NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 21-2123

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UNITED STATES OF AMERICA ex rel.
CHRIS O'BIER

v.

TIDALHEALTH NANTICOKE, INC.; KUNAL AGARWAL, M.D.; CANDACE MCKNIGHT JOHNSON; BAY VIEW HOMECARE, INC.; LINCARE, INC.; DOES 1-50

Chris O'Bier,
Appellant

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Appeal from the United States District Court
for the District of Delaware
(D.C. No. 1:19-cv-00687)
District Judge: Honorable Stephanos Bibas**, U.S.C.J., by designation

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Submitted Under Third Circuit L.A.R. 34.1(a)
January 27, 2022

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Before: HARDIMAN, SHWARTZ, and SMITH, Circuit Judges

(Filed: January 28, 2022)

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OPINION*

**The Honorable Stephanos Bibas, Circuit Judge sitting by designation pursuant to 28 U.S.C. Section:291(b).

SHWARTZ, Circuit Judge.

Chris O'Bier, owner of a durable medical equipment ("DME") supply company, brought this action against a hospital, two prescribers, and two of her competitors for allegedly engaging in a scheme to submit false claims for payment from the United States. Because the complaint fails to allege unlawful conduct and amendment would be futile, we will affirm the District Court's order dismissing the complaint.

I

TidalHealth Nanticoke, Inc., operates a hospital ("Hospital") that employs Dr. Kunal Agarwal and nurse practitioner Candace Johnson ("Prescribers"). The Prescribers prescribe DME to patients who obtain the DME from suppliers, including O'Bier's company, Peninsula Home Health Care, Inc. ("Peninsula" and two of its competitors, Bay View Homecare, Inc., and Lincare, Inc. ("Competitors"). O'Bier alleges that the Prescribers "almost exclusively" refer patients to the Competitors, A25 ¶ 80, and discourage patients from using Peninsula.

To support these allegations, O'Bier relies on the experiences of thirteen patients who received prescriptions for DME. The Prescribers relayed or sought to relay those prescriptions for these patients to specific suppliers. The patients can be grouped into four categories: (1) patients who wanted their DME prescription filled by Peninsula but

[*] This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

were denied; (2) patients who asked to have their DME prescription filled by Peninsula, were met with resistance, but ultimately received Peninsula DME; (3) patients whose prescriptions were filled by another supplier; and (4) patients who never received, or received a delayed shipment of, their DME because of a Prescriber's refusal to have Peninsula fill the DME prescription. O'Bier asserts that she "is currently unable to provide further evidence of the Defendants' alleged unlawful referral scheme because all necessary information lies within the Defendants' exclusive possession and control." A30 ¶ 98.

O'Bier sued Defendants for violating the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(C), premised on violations of (1) the Stark Act, 42 U.S.C. § 1395nn(a)(1)(A)-(B); (2) the federal Anti-Kickback statute, 42 U.S.C § 1320a-7b(b)(1)-(2); (3) Medicare's "freedom of choice rule," 42 U.S.C. § 1395a(a); and (4) Medicare's prohibition on billing for medically unnecessary services, 42 U.S.C. § 1395y(a).

The District Court dismissed the complaint with prejudice, United States ex rel. O'Bier v. TidalHealth Nanticoke, Inc., No. 1:19-CV-687-SB, 2021 WL 1895049, at *2 (D. Del. May 11, 2021), holding: (1) O'Bier failed to plausibly allege violations of the Anti-Kickback statute and Stark Act because "[t]here are . . . reasons why the [H]ospital might not send patients to her" aside from illegal kickbacks, and the Hospital did send some patients to her, id. at *2; (2) O'Bier failed to plausibly allege a violation of the "freedom of choice" rule as the Hospital did not forbid anyone from dealing with Bier, id.; (3) the fact that patients obtained DME from other suppliers does not mean

Defendants billed Medicare for unnecessary services, id.; and (4) amendment would be futile because O'Bier admitted that she could provide no other evidence about the "Defendants' alleged unlawful referral scheme," id.

O'Bier appeals.

II[1]

A[2]

"The False Claims Act seeks to redress fraudulent activity which attempts to or actually causes economic loss to the United States government." Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 184 (3d Cir. 2001). To state a claim under the False Claims Act, a plaintiff must allege: "(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

[1] The District Court had jurisdiction under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291.

[2] We review the District Court's order dismissing the complaint under Fed. R. Civ. P. 12(b)(6) de novo. United States ex rel. Bookwalter v. UPMC, 946 F.3d 162, 168 (3d Cir. 2019), cert. denied, 140 S. Ct. 2720 (2020). "Our job is to gauge whether the complaint states a plausible claim to relief," id., based on "the allegations contained in the complaint, exhibits attached to the complaint, and matters of public record," Maiden Creek Assocs., L.P. v. U.S. Dep't of Transp., 823 F.3d 184, 189 (3d Cir. 2016). A claim is not plausible when "the allegations are merely consistent with misconduct." Bookwalter, 946 F.3d at 168 (quotation marks omitted). Here, because O'Bier alleges fraud, her allegations "must also meet Rule 9(b)'s heightened pleading requirement," which requires her to "state with particularity the circumstances constituting fraud." Id. (quoting Fed. R. Civ. P. 9(b)). This means that she "must [] support [her] allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016) (quoting In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002)).

fraudulent; and (3) the defendant knew the claim was false or fraudulent." United States ex rel. Bookwalter v. UPMC, 946 F.3d 162, 175 (3d Cir. 2019) (quoting United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004)), cert. denied, 140 S. Ct. 2720 (2020); 31 U.S.C. § 3729(a).

As to the first element, O'Bier alleges that Defendants presented to the United States claims for payment for services covered under the federal Medicare program. As to the second and third element, O'Bier claims that Defendants knowingly violated four federal healthcare laws by allegedly receiving Medicare payments through an illegal kickback scheme. We will examine these allegations in turn.

1

The Stark Act "forbids submitting Medicare claims for 'designated health services' provided under a 'referral' made by a doctor with whom the entity has a 'financial relationship.'" Bookwalter, 946 F.3d at 168 (quoting 42 U.S.C. § 1395nn(a)(1)). Thus, "[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." Id. at 169. A compensation arrangement is "any arrangement involving any remuneration between a physician" and a healthcare provider.[3] 42 U.S.C. § 1395nn(h)(1)(A). Remuneration

[3] There is a question as to whether the Stark Act even applies to Johnson, a nurse practitioner. See 42 U.S.C. § 1395x(r) (enumerating the types of healthcare providers that qualify as a "physician" under the statute, such as (1) "a doctor of medicine or osteopathy," (2) "a doctor of dental surgery or of dental medicine," (3) "a doctor of

"includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B). Here, O'Bier does not allege that the Prescribers or Hospital have an ownership or investment interest in the Competitors or that the Competitors directly pay the Prescribers or Hospital.

Moreover, O'Bier has not plausibly alleged an indirect compensation arrangement. An indirect compensation arrangement requires: (1) "an unbroken chain . . . of persons or entities that have financial relationships connecting the referring doctor with the provider of the referred services," (2) that the prescriber receives "aggregate compensation . . . that varies with, or takes into account, the volume or value of referrals," and (3) that "the service provider [] know[s], recklessly disregard[s], or deliberately ignore[s] that the [prescriber]'s compensation varies with, or takes into account, the volume or value of referrals." Bookwalter, 946 F.3d at 171 (quotation marks omitted) (quoting 42 C.F.R. § 411.354(c)(2)(i)-(iii)).

O'Bier's allegations do not satisfy these elements. First, she does not allege an unbroken chain of financial relationships between the Prescribers and the Competitors. The Hospital's employment of the Prescribers is the only financial relationship alleged in the complaint. Second, she does not allege that the Prescribers' compensation varies with, or takes into account, the volume or value of the Prescribers' DME referrals to the Competitors. Moreover, although O'Bier alleges that the Prescribers "almost exclusively

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podiatric medicine," (4) "a doctor of optometry," and (5) "a chiropractor," but not mentioning a nurse practitioner).

refer" patients to the Competitors, A25 ¶ 80, and asserts this practice "strongly suggests that the Defendants are engaging in a prohibited referral scheme," A29 ¶ 96, this assertion is insufficient to state a Stark Act claim, as there are many lawful reasons for a prescriber to prefer certain DME suppliers. Third, she does not allege that the Competitors are aware of the Prescribers' compensation structure. For these reasons, O'Bier's Stark Act claim fails.

2

O'Bier's federal Anti-Kickback statute claim fails for a similar reason. In pertinent part, the federal Anti-Kickback statute prohibits "knowingly and willfully" offering, paying, soliciting, or receiving "any remuneration . . . to induce [any] person . . . to refer an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under [Medicare]." United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 94-95 (3d Cir. 2018) (first quoting 42 U.S.C. § 1320a-7b(b)(2)(A); and then quoting 42 U.S.C. § 1320a-7b(b)(1)(A)).

As explained above, O'Bier does not plausibly allege remuneration. She asserts only that the Prescribers "almost exclusive[ly]" referred patients to the Competitors. A29 ¶ 96. She does not allege how the Competitors incentivized the Prescribers to do so. Thus, O'Bier's conclusory allegations of an illegal kickback scheme are insufficient to state an Anti-Kickback claim.

3

O'Bier also fails to state a claim that Defendants violated Medicare's "freedom of

choice rule," 42 U.S.C. § 1395a(a). The freedom of choice rule provides that "[a]ny individual entitled to insurance benefits under [Medicare] may obtain health services from any institution . . . or person qualified to participate under this subchapter if such institution . . . or person undertakes to provide him such services." 42 U.S.C. § 1395a. Even assuming that the freedom of choice rule applies to private parties, see MacArthur v. San Juan Cnty., 416 F. Supp. 2d 1098, 1141-42 (D. Utah 2005) (holding § 1395a only restricts the Government), O'Bier does not allege that any of the thirteen identified patients received Medicare. Further, even if the Prescribers encouraged use of the Competitors over Peninsula to fill the prescriptions, the Prescribers did not require that patients exclusively use the Competitors. Indeed, the Prescribers referred at least six of the thirteen patients to Peninsula. Thus, O'Bier's claim that the Prescribers violated the freedom of choice rule fails. See Am. Acad. of Ophthalmology, Inc. v. Sullivan, 998 F.2d 377, 387 (6th Cir. 1993) ("Because the [referring parties] d[id] not compel Medicare beneficiaries to use any particular doctor or facility, we reject the appellants' 'freedom of choice' claim.").

4

O'Bier's allegation that Defendants violated Medicare's prohibition on billing for medically unnecessary services also lacks merit. Section 1395y(a) provides, in relevant part, that Medicare payments may not be made for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). The statute, however, generally does not mandate how prescribers

provide reasonable and necessary services. See Hultzman v. Weinberger, 495 F.2d 1276, 1282 (3d Cir. 1974) (holding that Section 1395y(a) "does not speak at all to the question of whether [a health care provider must] provide [medically necessary] services on an inpatient or outpatient basis or in a hospital rather than extended care facility"). Moreover, even Medicare guidance recognizes that DME occasionally must be replaced. Ctrs. for Medicare & Medicaid Servs., No. 100-04, Medicare Claims Processing Manual § 50 (2021), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf ("Replacement of equipment . . . is covered in cases of loss, or irreparable damage or wear, and when required because of a change in the patient's condition.").

Here, O'Bier does not plausibly allege that the Prescribers prescribed medically-unnecessary DME. At best, she complains about the manner in which the Prescribers prescribed it. She asserts that, on three occasions, the Prescribers referred patients who had Peninsula DME to the Competitors, suggesting that new DME was medically unnecessary. In each situation, however, there is no allegation that Medicare was ever billed and thus no plausible basis to infer that Defendants billed Medicare for DME that was not medically necessary. Thus, O'Bier's medical necessity claim fails.

Since O'Bier has not plausibly alleged any underlying federal violation, O'Bier fails to state a claim under the False Claims Act.[4]

[4] Assuming O'Bier has not forfeited arguments concerning her conspiracy claim by mentioning it only "in passing," Fed. Trade Comm'n v. AbbVie Inc., 976 F.3d 327,

B[5]

O'Bier argues that she should have been given leave to amend her complaint. Under Rule 15(a), "the court should freely give leave [to amend a complaint] when justice so requires." Fed. R. Civ. P. 15(a)(2). However, "[a] district court may deny leave to amend a complaint where it is apparent from the record that . . . the amendment would be futile." United States ex rel. Schumann v. AstraZeneca Pharms. L.P., 769 F.3d 837, 849 (3d Cir. 2014) (quotation marks omitted) (quoting Lake v. Arnold, 232 F.3d 360, 373 (3d Cir. 2000)).

Here, the District Court acted within its discretion in dismissing the complaint with prejudice. First, O'Bier did not request leave to amend. See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 253 (3d Cir. 2007) (observing that a plaintiff "can hardly fault the Court for not granting relief it never requested"). Second, O'Bier did not present a draft amended complaint. See id. at 252-53 (failing to submit a draft amended complaint when requesting leave to amend the complaint "is fatal to its request"). Third, any amendment would have been futile, as O'Bier alleged that she was "unable to provide further evidence of the Defendants' alleged unlawful referral scheme."

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368 (3d Cir. 2020), cert. denied sub nom. AbbVie Inc. v. Fed. Trade Comm'n, 141 S. Ct. 2838 (2021), the claim fails because she has not plausibly alleged any underlying violation of the False Claims Act. See United States ex rel. Petras v. Simparel, Inc., 857 F.3d 497, 507 & n.53 (3d Cir. 2017).

[5] "[W]e review the District Court's denial of leave to amend for abuse of discretion, and review *de novo* its determination that amendment would be futile." United States ex rel. Schumann v. AstraZeneca Pharms. L.P., 769 F.3d 837, 849 (3d Cir. 2014).

A30 ¶ 98. Thus, the District Court appropriately dismissed the complaint with prejudice.

III

For the foregoing reasons, we will affirm the District Court's order.