 (2d ed., Psychology Press 2005); see also Paul McFedries, Excel Data Analysis 202 (4th ed. 2013) ("[A] correlation does not prove one thing-causes another. The

most you can say is that one number varies with the other.") (emphasis added).

Courts-likewise use varies with as a synonym for correlation. Our Court has explained that "a correlation coefficient ... measures 'how consistently' the dependent variable varies in correspondence with the independent variable." Jenkins v. Red Clay-Consol. Sch. Dist. Bd. of Educ., 4 F.3d 1103, 1120 n.10 (3d Cir. 1993) (emphasis added). Other courts do too. E.g., NAACP v. City of Niagara-Falls, 65 F.3d 1002, 1005 n.2 (2d Cir. 1995) ("A 'correlation coefficient' is generated, demonstrating how consistently voter support for a candidate or group of candidates varies with the racial composition of the election districts.") (emphasis added) (quoting district court)); Citizens for a Better Gretna v. Gretna, 636 F. Supp. 1113, 1126 n.32 (E.D. La. 1986) (same). So we can plausibly read varies with to mean correlation, not just causation.

And that is the point. Here, varies with is about correlation, not causation. As our concurring colleague notes, we do not think the Stark Act requires relators to plead a "perfect positive"

correlation" between doctors' pay and referrals. Conc. Op. 7. The beauty of the phrase varies with is that it carries little technical baggage yet "make[s] clear that there is no need to establish causation." Loan Originator Compensation Requirements Under the Truth in Lending Act (Regulation Z), Supplementary Information, 78 Fed. Reg. 11280, 11325-26 (Feb. 15, 2013) (explaining that the final rule uses varies with as a non-technical substitute for correlates with).

More importantly, as he admits, our concurring colleague's approach makes varies with into surplusage, robbing it of any

useful role in the regulatory scheme. Conc. Op. 8. In 42-C.F.R. §411.354(e)(2)(ii), for example, varies with would be redundant of every takes into account. It would do no work. By contrast,—our—reading—casts—varies—with—as—the star—of §411.354(e)(2)(ii). Takes into account gets its turn to shine in the Stark Act exceptions, where varies—with—does not appear. Id. §§411.355, 357. On this reading, the scope of indirect compensation arrangements is broader than the scope of the exceptions. Each phrase does real work—and serves—an independent purpose.

Faced with two readings, one of which gives each phrase in a disjunctive list an operative meaning and another that makes a phrase surplus, we should follow the "elementary canon of construction" against surplusage. *Colautti v. Franklin*, 439 U.S. 379, 392 (1979); *United States v. Kouevi*, 698 F.3d 126, 133 34 (3d Cir. 2012) (collecting cases).

Structurally, our approach also reinforces the Stark Act's design. It easts a wide net of initial suspicion, followed by narrower safe harbors. A correlation between pay and referrals suggests that hospitals are rewarding doctors for referrals. And healthcare providers get to use the Stark Act's exceptions to show that there is no problematic causal relationship. Only if they cannot should those cases go to discovery.

Our concurring colleague's approach would upend that structure by denying relators the discovery they need to prove their cases. In *Tuomey*, for example, hospital insiders linked pay with referrals only during discovery—not in the complaint.

Compare First Amended Complaint, United States ex-rel. Drakeford v. Tuomey, 976 F. Supp. 2d 776 (D.S.C. 2013) (No.

3:05-2858-MBS), ECF No. 151, with J.A. Combined Vols. IXIII at 504-14, Tuomey, 792 F.3d-364 (No. 13-2219), ECF No. 39 (testimony of William (Paul) Johnson) (Tuomey's CFO admitting that he feared losing money if doctors treated patients offsite, so he analyzed the value of doctors' noncompete agreements that might recapture that revenue by requiring them to do their procedures at Tuomey's hospitals); id. at 1809-22 (testimony of Kimberly Saccone) (same, by senior consultant); id. at 335, 4594 (statement by Tuomey's lawyer Tim Hewson to CEO, several vice-presidents, and key doctors at a recorded meeting-on Jan. 19, 2004) ("Because of the Stark and Antikickback laws, you-can't explicitly say, 'Well, it's because we're getting all the referrals for these patients,' and of course that's what we're doing.").

And Tuomey was a close case at the motion to dismiss stage. Tuomey itself had received conflicting legal advice about whether its contracts violated the Stark Act. Compare Tuomey, 792 F.3d at 371-72 (advice from lawyer Kevin McAnaney), with First Am. Compl. 25 ¶97-98 (advice from law firm Hall & Render). The truth emerged only through the cleansing light of discovery, once the relators got to depose hospital executives and transcribe audio recordings of executive meetings. But our concurring colleague's approach would shut that door, dismissing such cases before discovery. That would make it all but impossible for the relator in the next Tuomey to prevail.

In-short, at the pleading stage, a plaintiff must plead-facts that make *either* correlation or causation plausible. Here, the relators do-both.

The structure of the surgeons' contracts plausibly al-leges correlation between their pay and referrals. The relators plead that two aspects of the surgeons' pay varied with their referrals: base salaries and bonuses. If the surgeons met their quota of Work Units, they protected their base salaries. And if they exceeded that quota, they earned a bonus for each additional Work Unit.

So the surgeons' pay was facially based only on the services they personally performed. But every time they "performed a surgery or other procedure at the UPMC Hospitals, [they] made a referral for the associated hospital claims," like nursing services or hospital overhead. App. 193 ¶234. And the defendants got to bill Medicare for those referred services, which could be worth many times more than the surgeon's own services.

As a result, the surgeons' salaries rose and fell with their referrals. The more procedures they did at the hospitals, the more referrals they made, and the more they would earn by maintaining their base salaries and earning higher bonuses. And just as their salaries flowed, they also ebbed: the fewer procedures they did, the fewer referrals they made, and the less they got paid. Thus, their aggregate compensation varied with their referrals' volume and value.

The Fourth Circuit agrees. In *Tuomey*, as here, the doctors' base salaries and bonuses rose and fell each year "based solely on" their "personally—performed—professional services." 792 F.3d at 379 (internal quotation marks omitted). Our concurring colleague reads the Fourth Circuit's opinion as limited to com-

pensation agreements that expressly give doctors a cut of expenses-like technical or facility fees, beyond the work doctors do personally. Conc. Op. 9 11. But that reading overlooks *Tuomey*'s facts.

The *Tuomey* court did not say that the doctors there took a straight percentage cut of referrals. It says only that as doctors did more procedures, the number of Tuomey's referrals went up—and-so did the doctors' compensation. *Sec.* 792—F.3d at 379.

And the briefing in *Tuomey* clarifies any-possible ambiguity about which collections affected pay by falling within the scope of a doctor's "personally performed professional services." *Id.* (internal quotation marks omitted). The hospital there insisted that "[n]o component of the physicians' pay depended on the amount of Tuomey's charges or collections for facility fees." Appellant's Final Br. 44, *Tuomey*, 792 F.3d 364

(No. 13-2219), ECF No. 50. In fact, the hospital had rejected "suggested modifications" to its contracts that would have made "technical fees ... a component of the physicians' compensation." Id. Contrary to our concurring colleague, the Tuomey record shows that the doctors' pay was "based on their professional collections for services that they personally perform[ed], not on any billings or collections of the Hospital for its services." Mem. in Supp. of Def.'s Mot. to Dismiss 5, Tuomey, 976 F. Supp. 2d 776, ECF No. 64-1 (emphasis added). The same is true here.

But as the Fourth-Circuit-observed, these-personally-performed services almost-always came with referrals for ancil-

lary hospital services. 792 F.3d at 379. And the healthcare provider got to bill Medicare for those services. *Id.* The more procedures a doctor did at the hospital, the more referrals he made, and the more he could make in both base salary and bonuses. *Id.* Thus, the Fourth Circuit "th[ought] it plain that a reasonable jury could find that the physicians' compensation varied with the volume or value of actual referrals." *Id.* at 379–80 (emphasis added).

We agree with the Fourth Circuit's logic. It applies equally here. So the relators have pleaded that the surgeons' pay varied with their referrals.

Our concurring colleague fears that our rationale casts suspicion on any compensation agreement based on a doctor's "own labor." Conc. Op. 11. Not so. The Stark Act kicks in only when a doctor's pay varies with Medicare or Medicaid referrals tied to that doctor's personal labor. If a doctor's pay does not vary with the volume or value of Medicare or Medicaid referrals, the Stark Act plays no role.

But here, the relators have pleaded that the doctors' pay correlated with the value of their Medicare referrals. That correlation is enough to plead the second element of an indirect compensation arrangement. The relators need not also plead causation. But they do anyway.

We need not resolve the meaning of varies with here. Regardless, the complaint plausibly alleges that the surgeons' compensation takes into account the volume or value of their referrals. Under the Stark Act and its regulations, compensation takes into account referrals if there is a causal relationship between the two. And here, the surgeons' suspiciously high compensation suggests causation.

Compensation for personal services above the fair market value of those services can suggest that the compensation compensation is really for referrals. This is just common sense. Healthcare providers pro-viders would not want to lose money by paying doctors more than they bring in. They would do so only if they expected to make up the difference another way. And that way could be through the doctors' referrals.

This may not be obvious on the face of the statute and regulations. The Stark Act often treats fair market value as a concept distinct from taking into account the volume or value of referrals. For example, these two concepts are separate elements of many Stark Act exceptions. E.g., 42 U.S.C.

§1395nn(e)(2) (bona fide employment), (e)(3) (personal service); 42 C.F.R. §411.357(*l*) (fair-market-value compensation), (p) (indirect compensation). And the definition of an *indirect compensation arrangement* includes taking referrals into account, but not fair market value. 42 C.F.R. §411.354(c)(2)(ii).

But the Act's different treatment of these concepts does not sever them. To start, just because a statute has two elements does not mean that one can never be evidence of the other. Theft requires taking another's property with intent. Those are two elements, but the fact of taking property can be circumstantial evidence of intent.

So too here. Perhaps not all payments above fair market value are evidence of taking into account the doctor's referrals. But common sense says that marked overpayments are a red flag. Anyone would wonder why the hospital would pay so much if it was not taking into account the doctor's referrals for other services. And we do no violence to the statutory text by seeking an answer to that question.

The agency confronted this question directly. It remarked that even "fixed aggregate compensation can form the basis for a prohibited ... indirect compensation arrangement" if it "is *inflated* to reflect the volume or value of a physician's referrals." 69 Fed. Reg. at 16059 (emphasis added). The same is true of "unit-of-service-based compensation arrangements," like the one here. *Id.* Excessive compensation is thus a sign that a surgeon's pay in fact takes referrals into account.

So aggregate compensation that <u>far</u> exceeds fair market value is smoke. It suggests that the compensation takes referrals refer- rals into account. And the relators here plead five facts that, viewed to—gethertogether, make plausible claims that the surgeons' pay <u>far</u> exceeded their fair market value. First, some surgeons' pay exceeded their collections. Second, many surgeons' pay exceeded <u>ex-ceeded</u> the 90th percentile of neurosurgeons nationwide. Third, many <u>generated generated</u> Work Units far above industry norms. Fourth, the <u>sur-geonssurgeons</u>' bonus per Work Unit exceeded what the <u>defendants coldefend-lected ants collected</u> on most of those Work Units. And finally, the <u>govern-ment government</u> alleged in its settlement agreement that the <u>Medical CenMediter-cal Center</u> had fraudulently inflated the surgeons' Work Units. That much smoke makes fire plausible.

- a. Pay exceeding collections. Paying a worker more than he brings in is suspicious. And the complaint alleges that at least three surgeons (Drs. Bejjani, Spiro, and El-Kadi) were paid more than the Medical Center collected for their services. The complaint also alleges that the Medical Center credits surgeons-sur- geons with 100 percent of the Work Units that they generate, even if it cannot collect on all of them. So at least three surgeons-sur- geons (maybe more) were paid more than they bring in.
- b. Pay exceeding the 90th percentile. The relators allege that "[c]ompensation exceeding the 90th percentile is widely viewed in the industry as a 'red flag' indicating that it is in excess of fair market value." App. 191 ¶223. The defendants do not deny this.

Several surgeons were paid more than the 90th percentile. For example, the relators point to the compensation of Drs. Abla, Spiro, Kassam, and Bejjani between 2008 and 2011. Apart from Dr. Spiro in 2008, each of these surgeons was paid

more than even the highest estimate of the 90th percentile for all U.S. neurosurgeons in all four years. And depending on which estimate of the 90th percentile you use, they were sometimes paid two or three times more than the 90th percentile. Dr. Bejjani's 2011 bonus alone exceeded the 90th percentile of total compensation in some surveys.

c. Extreme Work Units. The relators also allege facts from which we can reasonably infer that the surgeons generated far more Work Units than normal. Many neurosurgeons "were routinely generating [Work Units] exceeding by an enormous margin the 90th percentile as reflected in widely-accepted market surveys." App. 171 ¶126. Even if we look only at the highest industry estimates, all but one of the surgeons reported Work Units above the 90th percentile in 2006 and 2007. In 2008 and 2009, eight of the twelve named surgeons exceeded the highest estimate of the 90th percentile. A few even seemed "super human," racking up two to three times the 90th percentile. App. 169 ¶117.

In short, most of the surgeons generated Work Units at or above the 90th percentile. Some of their numbers were unbelievably high. And because their pay depends in large part on their Work Units, it is fair to infer that most of their pay was also at or above the 90th percentile.

d. Bonuses exceeding the Medicare reimbursement rate. Once a surgeon had enough Work Units to earn bonus pay, the bonus per Work Unit was more than Medicare would pay for each one. The surgeons' bonus per Work Unit was \$45. But the Medicare reimbursement rate was only about \$35. So once surgeons became eligible for bonuses, the defendants took an immediate loss on every Work Unit submitted to Medicare.

On its own, this would not show that the surgeons were overpaid. Medicare and Medicaid are well known as bottom-billers. They pay less than private insurers. Though the defendants lost some money on Medicare Work Units, perhaps they made it back with Work Units billed to other insurers.

But the relators also allege that "the majority of all claims

submitted by the [defendants] ... were submitted to federal health insurance programs such as Medicare and Medicaid." App. 193 ¶233. We cannot assume that private payments suffice to make up the difference. Doing so would disregard our job at this stage: to draw reasonable inferences in favor of the plaintiffs.

In short, the defendants took an immediate financial hit on Work Units for a majority of their claims. This is yet another sign that the surgeons' pay took referrals into account.

The defendants disagree. They argue that the surgeons earn high salaries because of bona fide bargaining with their employers. Their salaries supposedly represent the market's demand for their surgical skill and experience.

This argument fails for two reasons. First, the complaint says nothing about the surgeons' skill and experience or the Pittsburgh market for surgeons. On this motion to dismiss, we cannot go beyond the well-pleaded facts in the complaint.

Second, a bare claim of bona fide bargaining is not enough. The Stark Act recognizes that related parties often negotiate agreements "to disguise the payment of non-fair-market-value compensation." *Kosenske*, 554 F.3d at 97. We trust that bona fide bargaining leads to fair market value only when neither party is "in a position to generate business for the other." *Id.*; 42 C.F.R. §411.351 (defining "fair market value" and "general market value"). But that is not true here. The surgeons and the Medical Center can generate business for each other. So we cannot assume that any bargaining was bona fide or that the resulting pay was at fair market value.

e. The possibility of fraud. Finally, the surgeons' high pay may have been based on fudging the numbers. Not only were their individual Work Units "significantly out of line with industry benchmarks," but the Neurosurgery Department as a whole realized astounding "annual growth rates of work [Units] ... of 20.3%, 57.1% and 20.0%" in 2007, 2008, and 2009. App. 171 ¶127–28. Two of the surgeons more than doubled their output in just a few years. The relators allege that the defendants got this growth by "artificially inflat[ing] the num-

ber of [Work Units] in a number of ways." App. 171 ¶130.

Alleging this fraud, the relators' first complaint included claims "relating to <u>physician</u> services submitted by" the defendants along with the "<u>hospital</u> claims" currently before us. App. 189 ¶217 (emphases in original) The government chose to intervene as to the former claims, settling them with the defendants for almost \$2.5 million.

The relators' current complaint quotes that settlement agreement. In it, the government accused the surgeons of many fraudulent practices: They claimed to have acted as assistants when they did not. They claimed to have done more extensive surgeries than they did. And they chose the wrong codes for surgeries. So "claims submitted for these physician services resulted in more reimbursement than would have been paid" otherwise. App. 188–89 ¶216.

We are careful not to overstate the point. This settlement is not an admission of guilt. It proves no wrongdoing. But at the 12(b)(6) stage, we are looking only for plausible claims, not proof of wrongs. And the government's choice to intervene after years of investigation and its allegations in the settlement are cause for suspicion.

The question is not whether a doctor was able to use an oth-erwise-valid otherwise-valid compensation scheme as a vehicle for fraudulent fraudu-lent billing. Not every fraudulent Medicare bill made at a hospital hos-pital will give rise to a Stark Act violation. Here, however, where the compensation scheme produced results bordering on the absurd, relators plausibly assert that the system may have been designed with that outcome in mind.

The relators allege five sets of facts that suggest that the surgeons' pay <u>far</u> exceeded fair market value: pay exceeding <u>eol-lections</u> pay above the 90th percentile, extreme Work Units, bonuses above the Medicare reimbursement rate, and the <u>set-tlementsettlement</u>. That is plenty of smoke. We need not decide whether any of these allegations alone would satisfy the <u>relators' pleadrela-ing-tors' pleading</u> burden. Together, they plausibly suggest that the surgeons' pay took

their referrals into account. Thus, the rela-tors

* * * * *

So the relators have met their burden twice over. They allege that the surgeons' pay correlated with their referrals. That alone is enough to meet their burden. They also plausibly allege causation. Thus, the relators have pleaded more than enough facts to suggest an indirect compensation arrangement.

that the surgeons' 3. 3.—The hospitals knew compensation varied with, or took their referrals into account, referrals. The final element of an indirect compensation show scienter, the relators' arrangement is scienter. To pleadings must allege that the hospitals that provided the referred services either (1) knew, (2) deliber- ately ignored, or (3) recklessly disregarded that the surgeons got "aggregate compensation that varie[d] with, or t[ook] into account, the volume or value of referrals." 42 C.F.R. $\S411.354(c)(2)(iii)$. They allege this too.

To begin, the Medical Center controls all the hospitals and the surgeons' direct employers. It owns each hospital. And it owns Pittsburgh Physicians, Community Medicine, and Tri-State. So the Medical Center "has unfettered authority with respect to most members of the [medical system] and significant authority (including with respect to financial and tax matters) with respect to the remaining members." App. 146–47 ¶19 (quoting a Medical Center tax filing).

Further, many officers and board members of these entities overlapped. For example, one person simultaneously served as an executive vice president of the Medical Center as well as the president and a board member of Pittsburgh Physicians. And he signed surgeons' pay agreements for Pittsburgh Physicians. The relators identify nine others who served on the board of both the Medical Center and another entity in the medical system. Authority was so centralized that a single person signed a settlement agreement on behalf of all the defendants that were part of the medical system. And with common control comes common knowledge.

The common knowledge included both the surgeons' pay and their referrals. The Medical Center took part in forming, approving, and implementing the surgeons' pay packages. So it knew their structure. The Medical Center also had a central coding and billing department that handled billing for its subsidiaries. So it knew about the surgeons' referrals.

With both sets of data in front of it, we can plausibly infer that the Medical Center knew the surgeons' compensation varied with or took into account their referrals into account. And as the Medical Center knew that, so did the hospitals. They had all the data right in front of them. They knew that the surgeons' pay and Work Units were out of line with industry survey data. Even if they did not actually know that the surgeons' pay was correand work levels were sus-lated with their referralspiciously high, they at least deliberately ignored or recklessly disregarded that fact. Thus, the complaint alleges that both the Medical Center and hospitals had scienter.

* * * * *

This means that the relators have successfully pleaded the third and final element of a Stark Act violation: scienter. But they must plead one more thing to survive a motion to dismiss. We must now consider whether the relators have pleaded a plausible prima facie case under the False Claims Act.

V. THE RELATORS PLEAD FALSE CLAIMS ACT VIOLATIONS VIOLATIONS

The relators plead their Stark Act claims as violations of the False Claims Act. So their pleadings must satisfy all the elements of the False Claims Act. They do. And they satisfy Rule 9(b)'s heightened pleading standard. Last, we hold that the Stark Act's exceptions are not additional elements of a prima facie case. But even if they were, the relators have plausibly pleaded that no exception applies here.

A. The pleadings satisfy all three elements of the False Claims Act

To make out a prima facie case, the relators must plead

three elements: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment;

(2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." Schmidt, 386 F.3d at 242 (quoting Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182 (3d Cir. 2001)). They have alleged enough facts to plead all three elements.

First, by submitting claims to Medicare and other federal health programs, the defendants presented claims for payment to the government.

Second, the relators allege that these claims were false. A Medicare claim that violates the Stark Act is a false claim. *Kosenske*, 554 F.3d at 94. And we have already explained at length why the Medicare claims here plausibly violated the Stark Act.

Third, the relators' allegations plead scienter. Just like the Stark Act, the False Claims Act requires that the defendants know, deliberately ignore, or recklessly disregard the falsity of their claim. 31 U.S.C. §3729(b)(1)(A). But it does not require a specific intent to defraud. *Id.* §3729(b)(1)(B).

The claims are false because they allegedly violated the Stark Act. The question is whether the defendants at least recklessly disregarded that possibility. The defendants had a centralized billing department and were familiar with the Stark Act itself, so they knew that they submitted Medicare claims for referred designated health services. That leaves only whether the defendants knew that the hospitals and surgeons had an indirect compensation agreement.

The complaint alleges that the defendants at least recklessly disregarded that possibility. They knew their own corporate structure. We have already explained how they knew or recklessly disregarded that the surgeons' pay varied with their referrals. And we have also explained how they knew or recklessly disregarded that their surgeons' pay <u>far</u> exceeded fair <u>market market</u> value and thus plausibly took referrals into account. So the relators have pleaded a prima facie claim under

the False Claims Act.

B. The pleadings satisfy Rule 9(b)

The relators' complaint also satisfies Rule 9(b)'s particularity requirement. To do so, the allegations must go well beyond Rule 8's threshold of plausibility. A mere plausible inference of illegality is not enough. Instead, "a relator must 'establish a "strong inference" that the false claims were submitted."

United States ex rel. Silver v. Omnicare, Inc., 903 F.3d 78, 92 (3d Cir. 2018) (quoting Foglia v. Renal Ventures Mgmt., 754 F.3d 153, 158 (3d Cir. 2014)).

This—Rule 9(b)'s particularity requirement requires a plaintiff to allege "all of the essential factual background that would accompany accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue." Majestic Blue Fisheries, 812 F.3d at 307 (quoting In re Rockefeller Rock-efeller Ctr. Props., Inc. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002)). The complaint gives us all these necessary details:

- Who? The defendants: the Medical Center and Pittsburgh Physicians.
- What? The defendants submitted or caused to be submitted false Medicare claims.
- When? From 2006 until now.
- Where? The Medicare claims were submitted from the Medical Center's centralized billing facility, while the referred services were provided at the Medical Center's twenty hospitals.
- How? When the Medical Center submitted a claim, it certified compliance with the Stark Act. The complaint makes all the allegations discussed above. We will not repeat them. But they detail exactly how these claims violated the Stark Act.

Rule 9(b) does not require the relators to plead anything more, such as the date, time, place, or content of every single allegedly false Medicare claim. The falsity here comes not from a particular misrepresentation, but from a set of circumstances that, if true, makes a whole set of claims at least prima facie false. It is enough to allege those circumstances with particularity. Doing so "inject[s] precision or some measure of substantiation into [the] fraud allegation" and "place[s] the defendant on notice of the precise misconduct with which [it is] charged." *Alpizar-Fallas v. Favero*, 908 F.3d 910, 919 (3d Cir. 2018) (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)) (last alteration in original; internal quotation marks omitted). And the relators have done-so.

And the relators have done so. The second amended complaint runs 57 pages (plus exhibits) and comprises 257 numbered paragraphs. Dozens of these paragraphs go into great detail about specific physicians' Work Units and pay levels. The complaint compares those figures at length with industry benchmarks, medians, and 90th percentiles. It alleges specific ways that surgeons padded their bills, by for instance falsely reporting unperformed work assisting other surgeons or physically supervising residents and interns. The complaint also quotes the government's settlement agreement, alleging specific ways that surgeons had been padding their bills. The sum total of these allegations tells a detailed story about how the defendants designed a system to reward surgeons for creating and submitting false claims. See Omnicare, 903 F.3d at 91–92 (quoting Foglia, 754 F.3d at 158). And that is particular enough to satisfy Rule 9(b).

C. Pleading Stark Act exceptions under the False Claims Act

One final issue is how the Stark Act interacts with the False Claims Act. The defendants argue that the False Claims Act's elements of falsity and knowledge turn the Stark Act's exceptions into prima facie elements of the False Claims Act. On their reading, the relators would have to plead that no exception applies here.

We reject that argument. The defendants retain the burden of pleading Stark Act exceptions even under the False Claims Act. And even if the relators bore that burden, they have met it here: 1. The burden of pleading Stark Act exceptions stays with the defendant under the False Claims Act. The defendants argue that the False Claims Act's knowledge and falsity elements turn the Start Act's exceptions into prima facie elements. Their logic is simple and cogent: The False Claims Act penalizes only false claims. 31 U.S.C. §3729(a)(1). False claims include claims submitted in violation of the Stark Act. See Kosenske, 554 F.3d at 94. But if an exception to the Stark Act applies, then the claim is not false. And if the defendant thinks that an exception applies, then the defendant does not know that the claim is false. So, according to the defendants, to plead a False Claims Act claim based on Stark Act violations, a relator must plead that no Stark Act exception applies and that the defendant knows that none applies. Otherwise, the relator pleads neither falsity nor knowledge.

Though this argument has force, we reject it. Our precedent compels this result. Like this case, *Kosenske* was a False Claims Act case based on Stark Act violations. *Id.* It placed the burden of proving a Stark Act exception on the defendant. *Id.* at 95; *accord Tuomey*, 792 F.3d at 374. And we see no reason to split up the burdens of pleading and persuasion. It is thus the

defendants' burden to plead a Stark Act exception, not the relators' burden to plead that none exists.

2. Even if the relators bore this pleading burden, they have met it. In any event, the relators here plausibly plead that no Stark Act exception applies. The parties identify four that could apply here: exceptions for bona fide employment, personal services, fair-market-value pay, and indirect compensation. All four exceptions require that the surgeons' compensation not exceed fair market value and not take into account the volume or value of referrals.

We have already explained how the relators plausibly plead that the surgeons were paid more than fair market value. And that itself suggests that their pay may take into account their referrals' volume or value. So the relators plausibly plead that no Stark Act exception applies.

Practical concerns

Our concurring colleague raises legitimate concerns about opening the floodgates of litigation. Top hospitals that offer doctors performance bonuses, he argues, could be sued and forced to suffer through discovery or to settle.

Although understandable, this fear is overstated. Qui tam actions face hurdles even before they reach a motion to dismiss. The government can dismiss them over the relator's objection. 31 U.S.C. §3730(c)(2)(A). Federal courts are not the first line of defense against abusive suits; the Justice Department is. Indeed, it recently took a more aggressive approach to dismissing qui tam actions, urging its lawyers to consider dismissal every time the government decides not to intervene. Michael D. Granston, U.S. Dep't of Justice, Memorandum: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A), at 1 (2018).

While our Court has not yet specified the standard of review for a §3730(c)(2)(A) dismissal, our sister circuits defer a great

deal to the Justice Department. Swift v. United States, 318-F.3d 250, 252 (D.C. Cir. 2003) (recognizing the government's "unfettered right" to dismiss qui tam-actions); United States ex rel. Sequoia Orange Co. v. Baird Neece Packing Corp., 151-F.3d 1139, 1145 (9th Cir. 1998) (adopting a "rational relation" test for reviewing dismissals). That deference gives the government plenty of room to make good on its stated intention to serutinize and dismiss more qui tam-actions than in the past. So there is little reason to fear that a flood of frivolous cases will reach discovery.

VI. CONCLUSION

Evaluating a motion to dismiss is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. Our experience and common sense tell us that the relators state a plausible claim that the Medical Center and Pittsburgh Physicians have violated the Stark Act and the False Claims Act.

The facts they plead, if true, satisfy every element of those statutes: A chain of financial relationships linked the surgeons to the hospitals to the surgeons. The surgeons referred many designated health services to the hospitals, generating ancillary hospital services and facility fees. It is plausible that their pay necessarily varied with takes into account the volume of those referrals. The hospitals made Medicare

claims for those referrals. And the defendants allegedly knew all this.

With all this smoke, a fire is plausible. So this case deserves to go to discovery. Once the discovery is in, it may turn out that there is no fire. We do not prejudge the merits. But this is exactly the kind of situation on which the Stark and False Claims Acts seek to shed light. We will thus reverse the District Court's dismissal and remand for further proceedings.

AMBRO, Circuit Judge, concurring in the judgment

The Stark Act prescribes strong medicine for a very specific evil. The core concern is that if doctors have financial interests in other medical service providers, they will have a

monetary incentive to refer patients to those providers, even if that is not in the patient's best interest. For example, if a doctor owns a stake in an entity that does blood tests and other lab work, she or he might send patients to that entity for tests even though it is not as good as its competitors, or might recommend tests that the patient does not truly need. The key is that the doctor has a financial interest in the services that someone else performs.

That is very different from this case. The physicians operating at UPMC's neurosurgery department are, according to the terms of their contracts, paid for the work they personally perform. True, this encourages the surgeons to perform more procedures, creating a similar potential for misaligned interests as the arrangements proscribed by the Stark Act. And true, the relators have alleged significant fraud by the hospital, inflating the work these surgeons performed and billing the Government for things that never happened. The majority places great emphasis on the general atmospherics of fraud around UPMC, and certainly if these allegations are true, then the hospital has much it must answer for.

But the Stark Act is not concerned with general fraud and misrepresentation. Those claims were addressed by UPMC's settlement with the Government. Nor, as I read the statute and its accompanying regulations, are they concerned with the entirely standard compensation structure between UPMC and these surgeons. The majority makes much of the notion that where there is smoke, there might also be fire, and I am-sympathetic to that approach. In this case, however, I

worry we are sending signals to hospitals throughout the Third Circuit, and the nation, that their routine business practices are somehow shady or suspicious and could leave them vulnerable to significant litigation, with all the trouble and expense that brings. Accordingly, I do not join in all the majority opinion's reasoning.

I do, however, agree with many of my colleagues' conclusions—enough that I am able to concur in allowing the case to proceed at this time. The Court is correct that there are referrals—when—one of the surgeons—employed by UPMC's subsidiary—UPP performs a procedure—at a UPMC hospital. Although the physician's own—part in the surgery is—not—a referred service, everything else that goes into the operation is, from the operating room itself to the equipment to the other hospital—employees—nurses, anesthesiologists,—medical technicians, and—so on—involved. This is the "technical component of the surgical—service." See Medicare—and Medicaid Programs; Physicians' Referrals to Health Care

Entities With Which They Have Financial Relationships (Phase I), 66 Fed. Reg. 856, 941 (Jan. 4, 2001). Because these are referred services for which the hospital billed Medicare, two of the three elements of a Stark Act violation are present. See Maj. Op. at 12–13 (stating the elements of a Stark Act claim as "(1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for the referred services."). The only question is whether there was a "compensation arrangement" within the meaning of the statute and regulations.

I also agree with the majority that the burden of pleading Stark. Act exceptions falls on the defendants. We held in United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88 (3d Cir. 2009), that these exceptions function as affirmative defenses. In theory things may be different in the context of a

False Claims Act suit, where the relators bear the burden of proving intent and therefore must plead that the defendants knew the claims they submitted were false. If they fail to do so, it would likely be appropriate to dismiss on that basis. But the majority persuasively explains why that is not what we have at this time: because the language of the exceptions tracks the relevant definition of a compensation arrangement, it is virtually impossible that the exceptions could apply if the defendants are covered by the Stark Act in the first place. Moreover, in order to invoke any of the exceptions, the defendants would have to show compensation that did not exceed fair market value, and the majority aptly explains why, at least at the motion to dismiss stage, the complaint plausibly alleges that the defendants knew the compensation here did exceed that standard.

And I agree with the Court that the relators have adequately pleaded a causal relationship between the physicians' referrals to UPMC and their compensation. This is a close question for me, because many of the factors the majority points to as suspicious and indicating causation would likely be present in many cases where nothing untoward has occurred. For example, aggregate compensation above the 90th percentile will be found, after all, in 10% of all cases by definition. The relators make much of the fact that the bonus for each "work relative value unit" ("wRVU") exceeds the Medicare reimbursement rate, but statistics cited in the complaint itself suggest that the \$45/wRVU rate is actually below the national average compensation per wRVU. See Appellee's Br. at 49. (Dividing the listed median total compensation figures by the median wRVU totals from 2009

suggests a rate between \$50 and \$70 per wRVU. This is not mathematically precise, because these are median rather than average figures, but it is clear enough that \$45 per wRVU is not aberrantly high. The difference is presumably made up through non-Medicare patients being charged at significantly

higher rates.) Thus, for me, that the physicians accrued large wRVU totals does not especially suggest that their rate of compensation was excessive.

Another problem I have is the possibility that UPMC may have defrauded the Government by inflating the physicians' wRVU totals does not suggest that the surgeons were compensated for the value of their referrals, but that they were compensated for nothing, as the hospital (if these allegations are true) simply stole money from the Government and distributed some of those ill-gotten-gains to the surgeons. That may well have been illegal, but it is not the kind of illegality covered by the Stark Act. Instead, these fraud claims were covered by the Government's \$2.5 million settlement with UPMC (which, for an organization that so dominates the market, is a modest figure), and are no longer before us.

I am therefore concerned if any one of these factors, standing alone, would be enough to raise a plausible inference of a Stark Act violation. But as the majority rightly notes, we are not dealing with only one of these indicators but with all of them together. In this context, I agree that there is enough "smoke," as the Court puts it, at this early stage. Very possibly there is no Stark Act problem here (whatever other problems there may have been with the UPMC neurosurgery department). But the collection of suspicious circumstances argues that the case should proceed to discovery so that we can find out one way or the other. I therefore concur in reversing the District Court and denying the motion to dismiss.

I write separately, however, because I cannot agree with the majority that the relators met their burden simply by pleading that the neurosurgeons' compensation correlated with the volume or value of their referrals. To show a compensation arrangement as defined by the Stark Act, relators must establish a number of elements, and, as the majority

correctly states, only one of those elements is in doubt here: Did the surgeons receive "aggregate compensation that varies with, or takes into account, the volume or value of referrals" from the surgeons to UPMC (emphasis added)? My colleagues understand the phrase "takes into account" to mean an express cause and effect relationship between referrals and compensation, while "varies with," on its understanding, applies to any situation in which the physicians' compensation

correlates with the volume or value of their referrals. This means any situation where, if one tends to be higher, the other tends to be higher as well.

I disagree, as I do not think that this language includes cases of mere correlation standing alone. To begin with, I have some doubt that the drafters of this regulation actually intended for there to be much difference between "varies with" and "takes into account." But assuming that a difference does exist, I would most naturally read "varies with" to mean that compensation is expressly based, at least in part, on the volume or value of referrals. "Takes into account," then, is a broader term that can include implicit (that is, unstated) causal relationships as well as explicit ones, but still requires more than mere correlation.

These relationships are somewhat difficult to understand in the abstract (set theory is notoriously counterintuitive), so here is an example of how the concepts might play out. If one physician's contract provided for a certain base salary (say, \$250,000) and then a bonus equal to a percentage of the hospital's revenues from any referred services, that would be compensation—that "varies with" referrals. On the other hand, if another surgeon's contract only provides for a flat annual salary (say, \$450,000), but there is evidence that the hospital chose the higher number because of the value it derived from the surgeon's referrals, that would be compensation that "takes into account" referrals, even though

it does not expressly "vary with" them. Of course, if compensation explicitly "varies with" referrals, then it will also "take-[them] into account," as on my reading the former is a subset of the latter.

As I read the regulations, however, neither term includes eases of correlation-standing by itself without any alleged causal relationship. This is consistent with common usage. If a baseball player's contract provided him a bonus for every base hit during the course of a season, we would not say that his compensation "varied with" his total number of runs batted in, even though hits and RBIs are closely correlated. The only dictionary I have found offering a definition of "varies with" is "to become different based on or according to some determining factor," or "to change according to

something." Vary with, Idioms by The Free Dictionary, https://idioms.thefreedictionary.com/vary+with—(last accessed August 15, 2019). Thus, in order for compensation to "vary with" a certain factor, that factor must be an express input to the compensation formula. Thus, where a surgeon gets a flat \$250,000 annually but with an added referral bonus for the hospital's facility fee, the referral fees are an express input into the higher-than \$250,000 total compensation.

The majority acknowledges this usage of "vary with," yet goes on to suggest that statisticians (as distinct from mathematicians, apparently) also use it to mean simple correlation. And, to be fair, it does cite a handful of examples of the phrase being used this way. Several of the authorities it cites for this proposition, however, do not actually use the phrase. Our Court's decision in *Jenkins v. Red Clay Consol. Sch. Dist. Bd. of Educ.*, 4 F.3d 1103, 1120 n.10 (3d Cir. 1993),

instead used "varies in correspondence with." This is a meaningful distinction because "in correspondence with" contemplates simply that two things tend to move together (i.e., are correlated), not that one of them changes directly as a function of the other. And the book on general statistics cited, as opposed to the one on data analysis in Microsoft Excel, offers only an explanation of the basic concepts of correlation; the phrase "vary with" or "varies with" does not appear either at the cited pages or elsewhere in the work. See Timothy C. Urdan, Statistics in Plain English 79–80 (3d ed., Psychology Press 2010).

That exposition of correlation does, however, expose a further problem with the majority's reading: correlation is not an absolute matter. Rather, it ranges from a perfect positive correlation of +1.00 to a perfect negative correlation of -1.00. Id. at 80. At what point along this range would the majority say that compensation "varies with" the volume or value of referrals? A correlation coefficient above 0.50? Above 0.75? The majority notes this ambiguity but does not resolve it,

¹ The majority evidently agrees that "takes into account" suggests a causal relationship. I therefore focus on the interpretation of "varies with," which is where we disagree.

instead claiming that this lack of "technical baggage," Maj. Op. at 18, is a point in its favor.²

² Indeed it is not clear from the majority's reading that a negative correlation would not suffice to show compensation that "varies with" referrals under the Stark Act regulations. The Federal Register commentary on a rule pertaining to the Truth in Lending Act that did use "vary with" essentially as a synonym for correlation made clear that the relationship could be positive or negative, so long as it is "consistent." See Loan Originator Compensation Requirements Under the Truth in Lending Act (Regulation Z), Supplementary Information, 78 Fed. Reg. 11280, 11326 (Feb. 15, 2013). Is the same true here? I would assume not, but the majority does not say.

Of course, there is nothing before us to suggest exactly what the correlation-coefficient is here. Instead we have only the general sense that two things-will tend-to happen at the same time. As UPMC points out, that is only a rough tendency. Two neurosurgeons-might perform surgeries at UPMC on the same day each involving 10-wRVUs from the surgeons, but one surgery involves \$100 of referrals to the hospital for facility services while the other involves \$1,000. Under the contract in this case, those two surgeons would be paid the same amount for their two procedures (effectively \$450, or \$45 per wRVU, assuming they have enough wRVUs to get their productivity bonus for the year). How, then, can we say that compensation "varies with, or takes into account," the volume or value of referrals when two procedures with the same wRVUs, but wildly different amounts of referrals, will result in the same compensation?

The majority charges that my reading of the statute creates surplusage because I see "varies with" as a subset of "takes into account." There would thus be no meaningful difference between the full phrase "varies with, or takes into account," which appears three times in 42 C.F.R. § 411.354, and "takes into account" standing on its own, which appears three more times in § 411.354 and throughout § 411.357 (which defines the exceptions to the definition of compensation arrangements from § 411.354). That is correct; as noted, I suspect the difference in wording does not signify any change in meaning. Rather I would take "varies with" as an archetypal example of what it means to "take [something] into account." The latter expression can then occur on its own

This usage is made clear by § 411.354(d), which uses "takes into account" on its own. That subsection defines "[s]pecial rules on compensation" applicable to the definitions in §-411.354(c)(2), where the full phrase "varies with, or takes into—account," is used.—It states that "[u]nit-based compensation . . . is deemed not to take into account 'the volume or value-of referrals' if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals." Id. § 41-1.354(d)(2). So whereas § 411.354(c)(2) speaks of compensation that "varies with, or takes into account," referrals, the special rule in § 411.354(d) states that compensation shall not be considered to "take into account" referrals if certain conditions are met. This implies that the drafters of these regulations did not intend any change in meaning based on whether they included the words "varies with" in a given instance of this phrase.

The majority invokes United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015), which held—after a jury trial where Tuomey Healthcare System was found to have violated the Stark Act—that a "reasonable jury could have found that Tuomey's contracts in—fact compensated the [ir] physicians in a manner that varied with the volume or value of referrals." The Tuomey physicians' compensation depended on the hospital's "collections" for "the physicians' personally

³Contrary to the majority's suggestion, this does not deny or rob "vary with" of "any useful role in the regulatory scheme." Making explicit what would otherwise be implicit, or offering

specific examples of general provisions, is a useful textual function even if the text would be fairly read to mean the same thing without the phrase in question. See generally Akhil Reed Amar, Constitutional Redundancies and Clarifying—Clauses, 33 Val. U. L. Rev. 1, 7 (1998) (noting that the United States Constitution itself "contains a good many provisions that are best read as declaratory and clarifying.").

performed services." The majority's extraordinarily thorough analysis of the record in *Tuomey* suggests convincingly that, in fact, this meant only the portion of the hospital's collections

that pertained directly to each physician's own labor. That would be analogous to the metric used here, wRVUs. Thus the majority sees *Tuomey* as supporting its position: the Fourth Circuit found that a similar contract structure could be understood as violating the Stark Act.

But the rub-is-this. The Fourth Circuit's-opinion reflects, I believe, a different factual understanding: that "collections for the physicians' personally performed services" included-all collections by the hospital relating to the service, not just to the physician's role in the service. Thus the Court states at one point that "there are referrals here, consisting of the-facility component-of-the physicians' personally-performed services, and the resulting facility fee billed by Tuomey [Healthcare] based upon that component." Id. at 379 (emphasis added)—(internal citations and quotation marks omitted). Elsewhere the Court took pains to distinguish regulatory language approving "productivity bonus[es] based on the fair-market value of the work personally performed by a physician" because it "says-nothing about the propriety of varying a physician's base salary based on the volume or value of referrals." Id. at 380-n.10. Again, the only theory the majority offers for why compensation here or in *Tuomey* varies with referrals is that compensation based on the work personally performed by a physician inherently varies with referrals, because each procedure a doctor performs will generate some referrals. But the Fourth Circuit was clear in its view that there was more than that present in Tuomey compensation based not only on the collections from the surgeon's own labor but also the facility-fees collected by the hospital. Even if that misread the facts of the case, it means that the Fourth Circuit-did not actually adopt the majority's preferred rule of law.

Of course, Tuomey is a Fourth Circuit case and therefore not binding—precedent.—And although—I believe my interpretation—of the regulations—is more—apt solely as—a linguistic matter, I also have a concern about the consequences of our-decision on myriad innocent contractual arrangements. At its conclusion the majority opinion offers this summation of the case against UPMC:

A chain of financial relationships linked the surgeons to the hospitals. The surgeons referred many designated health services to the hospitals, generating ancillary hospital services and facility

fees. Their pay necessarily varied with the volume of those referrals. The hospitals made Medicare claims for those referrals. And the defendants allegedly knew all this.

Maj. Op. at 40 (emphasis added). For the most part this simply describes an arrangement—where doctors are employed by hospitals to perform services at those hospitals, which is hardly suspicious. The only ingredient that transforms this innocuous set-up-into-a potential Stark Act violation is that the surgeons' pay "necessarily" varied with the volume of referrals. But the majority makes clear that any compensation based on a physician's own-labor, in its view, "necessarily" varies with referrals.

Today's decision suggests, therefore, that any hospital that pays its affiliated physicians according to some metric of the work they personally perform at the hospital falls under suspicion of violating the Stark Act, and it can only restore its good name by pleading one of the statutory exceptions presumably at the summary judgment stage at the earliest, i.e., after discovery has already taken place. If this is so, I cannot see why most of the top hospitals in the country, many of whom likely employ similar compensation—schemes—to

UPMC's, would not be vulnerable to a Stark Act lawsuit that could survive a motion to dismiss and proceed to discovery. Nor is it easy to say what those hospitals should do to avoid the prospect of litigation. If compensation that merely correlates with referrals, including correlation based solely on a physician's own work, is enough to place a hospital under suspicion of violating the Stark Act, then the only way to evade suspicion altogether, short of abandoning the widespread practice of hospitals employing their own doctors (whether directly or, as here, through a subsidiary), would be to pay those doctors a flat annual salary and a modest one at that.⁴

⁴The majority suggests that my concern about "opening the floodgates of litigation" is "overstated" because the Government can dismiss frivolous qui tam actions over the relators' objections. Thus "[f]ederal courts are not the first

line of defense against abusive suits; the Justice Department is." Maj. Op. at 39; see also 31 U.S.C. § 3730(c)(2)(A). That may be so, but it does not excuse us from playing our role and ensuring at the motion-to-dismiss stage that complaints are legally-sufficient. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility-of-entitlement to relief." Ashcroft v. Igbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic-Corp. v. Twombly, 550-U.S. 544, 557 (2007)) (internal citations and quotation marks omitted). In other words, a complaint must plead facts that are not only consistent with the defendant's liability but in some measure suggest it, as opposed to any innocent explanation. See id. at 680 (explaining that, in Twombly, the allegations were "consistent with-an-unlawful agreement" but "not only compatible-with, but indeed ... more likely explained by, lawful ... behavior.") Here, however, the majority would allow the relators' suit to proceed based on nothing more than allegations of entirely innocuous conduct: a hospital paying its affiliated physicians based-on the labor they personally perform at the hospital.

I do not believe that the Stark Act was written essentially to ban compensation based on wRVUs-or other measures of a physician's own productivity, or that its implementing regulations have this effect. To the contrary, the statute and regulations repeatedly express their approval of these compensation—schemes. See, e.g., 42—U.S.C. § 1395nn(e)(2) (indented text) ("Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician."); 42 C.F.R. § 411.352(i)(3)(i) (expressly listing wRVU as an acceptable basis for a productivity bonus for group practice doctors); Medicare and Medicaid Programs; Physicians' Referrals to Health-Care Entities With Which-They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054, 16067 (Mar. 26, 2004) ("[A]ll physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform.").

Thus, although I concur with the judgment of the majority that the relators here have done enough to survive a motion to dismiss, I cannot agree that correlation alone is enough to show that compensation "varies with, or takes into account, the volume or value of referrals" as required by § 411.354(c)(2)(ii). Instead I would hold that this language

requires—some showing of an actual causal relationship—to establish an indirect—compensation arrangement—under the Stark Act.

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Comparison Statistics	
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Changes	44
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