

United States Court of Appeals For the First Circuit

No. 23-1305

UNITED STATES EX REL. MARTIN FLANAGAN,

Plaintiff, Appellant,

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a Fresenius Medical
Care North America,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before

Montecalvo, Thompson, and Kayatta, Circuit Judges.

Jamie Michele Bennett, with whom Bennett Law, Christopher P. Sullivan, Pamela E. Berman, Robins Kaplan LLP, W. Scott Simmer, Noah M. Rich, and Baron & Budd, P.C., were on brief, for appellant.

James F. Bennett, with whom Maria R. Durant, Hogan Lovells LLP, Megan S. Heinsz, Hannah F. Preston, and Dowd Bennett LLP were on brief, for appellee.

Daniel Winik, Appellate Staff, Civil Division, U.S. Department of Justice, with whom Brian M. Boynton, Principal Deputy Assistant Attorney General, Joshua S. Levy, Acting U.S. Attorney, Michael S. Raab, Appellate Staff, Civil Division, U.S. Department of Justice, and Charles W. Scarborough, Appellate Staff, Civil Division, U.S. Department of Justice, were on brief, for the United States, amicus curiae.

June 27, 2025

MONTECALVO, Circuit Judge. Martin Flanagan brought this qui tam suit against Fresenius Medical Care Holdings, Inc. ("Fresenius"), under the False Claims Act ("FCA"), 31 U.S.C. § 3729, alleging a fraudulent kickback scheme related to referrals to Fresenius-operated dialysis clinics. The district court dismissed Flanagan's complaint for failing to meet the heightened pleading standard under Rule 9(b) of the Federal Rules of Civil Procedure, among other reasons. When Flanagan then sought leave to amend his complaint, the district court also denied that motion. Flanagan now appeals these decisions, arguing that the complaint satisfied the heightened pleading standard necessary to assert fraud claims and that the district court abused its discretion in denying his motion for leave to amend. For the reasons that follow, we affirm both decisions of the district court.

I. Background¹

A. The Parties

Fresenius is the country's largest dialysis services provider. Annually, it treats nearly 190,000 patients in approximately 2,400 outpatient dialysis clinics across the United States. Flanagan worked for Fresenius for twenty-nine years, most recently as Director of Acute Market Development for the Fresenius

¹ At this stage of the litigation, "[w]e draw the facts from the complaint, taking the well-pleaded facts as true and construing all reasonable inferences in [Flanagan]'s favor." Zhou v. Desktop Metal, Inc., 120 F.4th 278, 283 (1st Cir. 2024).

Western Business Unit. In that role, he was responsible for negotiating contracts under which Fresenius provided dialysis treatment to hospital inpatients. He also, as detailed below, observed what he believed to be an elaborate kickback scheme utilized to induce referrals to Fresenius clinics.

B. Relevant Underlying Facts

1. Medical Background

Chronic kidney disease is the progressive loss of a person's kidney function, which is typically irreversible. End-stage renal disease ("ESRD") is an advanced form of chronic kidney disease -- also classified as stage 5 chronic kidney disease -- that requires either dialysis treatments or a kidney transplant. At the end of 2017, almost 750,000 patients in the United States were suffering from ESRD. Many of those patients undergo a regular regimen of dialysis treatments; about half of those patients begin dialysis "emergently" after experiencing complications from kidney failure. The dialysis treatments are intended to replace some functions typically performed by the kidney; during treatment a patient's blood is gradually pumped through a device called a dialyzer that filters out excess water, solutes, and toxins before being returned to the body. Often, patients also receive separate injectable medications during their dialysis treatment. Most dialysis patients undergo treatment at a clinic three times per week.

2. Treatment Funding

The federal government helps cover costs for ESRD treatment. It does so primarily through two subsidized health insurance programs: Medicare and Medicaid.²

a. Medicare

All patients with ESRD are eligible for benefits from Medicare, a federally funded health insurance program. The Medicare program is administered through the Centers for Medicare & Medicaid Services ("CMS"), an agency within the Department of Health and Human Services.

One portion of Medicare covers dialysis services provided in outpatient clinics. Because of this coverage, Medicare is the primary payor for more than 80% of ESRD patients in this country for the cost of their dialysis treatments. These Medicare expenditures exceed \$40 billion annually. Medicare reimburses providers at a composite rate for outpatient maintenance dialysis services (including nursing and clinical services, social

² Other federal health programs also provide benefits to patients with ESRD, including the Civilian Health and Medical Program of the Uniformed Services (known as CHAMPUS/TRICARE), which is administered by the U.S. Department of Defense for individuals affiliated with the armed forces, and the Civilian Health and Medical Program of the Department of Veterans Affairs (known as CHAMPVA), which is administered by the U.S. Department of Veterans Affairs for the families of veterans. These programs are not part of the claims in this case.

services, supplies, equipment, and certain laboratory tests and drugs).

For Medicare reimbursement, ESRD treatment providers submit one reimbursement claim bill per month for each patient, which includes costs for dialysis treatment, laboratory costs, and separately billable drugs. These reimbursement claims include a variety of data, including information about the patient and the claims sought to be reimbursed. Fiscal intermediaries contracting with CMS process and pay out reimbursement claims. These payments are made directly to the ESRD treatment facilities; other entities providing services -- such as laboratories, suppliers, and physicians billing for ESRD-related drugs -- must then seek payment from those facilities.

Dialysis facilities must submit annual Medicare cost reports. These cost reports include a certification of adherence to applicable laws and regulations. The reports also include information about the percentage of hours that medical directors work at a dialysis facility.

b. Medicaid

Medicaid, a joint federal-state program administered by states, also provides payment for some costs for ESRD patients who do not qualify for Medicare or for treatment costs not covered by Medicare. Although CMS administers Medicaid at the federal level, each state sets its own guidelines regarding eligibility and

services. Funding for Medicaid comes from both the states and the federal government, and the states then utilize a combination of state and federal funds to pay claims submitted to Medicaid.

Because of this relationship between the state and federal governments, states must submit certain forms to CMS to receive federal funding for Medicaid. These forms include claims for reimbursement submitted to and paid through Medicaid. The federal government then utilizes these forms to determine whether any fraudulent claims were paid and may later recoup any erroneously paid funds by reducing the amount provided to the state in the future.

C. Alleged Wrongdoing

The amended complaint alleges that Fresenius created a kickback scheme to wrongfully induce referrals. Because the allegations regarding the kickback scheme are not directly at issue here, we summarize the scheme below.

1. Fresenius Hospital Contracts

Around 2007, Fresenius began to seek exclusive contracts with hospitals to provide inpatient dialysis care in the hospital setting. Fresenius instructed mid-level managers, including Flanagan, to obtain hospital contracts "at any cost," as this would help the managers to later secure referrals for patients at that hospital after they were discharged. To entice hospital contracts, Fresenius severely limited the costs and fees that would be

contractually passed on to the hospitals and did not enforce certain provisions that would have increased costs. Fresenius management specifically instructed Flanagan that entering into these below-cost contracts was the company's standard business practice.

Accordingly, Fresenius budgeted for -- and incurred -- losses in some of its contracts with larger hospitals. Fresenius's underlying goal for entering into these hospital contracts below cost was to secure more referrals for its outpatient facilities, thereby more than making up for its losses on the hospital contracts.

Efforts to sign hospital contracts intensified in late 2009 to early 2010, and several executives and upper-level managers told marketing directors that "if you lose a hospital, we lose referrals." In 2010, Flanagan spoke with both his supervisor and another executive in the company regarding his concerns that Fresenius appeared to be buying referrals from hospitals with below-cost contracts. Flanagan was told that he should not complain about or be concerned with this issue. Other employees throughout the country had similar experiences regarding their concerns about the below-cost hospital contracts.

2. Fresenius Medical Directors

Separate from its hospital contracts, Fresenius also contracted with hospital nephrologists to serve as medical

directors at Fresenius outpatient facilities. Medicare regulations require there to be a medical director overseeing the operation and safety of each dialysis clinic. 42 C.F.R. § 494.150 (2025). According to Flanagan, the regulations further require that medical directors "devote sufficient time" to this position and offer guidance that this time should amount to approximately one quarter of a typical forty-hour work week.

Fresenius targeted its recruiting of medical directors at those nephrologists who were in positions to refer high numbers of patients to Fresenius outpatient facilities. Although not made explicit in contracts, medical directors' compensation often correlated with the number of patients the doctor had and would increase as the number of patients in a clinic grew.

Although there was significant variation among medical directors' salaries, the medical directors were well-compensated. These salaries were often more than double those paid by Fresenius's primary competitor in the same localities. Reports from Fresenius claim that its medical directors worked eight to ten hours per week. However, Fresenius does not require its medical directors document their time.

Flanagan personally recollected that the medical directors spent little to no time at Fresenius outpatient facilities. He believed that their involvement was often limited to monthly reviews of documents that required a medical director's

signature, which took less than an hour of time. Flanagan's experience was that Fresenius did not track the services that the medical directors were performing.

Medical directors could also have a difficult time leaving their positions. All Fresenius medical directors sign contracts that include non-compete, non-solicitation, and non-disparagement provisions. To be released from the non-compete provisions, the medical directors would have to negotiate buyouts.

3. Fresenius Free or Below-Cost Services

In addition to below-cost contracts, Fresenius offered other benefits to hospitals, all allegedly tailored towards the same overarching goal of securing as many patient referrals to its facilities as possible. The amended complaint specifically highlights four different benefits: (1) the Bridge Program;³

³ This program provided free services to hospitals, which included providing a Fresenius employee to perform certain tasks and "funnel[]" ESRD patients to its own outpatient facilities. These free services were valued at more than \$10,000 annually per hospital.

(2) the Treatment Options Program;⁴ (3) value added services;⁵ and (4) practice management services.⁶

4. Lease Agreements

Fresenius entered extended, guaranteed lease agreements for office space in physician-owned buildings. These leases were at rates above fair market value and were often guaranteed for fifteen years. The leases also included annual escalator provisions. On the other side of transactions, Fresenius leased office space in buildings that it owned. Fresenius leased these spaces to its medical directors at rates below fair market value.

⁴ Fresenius made this educational service available to "interested hospitals, physicians, and community organizations," whether or not they participated in the Bridge Program. The program also promoted Fresenius's outpatient services.

⁵ These "value added services" or "services beyond the rate" included free nursing services, in-service training, transportation to and from dialysis treatments, and patient education.

⁶ These services provided physician practices with free or below-cost services, including specialty advice and technology solutions. Fresenius communicated to doctors utilizing this service that early referrals to Fresenius's outpatient clinics could be profitable to physician practices. Fresenius also provided physicians with a free recruiting service targeting nephrology fellows and practicing physicians to join the physicians' practices. Sometimes, the physicians involved in this service also entered into Confidentiality Agreements and Business Associate Agreements, through which they received additional free resources.

5. Joint Venture Agreements

In 2007, Fresenius began entering into joint venture agreements with nephrologists and other physicians, which allowed partners to share in the management, profits, and losses of the outpatient dialysis facilities. Fresenius anticipated a significant number of referrals to come from its joint venture partners and put pressure on the partners to refer patients to Fresenius clinics. The joint venture agreements also included non-compete clauses, which made it difficult for physicians to leave the joint venture.

D. Procedural History

In March 2014, Flanagan filed this qui tam suit against Fresenius in the U.S. District Court for the District of Maryland, alleging presentation of false claims in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A), and making or using false records material to a false or fraudulent claim in violation of the FCA, id. § 3729(a)(1)(B).

The complaint was initially sealed to give the U.S. Department of Justice time to investigate and determine whether the United States would intervene, as occurs in all FCA qui tam actions. See United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 31-32 (1st Cir. 2017); see also United States ex rel. Lovell v. AthenaHealth, Inc., 56 F.4th 152, 155 (1st Cir. 2022) ("A plaintiff's complaint may remain sealed for an extended

period while the government investigates the allegations prior to making its intervention decision."). In June 2020, the government declined to intervene. Cf. United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 119 (1st Cir. 2013) ("In a successful qui tam action, the relator collects a portion of the award to the government regardless of whether the government intervenes."). The complaint was unsealed shortly thereafter.

Fresenius moved to dismiss in January 2021. In response, Flanagan filed the amended complaint in February 2021. The amended complaint reasserted the claims under the FCA but also added over 100 pages of new allegations which detailed new fraudulent schemes not previously alleged in the original complaint.

In the amended complaint, Flanagan alleged that Fresenius defrauded the government by

[k]nowingly offering remuneration to hospitals in the form of no-cost or below-cost items and services (including but not limited to free discharge planners) in connection with the provision of inpatient dialysis care to ESRD patients, at least one purpose of which was to secure referrals from those hospitals for patients who would enter outpatient care at Fresenius dialysis clinics, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS") and which did not meet safe harbor requirements; and [i]n violation of the AKS (and which did not meet safe harbor requirements), knowingly offering remuneration to physicians (at least one purpose of which was to reward or induce referrals from those physicians to Fresenius'[s] network of outpatient clinics), including: medical director agreements

("MDAs") that were well above fair market value ("FMV") or commercially unreasonable; free patient education services and/or free or below-cost practice management services (including free recruitment services for new nephrologists entering the workforce); lease agreements that were commercially unreasonable and not at FMV[]; and joint venture agreements . . . in outpatient dialysis clinics that were commercially unreasonable and not at FMV.

Fresenius subsequently filed a motion to transfer the case from the District of Maryland. The court granted Fresenius's motion to transfer, and the case was transferred to the U.S. District Court for the District of Massachusetts in October 2021.

Once in the District of Massachusetts, Fresenius again filed a motion to dismiss, seeking dismissal under Rules 9(b), 12(b)(1), and 12(b)(6) of the Federal Rules of Civil Procedure. In support of dismissal, Fresenius raised five separate issues: (1) the amended complaint did not comply with the FCA's statutory requirements for filing new claims under 31 U.S.C. § 3730(b)(2); (2) the FCA's public-disclosure bar, 31 U.S.C. § 3730(e)(4), bars Flanagan's claims related to Fresenius's joint venture agreements and medical director arrangements; (3) the FCA's first-to-file rule, 31 U.S.C. § 3730(b)(5), bars Flanagan's joint venture claims; (4) Flanagan did not allege sufficient facts to support either a predicate violation of the AKS or a violation of the FCA with the particularity required by Rule 9(b); and (5) Flanagan failed to state a claim for FCA conspiracy. Specifically,

Fresenius argued that Flanagan failed to adequately plead causation under the FCA. Flanagan opposed the motion to dismiss.

On May 23, 2022, the district court held a hearing on the motion to dismiss and ultimately took the matter under advisement. On December 5, 2022, the district court granted Fresenius's motion to dismiss. In doing so, the court considered the mandatory pre-suit requirements under the FCA, the applications of the public-disclosure bar and the first-to-file bar, and the pleading standards under Rule 9(b).

First, the court explained that the amended complaint added 125 pages of allegations and multiple new claims to the original complaint. Specifically, the original complaint -- which complied with the FCA's filing requirements -- did not contain any allegations about the joint venture agreements or provisions providing free services. The amended complaint, on the other hand, did not comply with the FCA's mandatory filing requirements; namely, it was not filed under seal, and the government was not given the opportunity to determine if it would intervene. Accordingly, the district court dismissed those new claims.

Next, the district court found that, even if the joint venture claims in the amended complaint met the FCA's filing requirements, they were further precluded by both the public-disclosure and first-to-file bars. This was so because another lawsuit filed and unsealed prior to the amended

complaint -- Complaint, United States ex rel. CKD Project v. Fresenius Med. Care Holdings, 551 F. Supp. 3d 27 (E.D.N.Y. 2021) (No. 14-cv-6646) -- contained allegations substantially similar to those that Flanagan newly asserted regarding the joint venture claims. As to the public-disclosure bar, the district court concluded that Flanagan's allegations did not "materially add" to the public allegations in that lawsuit. And as to the first-to-file bar, the court determined that Flanagan alleged the same scheme that was alleged in the prior lawsuit and no exceptions to the first-to-file bar applied. Thus, the district court concluded that these were alternative bases for dismissing the amended complaint's new claims regarding joint ventures.

Lastly, the district court determined that the amended complaint, although lengthy and detailed regarding how claims are submitted generally and how Fresenius's alleged kickback scheme functioned, still failed to state a claim under the FCA because there were not "particularized allegations of claims for payment arising from that scheme." The district court also determined that, under Rule 9(b), the amended complaint did not describe the false claims with the requisite level of specificity. As to Medicare claims specifically, which Fresenius submitted directly to the federal government, the district court found that Flanagan had not identified a single specific false claim or provided any representative or sample claims, as required. The district court

also expressed doubt that the amended complaint adequately pled causation as required by the relevant statutes. Although the court also suggested that but-for causation was the proper standard, it ultimately decided the motion on other grounds. Accordingly, the district court also found dismissal appropriate under Rule 9(b).

In January 2023, Flanagan filed a motion for reconsideration and a motion to amend the amended complaint. The district court denied both motions. As to the motion to amend, the district court recognized that the case was, at that time, nearly nine years old and that Fresenius had filed three different motions to dismiss, all of which targeted Flanagan's failure to plead any false claims with particularity. For these reasons, the district court found that the "extensive delays" and "obvious prejudice to defendant" were sufficient reasons to deny the motion to amend.

Flanagan then filed a timely notice of appeal as to the order dismissing the complaint, the order denying his motion for reconsideration, and the order denying his motion for leave to file a second amended complaint.

II. Discussion

On appeal, Flanagan asserts that the district court made two central errors: first, that it should not have dismissed claims for failing to satisfy Rule 9(b); and second, that it abused its discretion in denying his motion to amend. The first issue

requires us to examine only the claims and allegations that the district court dismissed under Rule 9(b); thus, we do not address the alternative grounds for dismissal (in other words, we leave undisturbed the district court's rulings on the failure to meet statutory requirements, the public-disclosure bar, and the first-to-file bar). We address the granting of the motion to dismiss and the denial of the motion to amend in turn.

A. Motion to Dismiss

1. Standard of Review

A district court's decision granting a motion to dismiss is subject to de novo review. See Zhou v. Desktop Metal, Inc., 120 F.4th 278, 287 (1st Cir. 2024). Our review "requires that we separate factual allegations from conclusory ones and then evaluate whether the factual allegations support a 'reasonable inference that the defendant is liable for the misconduct alleged.'" United States ex rel. Zotos v. Town of Hingham, 98 F.4th 339, 343 (1st Cir. 2024) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). Because Flanagan alleges fraud claims, the complaint must also satisfy the heightened pleading standard under Rule 9(b), which requires the circumstances of fraud to be alleged with particularity. See Zhou, 120 F.4th at 287; United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 228 (1st Cir. 2004) (holding that "Rule 9(b) applies to claims under the

FCA"), abrogated on other grounds by, Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008).

Before examining the sufficiency of the complaint here, we first provide a brief overview of the relevant statutes.

2. Statutory Background

Flanagan's allegations center on two interlinked statutes: the FCA and the AKS. We briefly describe the relevant portions of each statute.

a. The False Claims Act

The FCA "is an 'expansive' statute, intended 'to reach all types of fraud, without qualification, that might result in financial loss to the [g]overnment.'" United States ex rel. Escobar v. Universal Health Servs., Inc., 780 F.3d 504, 512 (1st Cir. 2015) (cleaned up) (quoting Cook County v. United States ex rel. Chandler, 538 U.S. 119, 129 (2003)), vacated on other grounds, Universal Health Servs., Inc. v. United States, 579 U.S. 176 (2016). The FCA holds liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or 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)(A), (B). "For purposes of the statute, 'a claim includes direct requests to the government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefit programs.'" Guilfoile v.

Shields, 913 F.3d 178, 187 (1st Cir. 2019) (cleaned up) (quoting Universal Health Servs., Inc., 579 U.S. at 181).

b. The Anti-Kickback Statute

Flanagan's FCA claims are rooted in alleged violations of the AKS, which prohibits, among other things, "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" either "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program" or "to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b) (2).

"The AKS was designed to prevent medical providers from making decisions based on improper financial incentives rather than medical necessity and to ensure that federal health care programs do not bear the costs of such decisions." United States ex rel. Banigan v. PharMerica, Inc., 950 F.3d 134, 137 (1st Cir. 2020). "Essentially, the AKS targets any remunerative scheme through which a person is 'paid in return for referrals' to a program under which payments may be made from federal funds." Guilfoile, 913 F.3d at 189 (quoting United States v. Patel, 778

F.3d 607, 618 (7th Cir. 2015)). There is no question that liability under the FCA can be predicated on a violation of the AKS. See id.; Banigan, 950 F.3d at 137. There are two pathways to FCA liability for an AKS violation: (1) "when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim," United States v. Regeneron Pharms., Inc. ("Regeneron"), 128 F.4th 324, 333 (1st Cir. 2025), and (2) when claims for payment are made "resulting from" AKS violations, 42 U.S.C. § 1320a-7b(g). Flanagan asserts that the amended complaint presents claims under both pathways.

We have recently interpreted the meaning of "resulting from" under the AKS. See Regeneron, 128 F.4th at 328-36. In so doing, this court concluded that "to demonstrate falsity" under a theory that the claim resulted from an AKS violation, the plaintiff "must show that an illicit kickback was the but-for cause of a submitted claim." Id. at 336. Put another way, the phrase "resulting from" requires actual causality, which "demands proof 'that the harm would not have occurred but for the defendant's conduct.'" Id. at 329 (cleaned up) (quoting Univ. of Tex. Sw. Med. Ctr. v. Nassar, 570 U.S. 338, 346-47 (2013)).

3. False Claims

We now take on Flanagan's core allegations of FCA violations, concluding that the amended complaint fails to adequately plead that the alleged AKS violations were the but-for

cause of the submitted claims or that Fresenius falsely certified that it complied with the AKS.

a. "Resulting From" Claims

The issue of causation has loomed as a potential threat to Flanagan's claims since the outset of this lawsuit. In its motion to dismiss, Fresenius argued that the complaint failed to establish causation, citing the but-for standard applied by the district court in United States v. Regeneron Pharms., Inc., No. 20-11217, 2020 WL 7130004, at *14 (D. Mass. Dec. 4, 2020). In resolving the motion to dismiss, the district court suggested that but-for causation may be required but decided that motion on other grounds. Our circuit had not yet decided the issue, so on appeal, Flanagan initially argued that but-for causation was not required, but, even if it was, the complaint was adequate. Subsequently, Regeneron resolved the issue, and Flanagan now acknowledges that the law in this circuit requires such a standard.⁷ We now focus on Flanagan's alternative argument -- that the amended complaint adequately pleads but-for causation by articulating "specific compensation relationships with specific physicians which were intended to and did result in referrals." Flanagan's briefing

⁷ On March 7, 2025, Flanagan filed a letter with the Clerk's Office under Rule 28(j) of the Federal Rules of Appellate Procedure. In that letter, Flanagan conceded that our decision in Regeneron resolved the issue of what standard of causation should be applied.

goes on to focus on claims relating to only one physician -- thus, we do the same.⁸

In particular, Flanagan focuses on the allegations that Dr. Stephen Tilles held two medical director positions with Fresenius, that his compensation in those roles was meant to induce referrals, and that Tilles and his practice referred sixty patients to Fresenius clinics in 2012. The amended complaint also alleges that a Fresenius report stated that "Dr. Tilles['s] contract renewal is critical. Currently, he is [the] only physician referring to San Jose and has [the] majority of Los Gatos. He must be secured for at least one more year at San Jose and indefinitely in Los Gatos." The amended complaint further alleges that Fresenius tracked the number of patients that Tilles referred to non-Fresenius clinics.

These allegations, though, do nothing to tell us whether Tilles's referrals resulted from the alleged kickback scheme. There are no allegations that Tilles would not have made these referrals had he not been given the medical director position. At a minimum, Flanagan was required to plead some information that would have allowed us to reasonably infer in his favor that causation exists. Accordingly, the amended complaint lacks the

⁸ Flanagan's Rule 28(j) letter similarly only cited to the portions of the amended complaint that refer to a single physician in support of the proposition that the amended complaint satisfied the but-for causation standard.

detail needed to plausibly allege but-for causation. See United States ex rel. Martin v. Hathaway, 63 F.4th 1043, 1053 (6th Cir. 2023) (finding that but-for causation was not plausibly alleged when "[t]here's not one claim for reimbursement identified with particularity in this case that would not have occurred anyway"); see also Stop Ill. Health Care Fraud, LLC v. Sayeed, 100 F.4th 899, 909 (7th Cir. 2024) (noting that but-for causation would be established if plaintiff could show that "the defendants would not have provided service to [the relevant] patients" in the absence of the fraudulent referral scheme). Without any further details, no reasonable inference can be made in Flanagan's favor as to causation. See Comcast Corp. v. Nat'l Ass'n of Afr. Am.-Owned Media, 589 U.S. 327, 331-32, 336 (2020) (holding that but-for causation must be adequately pled and that such a rule cannot "be overlooked or modified in the early stages of a case").

Thus, Flanagan's claims arising under the theory that the reimbursement claims resulted from AKS violations were properly dismissed because the amended complaint failed to allege but-for causation.

b. False Representation Claims

Flanagan next argues that he has separate claims under 31 U.S.C. § 3729(a)(1)(B) that the district court did not address.

As a reminder, under subsection (a)(1)(B),⁹ a defendant can be held liable when they "knowingly make[], use[], or cause[] to be made or used, a false record or statement material to a false or fraudulent claim." Further, "[t]he defendant must have 'intended the [g]overnment to rely on that false statement as a condition of payment.'" United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009) (cleaned up) (quoting Allison Engine Co., 553 U.S. at 672). Unlike the "resulting from" claims addressed above, these types of claims do not require proof of causation. See Regeneron, 128 F.4th at 333-34.

Flanagan argues that the amended complaint alleges that Fresenius made false records by falsely certifying its compliance with the AKS annually and by falsely certifying cost reports that listed the number of hours that its medical directors work. He recites the details the complaint alleges regarding the kickback scheme and the allegedly tainted referrals and argues that "Fresenius fully intended to bill all payors, including federal health care programs, for treatments resulting from each referral."

However, the complaint is not as specific as Flanagan asserts. First, the complaint alleges that submitting certain

⁹ Subsection (a)(1)(B) was formerly subsection (a)(2) under the FCA. See United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir. 2009).

certifications and information in forms is required under the Medicare program and then broadly alleges that every Fresenius clinic submits these forms every year. But Flanagan has not pointed us to any allegations in the complaint that address what Fresenius actually submitted in those reports, either as to certifications or as to hours worked by medical directors. Further, with respect to the overarching kickback scheme, he still must plead with particularity the connection between false records and/or statements and the intent to have a false claim paid for by the government programs. See Gagne, 565 F.3d at 46. Broadly stating that Fresenius intended to have all claims paid, whether or not tainted by the kickback scheme, is not sufficient to satisfy our heightened standard under Rule 9(b).

For these reasons, Flanagan's claim under subsection (a)(1)(B) was also properly dismissed.

B. Motion to Amend

This court reviews the denial of a motion to amend for abuse of discretion. Ge, 737 F.3d at 127.

Flanagan argues that, in denying his motion to amend, the district court failed to identify any actual prejudice to Fresenius or explain why his motion constituted an "undue delay." Flanagan asserts that because there has yet to be discovery in this case and there is no trial date, Fresenius would not be prejudiced by an amendment simply because the case had been pending

for nearly a decade at the time of the proposed amendment. Further, because Flanagan, in his opening brief, primarily focuses on whether he sufficiently pled a false claim, he emphasizes that he did not have the necessary claims data needed to amend his complaint until after the motion to dismiss was decided, and, therefore, he could not have amended his complaint until that time.

"Amendments may be permitted pre-judgment, even after a dismissal for failure to state a claim, and leave to amend is freely given when justice so requires." Id. (quoting Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006)). "Nonetheless, grounds for denying leave include 'undue delay, bad faith or dilatory motive[,] repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party[,] and futility of amendment.'" Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 60 (1st Cir. 2018) (cleaned up) (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 55-56 (1st Cir. 2008)). Although our amendment rules are "liberal," the district court has "significant latitude" in determining whether to allow leave to amend. Id. at 60-61 (quoting Advest, Inc., 512 F.3d at 55). "[N]otably, 'undue delay in moving to amend, even standing alone,' can provide a court with adequate grounds to deny leave." Id. at 61 (quoting Zullo v. Lombardo, 755 F.3d 1, 3 (1st Cir. 2014)). "[W]e have explicitly condemned a 'wait and see' approach to pleading, whereby plaintiffs 'having the needed

information, deliberately wait in the wings with another amendment to a complaint should the court hold the first amended complaint was insufficient.'" Id. (cleaned up) (quoting Advest, Inc., 512 F.3d at 57).

As discussed above, the original complaint was filed in March 2014 and there was some delay in the case while the government decided whether to intervene. However, Fresenius filed its first motion to dismiss in January 2021, raising substantially the same arguments that are now before us. Although Flanagan attempted to cure these deficiencies by filing the amended complaint in February 2021, the government filed another motion to dismiss in March 2021, again asserting substantially the same arguments raised in its previous motion and now raised before us. Once the case was transferred to the District of Massachusetts, Fresenius (now for the third time) filed its motion to dismiss in January 2022. Only after the district court issued its order, almost a year after the most recent motion to dismiss was filed, did Flanagan then file his motion to amend the complaint.

Although Flanagan argued, both to the district court and before us, that this delay should be excused because he did not receive the claims information until after the motion to dismiss was granted, he has not provided the court with any information as to when he sought this claims information or why this claims information was needed to plead causation. Without more from

Flanagan, the district court could reasonably conclude that -- although Flanagan was aware of Fresenius's arguments and the potential need for an amendment for two years -- he waited until after the district court granted the motion to dismiss to seek the claims information he allegedly needed to amend his complaint. This two-year period is significantly longer than periods of time we have previously relied upon in upholding denials of leave to amend on undue delay grounds. See id.

Accordingly, the district court did not abuse its discretion in denying Flanagan's motion for leave to amend, and we affirm.

III. Conclusion

For the foregoing reasons, we affirm the decisions of the district court granting the motion to dismiss in favor of Fresenius and denying Flanagan's motion to amend.