22-0530-cv

United States Court of Appeals

for the

Second Circuit

JANE DOE 1, JANE DOE 2, SW CHALLENGER, LLC,

Plaintiffs-Appellants,

ABC, STATE OF TENNESSEE, STATE OF FLORIDA, STATE OF TEXAS, STATE OF NEW JERSEY, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, STATE OF CONNECTICUT, STATE OF LOUISIANA, STATE OF NEW YORK, STATE OF NEW MEXICO, STATE OF ALASKA, STATE OF OKLAHOMA, STATE OF MONTANA, STATE OF CALIFORNIA, STATE OF MICHIGAN, STATE OF WASHINGTON, UNITED STATES OF AMERICA ex rel. SW CHALLENGER, LLC,

Plaintiffs,

– v. –

EVICORE HEALTHCARE MSI, LLC.,

Defendant-Appellee,

DEF, WELLCARE HEALTH PLANS INC.,

Defendants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFFS-APPELLANTS

DAVID S. STONE
STONE & MAGNANINI LLP
400 Connell Drive, Suite 6200
Berkeley Heights, New Jersey 07922
(973) 218-1111

STEPHEN A. WEISS
CHRISTOPHER AYERS
DIOGENES P. KEKATOS
SEEGER WEISS LLP
55 Challenger Road
Ridgefield Park, New Jersey 07660
(973) 639-9100

Attorneys for Plaintiffs-Appellants

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned represents that Plaintiff-Appellant, SW CHALLENGER, LLC, is a privately-held Limited Liability Company and not a corporation that issues stock. SW CHALLENGER, LLC, has no parent corporation, and no publicly-held corporation owns ten percent of SW CHALLENGER, LLC.

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JURISDICTIONAL STATEMENT

On March 20, 2019, this case was filed under seal under the False Claims Act, 31 U.S.C. § 3729, *et seq*. ("FCA" or "Act"). The United States District Court for the Southern District of New York ("District Court") properly exercised federal question jurisdiction under 28 U.S.C. § 1331. The District Court entered a final judgment of dismissal on February 10, 2022, and Plaintiffs-Appellants ("Plaintiffs") timely filed their Notice of Appeal on March 14, 2022. This Court accordingly has appellate jurisdiction under 28 U.S.C. § 1291 because the appeal is from a final judgment.

ISSUES ON APPEAL

1. Did the District Court err in holding that Relators did not adequately allege false or fraudulent claims under the FCA?

2. Did the District Court err in holding that Relators did not plead their FCA claims with the particularity required under Fed. R. Civ. P. 9(b)?

STATEMENT OF THE CASE

I. INTRODUCTION

This case arises under the False Claims Act. The defendant, eviCore, is a subcontractor that provides so-called prior authorization services to companies that offer Medicare and Medicaid plans. In this role, eviCore is supposed to review treatment requests to ensure that they are medically necessary before approving them. The ultimate payor for such requests is the United States Government, through monthly "capitation" (per enrollee) payments that it pays to the plans that contract with eviCore.

Relators were formerly employed at eviCore as clinical reviewers. Based on personal knowledge gleaned from this role, they allege that eviCore has instituted a systemic scheme of auto-approving treatment requests for Medicare and Medicaid plans, rather than performing the individual medical necessity review of the treatment requests required by governing regulations and eviCore's contracts with Medicare and Medicaid Plan providers. As a result, false claims were submitted to the Government, including for (i) medical necessity reviews that were not performed; (ii) treatments that should not have been approved; and, (iii) for monthly capitation payments based on diagnosis codes supposedly based on proper medical necessity reviews.

The District Court dismissed Relators' Second Amended Complaint[1] for failure to state a claim. To reach this result, the court: (i) collapsed Relators' allegations into the judicially-created rubric of a "worthless services" claim, and misapplied this Court's precedents pertaining to such claims in wrongly holding that Relators did not allege false claims were submitted; and (ii) improperly applied the Rule 9(b) pleading standard to hold that Relators' detailed allegations were insufficient.

This was inappropriate. Relators stated a classic FCA claim by putting forward specific facts demonstrating that eviCore—rather than providing the individualized medical necessity reviews required by governing regulations—rubber-stamped treatment requests on a systemic basis. eviCore's conduct deprived the Government of the value of services that it paid for. These allegations are straightforward, and the well-pled facts underlying it are specific. The decision below should be reversed.

II. BACKGROUND

A. The False Claims Act

The FCA is the Government's primary tool to combat fraud by those who do business with the Government. Originally enacted to address contractors defrauding the Union Army during the Civil War, its most common use today is in combating

[1] Referred to in this Brief as the "complaint."

healthcare fraud—in particular, in redressing false claims submitted to Government health programs such as Medicare and Medicaid. *E.g.*, U.S. Dep't of Justice, Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 (vast majority of FCA recoveries in 2019, for example, were in the healthcare field) (last visited June 30, 2022).

The FCA imposes liability on "any person 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). "Congress wrote [the FCA] expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the government." *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quotation and citation omitted). "[A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345, at 9 (1986).

FCA practitioners have cataloged various categories of falsity under the Act. Thus, an FCA false claim may be "factually false" (seeking payment for goods or services not provided as promised) or "legally false" (seeking payment despite

noncompliance with a material legal requirement). Separately, FCA claims may be termed "expressly false" (when false statements appear on the face of the claim) or "impliedly false" (when the fact of submitting the claim implies the truth of a statement in fact false).

These categories can be combined. For example, an "implied false certification" claim combines legal falsity with implicit falsity. In an implied false certification claim, a party submits a claim for payment that impliedly certifies compliance with a legal requirement material to payment. Implied certification cases are distinct from, but may overlap with, "worthless services" cases, in which the claims at issue are factually false because the Government did not get what it paid for. *See United States ex rel. Insoon Lee v. SmithKline Beecham*, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) ("[K]nowingly billing for worthless services … may be actionable under § 3729, regardless of any false certification conduct.").

This case involves claims for payment to the Government for services not rendered. Supplying a remedy in such cases was one of the driving forces behind the FCA's enactment. *See United States v. McNinch*, 356 U.S. 595, 599 (1958) (FCA enacted to remedy "provisions and munitions to the War Department [during the Civil War]" of "nonexistent or *worthless* goods") (citing H.R. Rep. No. 2, pt. 2, (1862)) (emphasis added).

These categories can help classify FCA claims, but "can also create artificial barriers that obscure and distort [the FCA's] requirements[.]" *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385-86 (1st Cir. 2011). The FCA does not enumerate categories of falsehood or discuss certification—it imposes liability for "false" or "fraudulent" statements. Because the FCA leaves these terms undefined, they take their common law definitions. *Universal Health Servs. v. United States*, 579 U.S. 176, 187 (2016) ("[T]he term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud."). Thus, a claim may be "false" or "fraudulent" under the FCA when it is false on its face, or when, for example, it omits to state a fact required to make the statements made not misleading. *Id.*

The FCA defines certain key terms—as relevant, "claim," "knowing" or "knowingly," and "material":

- The FCA defines a "claim," as relevant, as "any request or demand, whether under a contract or otherwise, for money that … is made to a contractor … if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest," and if the Government will provide or reimburse any portion of the money. 31 U.S.C. § 3729(b)(2).[2]

[2] The specific reference to contractors is relatively new to the FCA: To "clarify" the FCA and legislatively overrule certain judicial interpretations of the Act—and as part of the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21—Congress amended the definition of "claim" to include payment requests made to contractors, grantees, and other recipients of federal funding without regard to "presentment" to a governmental entity. *See* S. Rep. No. 111-10 at 10-11, 111th Cong., 1st Sess. (2009), 2009 U.S.C.C.A.N. 430, 438-39 (2009).

- The FCA defines "knowing" or "knowingly" as including "actual knowledge"; "deliberate ignorance"; and, "reckless disregard of truth or falsity[.]" *Id.* § 3729(b)(1)(A)(i)-(iii). Unlike common law fraud, the FCA "require[s] no proof of specific intent to defraud[.]" *Id.* § 3729(b)(1)(B).

- The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). As with materiality at common law, the materiality inquiry under the FCA focuses not on whether statements in fact caused payments, but whether, viewed objectively, the statements were "capable of influencing" payments.

The FCA allows private individuals ("relators") to bring suit on behalf of the government (so-called qui tam actions, such as this one) and to share in any recovery. *Id.* § 3730(b).

B. Medicare Advantage and Medicaid

This case involves two federal programs: Medicare Advantage and Medicaid. The Centers for Medicare and Medicaid Services ("CMS") administers both programs. A-133 (¶¶ 2-3) .[3]

1. Medicare Advantage

Medicare is a federal program that offers health insurance to individuals who are aged 65 or older or permanently disabled, among others.[4] *See* A-147 (¶ 64). The program has four parts, Part A through Part D. A-133-34 (¶¶ 2-4); 42 CFR § 400.202. Parts A and B operate on a "fee-for-service" model, in which CMS

[3] The complaint will be cited as A-__ (¶ _).

[4] Medicare is provided for in subchapter XVIII of the Social Security Act. 42 U.S.C. § 1395c.

pays hospitals and physicians directly for each covered service provided to a beneficiary. But beneficiaries can elect to participate instead in Part C, also known as Medicare Advantage (or simply "MA").[5] Medicare Advantage operates on a "managed care model" and is handled by private health insurers. A-134 (¶¶ 4-5).

Under Medicare Advantage, CMS contracts with Managed Care Organizations ("MCOs") that offer and administer MA plans for Medicare beneficiaries. A-133 (¶ 2). CMS pays MCOs a "capitated" (per enrollee) monthly amount to provide all Part A and B benefits. A-13. Capitation payments are calculated based on a beneficiary's risk score—geographic location, income status, gender, age, and health status, etc.—modified by a base rate. *See* A-148 (¶¶ 68-70); 42 U.S.C. § 1395w 23(a)(1)(B) (C); 42 C.F.R. §§ 422.304(a)(1)(i), 422.308(c). (Separately, CMS also pays MCOs to provide prescription drug benefits under Medicare Part D. A-134 (¶ 4)).

The "base rate" that applies to an MA plan is calculated using a bidding process that factors in, among other things, the plan's per-enrollee costs from the past two years. *See* Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2020 (Apr. 5, 2019) at 7, 9, 43, https://www.cms.gov/files/document/draft-instructions-completing-medicare-advantage-bid-pricing-tools-cy2023.pdf (last visited July 7, 2022); *see*

[5] Medicare Part D covers prescription drug benefits. A-134 (¶ 4).

generally U.S. ex rel. Ormsby v. Sutter Health, 444 F. Supp. 3d 1010, 1025 (N.D. Cal. 2020).

Medicare coverage is limited to services that are medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1); A-135-36 (¶ 12). MA plans need not pay for treatments that do not meet this standard. *See United States ex rel. Nedza v. Am. Imaging Mgmt.*, No. 15 C 6937, 2020 U.S. Dist. LEXIS 52415, at *30 (N.D. Ill. Mar. 26, 2020) (noting that MA plans require "individualized coverage determinations based on medical necessity.") (citing 42 U.S.C. §§ 1395w-22(a), (g); 1395w-27(a),(g); 1395y(a),(l); 1395ff; 42 C.F.R. §§ 422.101(a),(b), 422.112(a)(6)(ii), 422.566(a),(d); CMS Managed Care Manual, §§ 4.10.2, 4.10.16, 4.90.1 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf (last visited July 7, 2022))); *see also* 42 C.F.R. § 422.566(a), (d).

To aid in making medical necessity determinations, MCO plans sometimes pay subcontractors—like eviCore here—to perform clinical reviews of treatment requests. A-135 (¶ 10). The governing regulations mandate that MCOs that engage such subcontractors must require these entities to agree to "comply with all applicable Medicare laws, regulations, and CMS instructions" in their contracts with the plans. 42 C.F.R. § 422.504(i)(4)(v); A-134 (¶ 8).

CMS may terminate an MCO's Medicare Advantage contract for, among other things, committing or participating in fraudulent or abusive activities affecting the Medicare program. A-134 (¶¶ 6, 8); 42 C.F.R. § 422.504(h)(1). Furthermore, 42 C.F.R. § 422.510 (titled "Termination of Contract by CMS") provides that CMS may terminate a contract with an MCO administering an MA plan that "[h]as failed substantially to carry out the contract;" "[i]s carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part;" or "commit[ing] any of the acts in § 422.752(a) that support the imposition of intermediate sanctions or civil money penalties under subpart O[.]" *Id.* § 422.510(a)(1), (2) (4)(xiv). Acts that support sanctions or penalties include, among others, "[m]isrepresent[ing] or falsif[ying] information" furnished to "CMS" or "an individual or to any entity." *Id.* § 422.752(5).

2. Medicaid

Medicaid[6] is a joint federal-state program that provides healthcare benefits for certain groups, mainly indigent and disabled individuals. Medicaid provides medical assistance to "families with dependent children and of aged, blind and disabled individuals, whose income and resources are insufficient to meet the costs of *necessary* medical services." 42 U.S.C. § 1396-1 (emphasis added). The federal

[6] Medicaid was created by Title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396, *et seq*.

portion of each state's Medicaid payments is known as the Federal Medical Assistance Percentage ("FMAP"). A-149 (¶ 74). FMAP is calculated by comparing a State's per capita income to the national average under a statutory formula set forth in section 2105(a) of the Social Security Act, 42 U.S.C. § 1397ee.

Each participating state must implement and administer a plan for medical assistance services with specified minimum criteria for coverage and payment of claims. *Id.* §§ 1396, 1396a(a)(10). States must implement "methods and procedures" to "safeguard against unnecessary utilization" of Medicaid care and services. *Id.* § 1396a(a)(30)(A); *see generally Universal Health Servs. v. United States*, 579 U.S. 176 (2016) (describing contours of Medicaid program in context of evaluating FCA claims).

As with Medicare, Medicaid agencies may delegate duties to private insurance carrier contractors—including MCOs—with which they contract to administer health plans under state Medicaid managed care programs. A-150 (¶ 82). Those delegated duties may include determining whether services a provider requests are medically necessary and appropriate. A-150 (¶ 82).

3. Utilization Management in Medicare and Medicaid

"Utilization management"—a healthcare term of art—refers to the management of how healthcare is used. "Prior authorization" is a type of utilization management. It refers to a utilization management determination that takes place before the treatment or procedure.

In order to control costs and ensure quality of service, the laws and regulations governing Medicare Advantage and Medicaid require utilization management programs that meet certain specified standards. MA plans must maintain "written standards" for "utilization management[] that allow for individual medical necessity determinations." 42 C.F.R. §422.112(a)(6)(ii); s*ee also* Medicare Managed Care Manual ch. 4 § 90.5 (Rev. 121), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf (last visited July 8, 2022) (setting out criteria required for creating utilization management coverage policies, including that the MCO "[m]ust provide CMS an objective evidence-based rationale relying on authoritative evidence;" and, "may not use conclusory statements with no accompanying rationale.").

Utilization management is a core function in MCOs' administration of Medicare Advantage and Medicaid plans. A-135 (¶¶ 10-11). MCOs often hire contractors for utilization management to determine whether medical treatments and procedures are reimbursable under a Medicaid Plan or Medicare Advantage. A-

135-36 (¶ 12). Among other things, these reviews seek to ensure that procedures and treatments are covered by Medicare and Medicaid are reasonable and necessary. *See* 42 U.S.C. § 1395y(a)(1) ("[N]o payment may be made … for any expenses incurred for items or services … which … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

C. The Parties

Plaintiffs-Appellants include the two Relator Plaintiffs and Plaintiff SW Challenger, LLC, a limited liability company whose members are the two Relators. A-142-43 (¶¶ 43). The Relators are former eviCore employees with personal knowledge of eviCore's misconduct. A-142-43 (¶¶ 43). One Relator worked as a Clinical Reviewer for eviCore from July 17, 2017, to March 20, 2020. A-165 (¶ 139), A-167 (¶ 150). Her work provided her personal knowledge of eviCore's pre-approval criteria and operations. A-165-66 (¶¶ 140-145). The other Relator worked at eviCore as a Clinical Reviewer from November 7, 2016, to May 26, 2020, and she, too, has personal knowledge of eviCore's pre-approval criteria and operations. A-168 (¶¶ 151-57), A-169 (¶ 163).

Defendant eviCore is a Tennessee LLC with its principal place of business in South Carolina. A-144 (¶ 51). eviCore is a direct successor to CareCore National, which was previously implicated in a Medicare and Medicaid fraud scheme similar

to the scheme involving faulty clinical review processes.[7] A-144-45 (¶¶ 52-53). In 2014, CareCore merged with MedSolutions, Inc., and the resulting entity rebranded itself as eviCore in 2015. A-144 (¶ 52).

D. The Allegations Against eviCore

1. eviCore's Government Contracts

eviCore provides prior authorization services to MCOs—e.g., WellCare Health Plans, Inc.—which are carrier contractors for Medicare Advantage and Medicaid Plans. A-154 (¶ 85). In this role, eviCore makes reimbursement determinations for services ordered by physicians and allied health professionals for hundreds of thousands of beneficiaries covered by Medicare Advantage and Medicaid. A-154 (¶ 86).

[7] Between 2007 and 2013, CareCore engaged in Medicaid and Medicare fraud on a national scale. The U.S. Department of Justice reported that it had "blindly approved hundreds of thousands of medical procedures over a period of many years, leaving Medicare and Medicaid to foot the bill." That misconduct eventually resulted in CareCore paying a $54 million settlement. Several members of eviCore's current executive leadership team are CareCore holdovers, including eviCore's CEO. A-144-45 (¶¶ 52-53).

2. eviCore's Operations

eviCore uses two request management systems—databases with front-ends—to handle incoming requests for payment authorization from physicians and other health professionals: "Image One" and "ISAAC." A-155 (¶ 89). The system used depends on the nature of the request—such as physical therapy, cardiology, or radiology. A-155 (¶ 89).

The Image One system prompts users—eviCore intake personnel, eviCore Clinical Reviewers, or healthcare providers—to furnish certain points of demographic and clinical information necessary to determine whether a request is reimbursable. A-155 (¶ 89). The Image One system contains a "journal" data field, which tracks the lifetime of the request in narrative form. A-155 (¶ 93).

eviCore also uses a data analytics system with a web portal called "CorePath" to manage, and partially automate, incoming treatment approval requests. A-155 (¶ 90). CMS has published guidance that "encourage[s]" MCOs to employ such automation, but has cautioned that "it may require the evaluation of medical records and related documents to determine whether Medicare claims were billed in compliance with coverage, coding, payment, and billing policies." CMS, Medicare Program Integrity Manual, Ch. 1 § 1.3.7 (Rev. 11032), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c01.pdf (last visited July 8, 2022). CMS then cites (among other things)

"Section 1862(a)(1) [of the Social Security Act, 42 U.S.C. § 1395y], which states no Medicare payment shall be made for expenses incurred for items or services that 'are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member')." *Id.* Thus, in providing prior approval services for Medicare and Medicaid plans, eviCore's CorePath system was required to collect sufficient information so as to ensure that the treatments requested met the governing reasonable and necessary standard.

All of eviCore's intake channels—Image One, ISAAC, and CorePath—require that certain data fields be filled out to process the prior authorization request. *See* A-156 (¶ 97). Assembling the required information is called "building" the request. A-156 (¶ 97). Under governing law, when requests for Medicare or Medicaid coverage came in, eviCore was supposed to assemble sufficient information and adequately review the request to determine whether the service was medically necessary before authorization. Part II.A.1-3, *supra*.

3. eviCore's Auto-Approval Scheme, Including "Manual" And "Automated" Auto-Approvals

Rather than perform the required medical necessity review of all treatment requests, eviCore deployed a scheme designed to ensure fast turnaround times (in conformance with its contract mandates), high approval rates—100% approvals for certain (broad) request categories—and low review costs. A-156 (¶ 98). The scheme

is simple: rather than collect sufficient data and perform the required review, eviCore simply rubberstamps provider requests when it is convenient. A-156-62 (¶¶ 99-123).

eviCore's rubberstamping scheme takes two forms. *First*, eviCore instructs clinical reviewers that certain categories of treatment request are to be "auto-approved," regardless of any medical necessity. A-156-59 (¶¶ 99-112). *Second*, eviCore embedded auto-approvals in its software systems. A-159-62 (¶¶ 113-123). Either way, the result is the same: treatment requests are pre-authorized as eligible for Medicare or Medicaid payments even though they have not undergone the required level of review—or *any* review.

a. "Manual" Auto-Approvals via eviCore's Directives to Clinical Reviewers

The requests for services directed by eviCore for "auto-approval" were in one respect handled "manually" in that an eviCore employee entered data. But eviCore did not perform a 'review' of these requests in any meaningful sense, because eviCore instructed its reviewers to approve whatever services a provider on auto-approval requested—the clinical reviewers' exercise of review and judgment was usurped as the process was reduced solely to data entry. A-156-57 (¶¶ 99-104).

This practice compelled Relators and other eviCore reviewers—on pain of losing their jobs—to lie and falsify data. For cases "in auto-approval status" in Image One, for example, eviCore directed Clinical Reviewers to enter pre-authorization "justifications" into the journal field. A-155 (¶ 93). Because the cases were in

"auto-approval" status, these justifications could not impact whether payment was approved. Moreover, the "justifications" that eviCore directed reviewers to enter for requests on auto-approval were unrelated to the clinical facts of the pertinent case. A-155 (¶¶ 91-93).

For example, an eviCore manager stated that for WellCare Florida Medicaid cases—which were subject to an "auto-approve" directive at the time—"the system should be preventing [reviewers] from making adverse determinations," i.e., denials or reductions in the number of doctor's visits to which the patient may be entitled. A-161 (¶ 120). This restriction on denials was embedded into the database system used by reviewers. A-161 (¶¶ 120-21).

The complaint lists examples of this auto-approval process in practice. For instance, on October 27, 2017, two eviCore executives (its Senior Vice President of Program Operations and Chief Medical Officer) instructed Relators to auto-approve all pediatric requests for Blue Cross Blue Shield of Texas. A-157 (¶ 102). The basis for this auto-approval given in the email was that providers had complained about approvals—there was no attempt at a justification under the governing medical reasonableness standard. *See* A-157 (¶ 102). At a meeting with Blue Cross Blue Shield about a month later, eviCore agreed that it would auto-approve pediatric developmental requests for six months. A157 (¶ 103). eviCore said it would reinstate medical necessity review, but never did so. A157 (¶ 103).

The complaint also provides examples of the auto-approval scheme leading to unnecessary treatments being approved, including a November 8, 2017, email from an eviCore manager describing auto-approval cases "that ask for significantly more visits than we would approve [under the full review process]," including a case in which a Clinical Reviewer had "to auto approve 200 visits for an ankle sprain [in a] … week." A-159 (¶ 111).

eviCore's use of this rubber-stamping process was pervasive and systemic. Relators directly encountered "auto-approvals" while working as physical therapy clinical reviewers, and through their interactions with other reviewers learned that such approvals also extend into (at least) radiology services, cardiology procedures, joint surgery, radiation therapy, interventional pain procedures, sleep therapy, and laboratory management. A-138 (¶ 24), A-159 (¶ 112).

Internal eviCore documents—such as its nurse reviewer job aid for the ISAAC platform—bespeak the scope of eviCore's auto-approval scheme. For example, the complaint describes an eviCore document that Relators unearthed before they were let go, entitled "Auto-Approvals (IO-CDP) 6-1-20," which stated that "[a]pprovals by QPID-sPA-PI-UPADS [an auto-approval code] are not health plan directed approvals. These are approvals based on survey responses and other data collected by the system." A-158 (¶ 105).

b. Auto-Approval Directives Embedded in Software

eviCore sought to automate its auto-approval process using its software portal and platform, CorePath. As deployed by eviCore, CorePath renders authorization decisions—including for Medicare and Medicaid plan beneficiaries—based on clinically meaningless factors (e.g., number of clinic visits). A-159-162 (¶¶ 113-123).

The complaint cites examples to illustrate eviCore embedding auto-approval determinations in CorePath. In a telephone call on September 14, 2017, Bruce Brownstein (eviCore's MSK Product Advisor) informed pediatric clinical reviewers that, in order to keep up with the volume of pediatric requests, eviCore management decided to have CorePath approve all first requests in the pediatric queue automatically—regardless of the nature of the services or the absence of clinical review. A-160 (¶ 116). As another example, Relators cite weekly meeting minutes from a July 23, 2019, team meeting showing that eviCore's senior leadership adjusted CorePath to auto-approve visits for every second request, with no clinical review. A-162 (¶ 123). On a September 15, 2018, telephone call, another eviCore executive stated that the goal was to make pre-approvals "scalable," and that pediatric therapy requests had been targeted by the CorePath automation program because of their long review time. A-160 (¶ 115).

As with "manual" auto-approvals, the scope of this practice was broad. As of

March 2019, eviCore had implemented CorePath logic processes to automatically authorize requests from healthcare providers including Affinity, Blue Cross Blue Shield, Passport, and WellCare, across many states, including, at least, Arkansas, Connecticut, Illinois, Kentucky, Louisiana, Maine, Missouri, Mississippi, New Mexico, New York, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas. A161-62 (¶¶ 122-23); *see also* A-139 (¶ 26) (for at least 126 days in 2018, eviCore established a protocol to approve the first three requests for any course of care).

4. eviCore's Attempts to Conceal Its Auto-Approval Practices

The complaint also alleges that eviCore knowingly covered up its auto-approval practices. eviCore told MCOs that it was performing full medical necessity review, but it used clinical reviewers to concoct fraudulent justifications for cases that were on auto-approval if questioned after the fact by MCOs. A-35 (¶ 77); A-162-63 (¶ 127). eviCore also purposely removed references to auto-approval from its pamphlets and brochures, despite not changing its underlying operations. A-162 (¶¶ 124-26)

E. eviCore's Motive for the Auto-approval Scheme

eviCore's motive is simple: to increase profits. Conducting the individualized medical necessity review required by governing law takes time, and skilled resources, while auto-approval requires only data entry. An example illustrates. On

March 23, 2018, when eviCore was "short staffed on the [occupational therapy] side," eviCore's Manager of MusculoSkeletal Specialized Therapy opened review of auto-approval occupational therapy requests to all pediatric physical therapy Clinical Reviewers. A-37 (¶ 87). By using its auto-approval scheme, eviCore avoided the cost of deploying skilled reviewers with specialized training and knowledge to perform the required medical necessity review for these requests. A-37 (¶ 87). eviCore's motive was particularly pronounced given that, on information and belief, its eviCore's contracts with MA Plans included provisions that penalized eviCore if it took too long to approve a request. A-158 (¶ 106).

In short, eviCore used auto-approvals to handle a higher volume of requests, and to do so more quickly and with decreased staffing, rubber-stamping as many requests as possible.

III. PROCEDURAL HISTORY

A. The Lawsuit

The initial complaint was filed under seal on March 20, 2019. A-90. After investigating, the Government declined to intervene, and the case was unsealed by order dated June 10, 2020. A-122. That same day, Plaintiffs filed an Amended Complaint. A-91. Later, after successfully requesting leave, Plaintiffs filed their Second Amended Complaint (the operative complaint) on September 23, 2020. A-129.

B. eviCore's Motion to Dismiss

eviCore moved to dismiss the complaint on November 23, 2020. A-7. The motion was fully briefed by April 12, 2021. A-9.

1. The Government's Statement of Interest

The United States took the affirmative step of filing a Statement of Interest in response to eviCore's Motion to Dismiss ("SOI"), 19-cv-2501-VM (ECF No. 39); *see* A-8 (docket sheet). Although the Government took no position on the merits of eviCore's motion, it presented its view that conduct such as eviCore's may qualify as a "claim" for purposes of the FCA.[8] SOI at 2. Specifically:

> In the context of the Medicare Part C program, a subcontractor like eviCore's improper approval of a medically unnecessary treatment *could* give rise to *three* types of false claims under 31 U.S.C. § 3729(b)(2)(A). First, insofar as an improper approval results in a healthcare provider billing a Part C plan for the medically unnecessary treatment, that payment request is a "claim" under § 3729(b)(2)(A)(ii). Second, when eviCore subsequently invoices the Part C plan for conducting a medical necessity review even though no "meaningful review" occurred, that invoice also is a "claim" under § 3729(b)(2)(A)(ii). Finally, when the Part C plan transmits to CMS inaccurate diagnosis codes that the Part C plan received from the treating provider, thus affecting CMS's calculation of the appropriate "risk score," the transmission of the invalid diagnosis data is a "claim" under § 3729(b)(2)(A)(i)[9].

[8] The Government also took pains to point out that the FCA applies to Medicare subcontractors such as eviCore. SOI at 5-7 (concluding that "the text of 31 U.S.C. § 3729(b)(2)(A)(ii) and FERA's legislative history both make clear that the direct "submi[ssion of] false claims to the government" is not necessary for stating an FCA claim, and that a request made to a contractor like a Medicare Part C plan is encompassed within the meaning of 'claim' under the FCA." (SOI at 7)).

[9] Under section 3729(b)(2)(A)(i), "claim" means "means any request or demand … for money … that— is presented to an officer, employee, or agent of the United States[.]"

SOI at 7-8 (emphasis in original).

In the Government's view, FCA liability for the first two scenarios—a healthcare provider billing Medicare for an unnecessary treatment, or eviCore invoicing for a medical necessity review even though no meaningful review took place—follows from section 3729(b)(2)(A)(ii)'s definition of "claim." As described (Part II.A, *supra*), this definition "encompass[es] demands or requests made to a contractor, grantee, or other recipient" as long as: (i) "the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest," and (ii) "'the [] Government provides or has provided any portion of the money or property requested or demanded[.]'" SOI at 6 (quoting *United States v. Wells Fargo & Co.*, 943 F.3d 588, 601-02 (2d Cir. 2019)).

Under this definition, MCOs that offer Part C plans are "contractors" because they are required by statute to contract with CMS to receive payments (SOI at 8-9 (citing 31 U.S.C. § 3729(b)(2)(A)(ii) & 42 U.S.C. § 1395w-27(a)). Moreover, the two conditions are met here because (i) bills submitted to a Part C Plan by a healthcare provider for services or by eviCore for performing a medical necessity review are for payments "used … to advance a Government program," *i.e.*, Medicare (SOI at 8 (quoting 31 U.S.C. § 3729(b)(2)(A)(ii) (FCA provision defining "claim")); and, (ii) CMS makes monthly capitated payments to MA plans in exchange for Medicare benefits (SOI at 9 (citing 42 U.S.C. § 3729(b)(2)(A)(ii)(I) ("claim"

includes circumstances when the "United States Government" "provides … [a] portion of the money [] requested")).

The Government also stated that the third scenario—an MA plan transmitting inaccurate diagnosis codes to CMS to compute a risk score—constitutes an FCA "claim" under 31 U.S.C. § 3729(b)(2)(A)(i). SOI at 8-9. This is so because these risk scores are used by CMS to calculate capitation rates for MA plans. SOI at 9. Separately, the Government noted that, under the same theory, it would constitute an FCA "claim" if eviCore's deficient pre-authorization review procedures raised costs, leading an MA plan to submit inaccurate data to CMS to determine its base rate. SOI at 9.

2. The Decision Below

The District Court issued a Decision and Order dismissing the action on August 13, 2021. A-220. At the threshold, the District Court confirmed its jurisdiction and rejected eviCore's argument that Relators had not alleged the submission of a false "claim" under the FCA. A-241-42. Next, the District Court characterized Relators' FCA causes as "aris[ing] from the provision of 'worthless services.'" A-244.

Proceeding from the premise that Relators' claims must rise and fall with the worthless services theory, the District Court ultimately dismissed Relators' FCA claims. This dismissal was based on two holdings. *First*, the District Court held that

Relators had failed to sufficiently allege falsity "because the services eviCore provided were not so 'worthless' that they were "the equivalent of no performance at all." A-245 (quoting *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001)). The District Court reasoned that even though eviCore instituted swinging-gate auto-approvals of certain services, no false claim had been submitted because "eviCore provided *some* legitimate prior authorization and utilization management services." A-246 (emphasis in original).

The District Court thus based its holding on the observation that eviCore—despite systemic departures from governing standards such as swinging gate approvals—at times actually provided services it was contracted to render. For example, the District Court acknowledged eviCore's "auto-approval for *pediatric* treatment requests from Blue Cross Blue Shield Texas," but declined to find falsity because Relators did not allege that eviCore "utilization management and prior authorization services provided were entirely worthless." A-245 (quotation and citation omitted; emphasis in original).

Second, the District Court held that Relators had not pleaded their FCA claims with sufficient particularity under Rule 9(b). A-247-251. To support this holding, the District Court pointed to Relators' failure to allege particular "records of requests for payment from eviCore to any MCOs for utilization management or prior authorization services." A-247-48. The District Court allowed that Relators had

alleged automatic approvals, but held that this did not satisfy Rule 9(b) because Relators had not identified "any specific approvals, much less d[id] they allege who approved the unnecessary services, where, or when." A-248.

The District Court also reasoned that the Relators had not met Rule 9(b)'s specificity requirements because, in its view, their "allegations f[e]ll short of alleging a 'detailed scheme' from which fraudulent claims [could] be 'easily' inferred." A-250 (quoting *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 84 (2d Cir. 2017)). The District Court supported this rationale by noting certain supposed inconsistencies in Relators' allegations, including: (i) eviCore's Manager of Clinical Review at one point encouraged auto-approvals but at another point tried to correct the practice; and (ii) the automatic approvals that Relators alleged were not applied in all cases. A-249-250 ("[W]hile the [complaint] alleges that the auto-approval processes were designed to approve requests indiscriminately … it also alleges that the automation software eviCore uses requires [in other cases] some 'demographic and clinical information' and suggests that the pathways were, … in at least some cases, developed by knowledgeable clinical reviewers").

The District Court conceded that that "the Second Circuit has held that Rule 9(b) may be satisfied by allegations 'based on information and belief when facts are peculiarly within the opposing party's knowledge.'" A-250 (quoting *Boykin v.*

KeyCorp, 521 F.3d 202, 215 (2d Cir. 2008)). Nevertheless, because "Relators allege[d] that they 'possess[ed] personal knowledge and experience regarding eviCore's 'auto-approve' activities," but had "not credibly allege[ed] that *all* specific facts regarding the scheme were exclusively known to eviCore" (A-251 (emphasis added)), the District Court required Relators to allege every particular of eviCore's scheme with specificity. For example, the District Court said that one of Relator's pleading deficiencies was that they had not "identif[ied] *any* records of requests for payment from eviCore to any MCOs for utilization management or prior authorization services." A250-51 (emphasis in original).

In sum, the District Court held that Relators failed to sufficiently plead an FCA violation because they had not alleged that eviCore's deficient practices were applied uniformly for the entirety of its operations (s*ee* A250 (holding that a "set of auto-approval processes that existed at various times for certain categories of requests …. falls short of alleging a 'detailed scheme' from which fraudulent claims can be 'easily' inferred") (quoting *Chorches*, 865 F.3d at 84) (record quotation omitted)). The District Court also held that, because Relators alleged they knew about some aspects of eviCore's operations, Relators were not entitled to allege on information and belief facts peculiarly within eviCore's knowledge. A250-51.

* * *

Given its holdings on falsity and the pleading standard, the District Court did not address the other elements of Relators' FCA claims. A-243 n.5. Following entry of a final judgment of dismissal on February 10, 2022, Plaintiffs timely filed a Notice of Appeal on March 14, 2022. A-263.

STANDARD OF REVIEW

"This Court review[s] *de novo* the grant of a motion to dismiss under Rule 12(b)(6), accepting as true the factual allegations in the complaint and drawing all inferences in the plaintiff's favor." *Mirkin v. XOOM Energy*, LLC, 931 F.3d 173, 176 (2d Cir. 2019).

SUMMARY OF ARGUMENT

The complaint states viable claims for relief against eviCore for presenting false or fraudulent claims. eviCore contracted with MCOs servicing Medicare and Medicaid beneficiaries to provide prior authorization services. eviCore was thus obligated to perform, for each and every incoming treatment request, the individualized review for medical necessity mandated by the governing regulations. BACKGROUND Part II.B, *supra*; *see* 42 U.S.C. § 1395y(a)(1); 42 C.F.R. § 422.566(d). Yet on a systemic basis, eviCore failed to do so. Instead, eviCore instituted swinging-gate auto-approvals across broad categories of treatment requests. This states a classic FCA claim: eviCore—through the MCOs—charged the Government for services that it did not provide.

Unsurprisingly, then, Plaintiffs adequately pleaded a false or fraudulent claim under the FCA. As the Government described in its Statement of Interest, eviCore's auto-approval schemes led to false claims being submitted on at least three theories, including: (i) MA plans submitting bills for medically unnecessary treatments authorized by eviCore; (ii) eviCore's bills to MA plans for medical necessity reviews not performed; and (iii) MA plans' submission of false data to CMS for computing monthly capitation payments. Because Plaintiffs plainly alleged facts from which an entitlement to relief can be inferred, dismissal was inappropriate.

The District Court committed two main errors of law in arriving at the opposite conclusion and dismissing Plaintiffs' claims. *First*, the District Court improperly collapsed Plaintiffs' allegations into the judicially created category of a "worthless services" claim, and proceeded to incorrectly construe that category in dismissing their claims. The District Court's worthless services analysis rested on two legal errors: (i) it wrongly held that Plaintiffs were required to allege that eviCore's *entire* bundle of services was *uniformly* worthless; and, (ii) it wrongly applied the standard for assessing medically necessary treatments to Plaintiffs' allegations that medical necessity reviews had not been performed. Each error alone merits reversal.

Second, the District Court misapplied the pleading standard under Rule 9(b). Plaintiffs satisfied the standard under governing law by pleading specific facts about eviCore's auto-approval schemes that support a strong inference false claims were submitted. The District Court held otherwise based on various reversible errors of law. Among these errors, the District Court misapplied controlling precedent in measuring Plaintiffs' allegations; improperly weighed credibility and drew inferences against Plaintiffs, which is improper on a Rule 12(b)(6) dismissal motion; demanded that Plaintiffs plead matters not peculiarly within their knowledge; and insisted that Plaintiffs identify specific invoices and bills.

At base, Plaintiffs' allegations plead FCA claims cognizable under both a worthless services theory and several other accepted theories. The District Court's errors, along with its failure to consider that Plaintiffs sufficiently pleaded the other elements of their FCA claims, warrant reversal and remand for further proceedings.

ARGUMENT

I. THE COMPLAINT PLEADS FALSE OR FRAUDULENT CLAIMS

Plaintiffs have alleged facts describing FCA violations cognizable under a number of legal theories, including but not limited to a "worthless services" theory. The District Court erred in collapsing these allegations into a claim for worthless services. As discussed in Part A below, Plaintiffs' allegations describe a classic FCA violation distinct from the "worthless services" rubric. Also, as discussed in Part B below, the District Court misapplied the law to hold that, for Plaintiffs to state a worthless services claim, eviCore's entire "bundle" of services had to be worthless in each and every instance. Such a standard is untenable and it conflicts with the FCA's text and this Court's controlling precedents.

A. Plaintiffs Sufficiently Pleaded a False or Fraudulent Claim

Plaintiffs sufficiently alleged that eviCore had submitted false claims or false statements to the Government in connection with demands for payment. The complaint describes a classic FCA violation: eviCore contracted to provide services paid for by the Government, but it cut corners and did not render the agreed-upon services. In servicing Medicare and Medicaid plans, eviCore was required under its contracts and governing regulations to make *individualized* medical necessity determinations of treatment requests. BACKGROUND Part B, *supra*. But on a systemic

basis, eviCore did not do so. BACKGROUND Part D, *supra*. As a result, false claims were submitted to the Government.

That eviCore is a subcontractor does not alter this analysis. As the Government explained in its Statement of Interest below (PROCEDURAL HISTORY Part B.1, *supra*), and as this Court has recognized, Title 31, section 3729(b)(2)(A)(ii) of the U.S Code "defines claim … broadly … to encompass demands or requests made to a contractor" (such as eviCore's here), as long as "the money or property is to be spent or used … to advance a Government program" and "the [] Government provides … any portion of the money … requested or demanded, or will reimburse [the recipient] for any portion of the money … requested" (as with the Medicare program and MCOs here). *United States ex rel. Kraus v. Wells Fargo & Co.*, 943 F.3d 588, 601-02 (2d Cir. 2019). Under this definition, eviCore submitted—or caused to be submitted—false "claims" when (i) MCOs' administering MA plans billed for medically unnecessary treatments authorized by eviCore; or (ii) eviCore billed MCOs administering MA plans for medical necessity reviews it did not, in fact, perform. Separately, eviCore caused false claims to be submitted under section 3729(b)(2)(A)(i) because the treatments that it improperly approved led MCOs administering Part C plans to submit false data to CMS for computing monthly capitation payments, which would necessarily be higher because of the additional treatment. *See* PROCEDURAL HISTORY Part B.1, *supra*.

Plaintiffs allege cognizable claims under the FCA on at least three theories:

1. **False claims for nonconforming ("worthless") services.** eviCore contracted with MCOs, which offer MA Plans that provide Medicare insurance, to make individualized determinations based on Medicare's coverage rules. BACKGROUND Parts B, D.1, *supra*; see 42 C.F.R. § 422.566(d); *Nedza*, 2020 U.S. Dist. LEXIS 52415, at *30 (MA plans require "individualized coverage determinations based on medical necessity") (citations omitted). eviCore claimed full payment from the MCOs offering MA plans—and thus from the Government—even though they did not provide the contracted-for review. As a result, claims for payment were false. *See generally United States v. Bornstein*, 423 U.S. 303, 307 (1976) (defendant who delivers a faulty product "not of the required quality" is liable under the FCA).[10]

2. **Implied certification**. MA plans such as those eviCore contracted with must submit monthly risk adjustment data—including diagnosis information for each enrollee of the plan—which CMS uses to calculate capitation payments. *See generally* CMS, Medicare Managed Care Manual, Chapter 7 – Risk Adjustment, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf (last visited July 8, 2022.) As part of this required submission, MA plans must acknowledge that the data affects CMS payments and certify that the data is complete, truthful, and accurate. 42 C.F.R. § 422.504(l)(2); BACKGROUND Part II.B, *supra*. By failing to perform the reasonableness reviews during the pre-authorization process it was contracted for, eviCore caused these certifications to be materially false or misleading.

3. **Fraudulent inducement.** Under this theory of FCA liability, which follows the common law, "a defendant's alleged misrepresentations at the time the government awarded the contract … render any subsequent claim under that contract fraudulent[.]" *United States v. Strock*, 982 F.3d 51, 61 (2d Cir. 2020). MCOs that hired eviCore to perform prior authorization reviews were

[10] That CMS pays MA plans capitated amounts in advance of the provision of the services, rather as reimbursement after the services, is of no moment. The payment rate is set on the premise that Medicare requirements, including a necessity review, have been met. The result is that Government has overpaid. *See United States ex rel. Silingo v.WellPoint, Inc.*, 904 F.3d 667, 673 (9th Cir. 2018) ("The Medicare Advantage capitation payment system is subject to the False Claims Act.").

> required to represent to the Government that coverage determinations would be made on an individualized basis using Medicare coverage rules. BACKGROUND Part II.B, *supra*. But eviCore violated those rules—and intended to violate and continue to violate them during the terms of contract renewals—by authorizing medical interventions for broad categories of cases without conducting the required review. BACKGROUND Part II.D.3, *supra*. Without the false statements that eviCore caused, the Government would not have paid any money to the MCO plans. *See* BACKGROUND Part B.1, *supra*; *see also* 42 U.S.C. § 1935w-27(a).

At bottom, whatever the precise legal theory of liability, Plaintiffs alleged facts describing FCA violations by eviCore. BACKGROUND Part D, *supra*. Because the complaint thus gave eviCore "full notice of the circumstances giving rise to [Plaintiffs] … claim for relief," Plaintiffs stated a claim for FCA violations. They were not required to "plead the legal theory or theories and statutory basis supporting the claim." *Marbury Mgmt., Inc. v. Kohn*, 629 F.2d 705, 712 n.4 (2d Cir. 1980) (collecting Circuit-level authorities), *cited in*, *e.g.*, *Morris v. Schroder Cap. Mgmt. Int'l*, 445 F.3d 525, 530 n.3 (2d Cir. 2006); *see also Newman v Silver*, 713 F.2d 14, 15 n.1 (2d Cir 1983) ("[T]he nature of federal pleading … is by statement of claim, not by legal theories.") (citing *Gins v. Mauser Plumbing Supply Co.*, 148 F.2d 974, 976 (2d Cir. 1945) ("particular legal theories of counsel yield to the court's duty to grant the relief to which the prevailing party is entitled, whether demanded or not")); *Doe v. Smith*, 429 F.3d 706, 708 (7th Cir. 2005) ("A complaint suffices if any facts consistent with its allegations, and showing entitlement to prevail, could be

established by affidavit or testimony at a trial.") (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

The District Court erred by collapsing Plaintiffs' FCA claims into the judicially-created category of "worthless services," and then dismissing those claims for not adhering to its interpretation of that category. Even adopting, however, the District Court's restrictive view of Plaintiffs' claims as limited to "worthless services," it erred as a matter of law in dismissing the complaint.

B. The District Court Dismissed the FCA Claims Based on the Erroneous Conclusion That, to Plead a Worthless Services FCA Claim, a Defendant's Entire Bundle of Services Must Be Uniformly Worthless

eviCore invited error below by arguing that Plaintiffs did not "allege worthless services" because, although Plaintiffs "allege[d] that eviCore performed 'auto-approvals' on a subset of the prior authorization reviews, … [those allegations] do not establish eviCore performed 'no services at all' for MCOs, much less that 'no services' were performed from the perspective of a federal program." Defs.' Mem ISO Mot. Dismiss 2d Am. Cmplt., 19-cv-2501 (ECF No. 22) at 15; *see* A-7 (docket sheet). Accepting this argument, the District Court wrongly dismissed Plaintiffs' claims. PROCEDURAL HISTORY Part B.2, *supra*.

In so doing, the District Court relied (A-244) on this Court's statement in *Mikes* that "[i]n a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."

Mikes, 274 F.3d at 703. But nothing in in *Mikes* suggests that, to plead false claims on a worthless services theory, a plaintiff must allege the defendant's *entire* bundle of services is *uniformly* worthless. In *Mikes*, the relator alleged that the defendants permitted untrained personnel to administer spirometry tests and failed to calibrate their spirometers up to American Thoracic Society standards, leading to submitting false claims for reimbursement of spirometry testing. *Id.* at 694. Addressing the worthless services theory of factual falsity, this Court "agree[d] that a worthless services claim is a distinct claim under the Act. … effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided," but held that the relator "fail[ed] to substantiate that defendants knew their Medicare claims for reimbursement were false." *Id.* at 703. The Court made this determination not because the defendant doctors sometimes offered valuable services besides spirometry testing, but because the evidence showed that scienter was lacking as to the challenged spirometry services. *Id.* ("Defendants have … proffered ample evidence—most of which derives from disinterested non-party witnesses— supporting their contention that they held a good faith belief that their spirometry tests were of medical value.").

At the threshold, it was inappropriate for the District Court to rely on the summary judgment decision in *Mikes* to dismiss Plaintiffs' claims at the pleading stage. Even more fundamentally, there is no warrant in the FCA's text or in this

Court's precedents for eviCore's "bundling" theory—which the District Court adopted in dismissing Relator's claims below—that a defendant is excused from performing contracted-for services to the Government so long as they are bundled with other services. For example, in the case that *Mikes* adopted and termed "the leading case on worthless services claims in the health care arena," *id.*, the relator had alleged that the defendant lab company "billed Medicare for … worthless tests[.]" *United States ex rel. Insoon Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1050 (9th Cir. 2001). The Ninth Circuit held that the relator sufficiently pleaded an FCA claim if he was alleging that "a party to a government contract knowingly or with deliberate ignorance charged the government for worthless services[.]" *Id.* at 1053. The court nowhere suggested that the testing company could escape liability for worthless tests by proving that it also sought reimbursement for useful tests.

Similarly, the Sixth Circuit considered an FCA claim brought against a radiology service business in *Chesbrough v. VPA. P.C.*, 655 F.3d 461 (6th Cir. 2011). There, the relators alleged that VPA billed the government for a few "x-ray … studies, all of which were allegedly defective or nondiagnostic[,] [m]ost of [which were] described as "'suboptimal' or of 'poor quality'" or as failing to meet 'standards of care.'" *Id*. at 467. The Sixth Circuit affirmed the dismissal of the relators' action with respect to x-ray studies that were "suboptimal" or of poor quality" (*id.* at

467-68), but it determined that the relators could go forward on the five studies that were "nondiagnostic," *i.e.*, worthless. *Id.* at 468. It reasoned that "[i]f VPA sought reimbursement for services that it knew were not just of poor quality but had no medical value, then it would have effectively submitted claims for services that were not actually provided. This would amount to a 'false or fraudulent' claim within the meaning of the FCA." *Id.* Once again, the court made no mention of the possibility that the diagnostic tests might somehow excuse billing the Government for the nondiagnostic tests.

Other courts have explicitly rejected the bundling theory of worthless services that undergirds the decision below. In *United States v. Houser*, 754 F.3d 1335 (11th Cir. 2014), the defendant nursing home operator argued that since, "for purposes of Medicare and Georgia Medicaid reimbursements, services [were] 'bundled[]' … [the court must] evaluate the provision of services as a whole and cannot evaluate whether residents were deprived of a single, although necessary, service." *Id.* at 1346-47. The Eleventh Circuit rejected this argument, noting that, despite providing *some* services, the defendant had knowingly or recklessly failed to provide one or more *particular* services reimbursed by Medicare, and was thus properly charged with FCA violations. *Id.*

Apart from its misguided adoption of the "bundle" theory of worthless services—which alone merits reversal—the District Court also misapplied this

Court's precedent in *Mikes* in another, more subtle way. In *Mikes*, the plaintiff's allegations "challenge[d] only the quality of defendants' spirometry tests and not the decisions to order this procedure for patients[.]" 274 F.3d at 699. For this reason, this Court held that allegations did not implicate the Medicare standard of "medical necessity," because this standard applies "to ex ante coverage decisions but not ex post critiques of how providers executed a procedure." *Id.* at 698; *see also id.* ("The term 'medical necessity' does not impart a qualitative element mandating a particular standard of medical care") (citing 42 U.S.C. § 1395y(a)(1)(A), which "disallow[s] payment for items or services not reasonable and necessary for diagnosis or treatment"). In contrast, Plaintiffs' allegations that eviCore failed to provide contracted-for pre-authorization medical necessity reviews directly implicate the medical necessity standard of the Medicare statute. BACKGROUND Parts B1, B3, D1-4, *supra*.

The District Court thus erred by applying the standards of "ex post critiques of how providers executed a procedure[ ]" to Plaintiffs' claims about "ex ante coverage decisions." *Mikes*, 274 F.3d at 698. Illustrating this point is *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125 (E.D. Pa. 2012), in which the defendants argued "that a challenge to the level of care and amount of services provided by a medical professional is insufficient to state a worthless services claim where there is no allegation that the defendant failed to provide any services to its

patients." *Id.* at 161. The court properly rejected this argument because "Plaintiff specifically allege[d] that, pursuant to its contractual obligations and federal/state laws, Defendant was obligated [under] Medicare … to perform certain … services[ ]" which it "did not provide … at all." *Id.* Thus, "to the extent that Defendants were required to ensure prior authorization for certain drugs before dispensing them, but did not do so, they are subject to a worthless services claim." *Id.* at 165. So, too, here.

At bottom, whether classified as a "worthless services" claim or otherwise, Plaintiffs pleaded the submission of false claims with specific allegations that eviCore contracted to provide medical necessity reviews required for Medicare reimbursement but systematically failed to perform. BACKGROUND Part D, *supra*. Plaintiffs thus pleaded falsity, in that eviCore "misrepresent[ed] what … services that it provided to the Government[.]" *United States ex rel. Wilkins v. United Health Grp. Inc.*, 659 F.3d 295, 305 (3d Cir. 2011).

II. THE COMPLAINT SATISFIES RULE 9(B)

"False Claims Act plaintiffs must … plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Universal Health Servs. v. United States*, 579 U.S. 176, 195 n.6 (2016). Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud," and so FCA plaintiffs must "plead the factual basis which gives rise to a strong inference of fraudulent

intent." *Strock*, 982 F.3d at 66 (quotation and citation omitted). At the same time, however, because "the adequacy of particularized allegations under Rule 9(b) is … case-and context-specific," *Espinoza ex rel. JPMorgan Chase & Co. v. Dimon*, 797 F.3d 229, 236 (2d Cir. 2015), "Rule 9(b) does not require that every qui tam complaint provide details of actual bills or invoices submitted to the government, so long as the relator makes plausible allegations … that lead to a strong inference that specific claims were indeed submitted and that information about the claims submitted are peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 86.

Plaintiffs satisfied this standard by alleging specific facts detailing eviCore's systematic practice of auto-approving treatment requests without performing the medical necessity review required by the governing regulations and eviCore's contracts. BACKGROUND Part D.3, *supra*. Given eviCore's line of business, the scheme that Plaintiffs allege led to the submission of many false claims; yet the details of those claims (e.g., the invoices and eviCore's contracts with MCOs offering MA plans) are "peculiarly within eviCore's knowledge." *Chorches*, 865 F.3d at 86; *see also, e.g.*, *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155-56 (3d Cir. 2014) (collecting cases and rejecting argument that relator must plead specific false claims where scheme is alleged); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (FCA complaint is sufficient when it

"alleg[es] particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").[11]

The District Court's contrary conclusion is puzzling. It acknowledged that Plaintiffs had described the auto-approval scheme in detail, including dates, locations, lines of business impacted, and "individuals involved[.]" A-248. Nevertheless, it somehow concluded that because "none of [the] … individuals [whom Plaintiffs identified as involved in the scheme] allegedly submitted any of the 'false claims," "[t]he allegations [we]re therefore insufficient to provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue." A-248-249 (quotation and citation omitted). The District Court did not explain how reciting precise details—to which Relators are not privy—of eviCore's invoicing practices would somehow help provide eviCore with "fair notice of [their] … claim[.]" *O'Brien v Nat'l Prop. Analysts Partners*, 936 F.2d 674,

[11] Plaintiffs also alleged statements by eviCore and its management describing the auto-approval scheme. BACKGROUND Part D.3, *supra*. Such admissions of fraud, even without examples, have been widely held to satisfy Rule 9(b). *E.g.*, *United States of Am. ex rel. Howard v. KBR, Inc.*, 139 F. Supp. 3d 917 (C.D. Ill. 2015) a motion to dismiss an FCA complaint that did not plead "that any particular costs incurred by [Defendant] were unreasonable" because it pled defendant's admissions that costs were unreasonable); *United States v. R&F Properties of Lake Cty., Inc.*, 433 F.3d 1349, 1359-60 (11th Cir. 2005) (FCA claim sufficiently pled with details of billing scheme admitted by a manager for the defendant, even absent single example).

676 (2d Cir 1991) (discussing purpose of Rule 9(b)) (quotation and citations omitted).

It would not. The complaint here disclosed extensive information about the auto-approval practices at issue so as to place eviCore on full notice of the claims alleged. Rule 9(b) does not require more. *See Ross v. A.H. Robins Co*., 607 F.2d 545, 557 (2d Cir. 1979) (allegations of fraud must be specific enough to give defendants "a reasonable opportunity to answer the complaint" and must give them "adequate information" to allow defendants to frame a response).

Equally infirm is the District Court's holding that Plaintiffs flunked Rule 9(b) because they did not "identif[y] a single request for payment for prior authorization services, []or … who made such requests, when, or where." A-248. Plaintiffs were not required to point to specific invoices because they alleged a scheme that *inevitably* led to many false claims being submitted, including (i) MA plan bills for medically unnecessary treatments authorized by eviCore; (ii) eviCore's bills to MA plans for medical necessity reviews it did not, in fact, perform; and (iii) MA plans' submission of false data to CMS for computing monthly capitation payments. ARGUMENT Part I.A, *supra*; *see Chorches*, 865 F.3d at 86.

Contrary to the District Court's faulty assumption, "[t]o say that fraud has been pleaded with particularity is not to say that it has been proved (nor is proof part of the pleading requirement)." *United States ex rel. Lusby v. Rolls-Royce Corp.*,

570 F.3d 849, 855 (7th Cir. 2009) (rejecting argument that FCA plaintiff should have to "produce the invoices (and accompanying representations) at the outset of the suit"); *see also, e.g.*, *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019) (similar). For example, in an analogous case—*United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016)—the defendant MA plans had hired a subcontractor to manipulate medical diagnosis records through a review process purposefully rigged to violate MA rules and unfairly seek upward adjustments to capitation payments. *Id.* at 1183. Because he had pled details of the subcontractor's fraudulent system, the relator was not required to identify patient examples or "identify specific [false] diagnosis codes[.]" *Id*. The logic of this holding applies with equal force here.

The District Court also departed from the settled rule that "even when fraud is pleaded," a motion to dismiss should be denied "unless it appears to a certainty that a plaintiff can prove no set of facts entitling him to relief." *IUE AFL-CIO Pension Fund v. Herrmann*, 9 F.3d 1049, 1052-53 (2d Cir. 1993) (citing cases; internal quotation marks omitted). Specifically, the District Court termed Plaintiffs' allegations "confused and contradictory" because "the Manager of Clinical Review is alleged to have, on the one hand, encouraged and directed inaccurate auto-approvals, and on the other, scrutinized and attempted to correct the practice," A-233 (citing A-140 (¶ 30), A-158-59 (¶¶ 108, 111)). But there is no inherent

contradiction between managers implementing a scheme while at times complaining of it. Indeed, the two Relators themselves illustrate this: They were compelled to adhere to eviCore's unlawful policies but raised their concerns with superiors and sought to reform those policies. A-167 (¶¶ 147-50), A-168 (¶¶ 154-57).

Relatedly, the District Court's erroneous conclusion that Plaintiffs had to allege that eviCore's entire bundle of services was uniformly worthless (ARGUMENT Part I.B, supra) also appears to have led it astray in applying the pleading standard. Thus, the District Court held that Plaintiffs did not sufficiently plead an FCA claim because they alleged that eviCore deployed auto-approval processes "at 'various times' for '*certain* categories'" (A-250 (emphasis added))—even though nothing in the FCA requires that Plaintiffs allege that eviCore's services were worthless at *all* times and in *every* category.

Also, the District Court acknowledged that "Rule 9(b) may be satisfied by allegations 'based on information and belief when facts are peculiarly within the opposing party's knowledge,'" A-250 (quoting *Boykin v. KeyCorp*, 521 F.3d 202, 215 (2d Cir. 2008)), but then unaccountably concluded that because Relators had alleged personal knowledge of *some* aspects of eviCore's scheme, they thus could not plead *any* fact on information and belief. A-250-51 (because "Relators allege[d] that they "possess personal knowledge and experience regarding eviCore's 'auto-approve' activities," they "d[id] not credibly allege that all specific facts regarding

the scheme were exclusively known to eviCore."). This conclusion is erroneous as it is patently inappropriate to assess the "credib[ility]" of allegations on a motion to dismiss. *See Palin v. N.Y. Times Co.*, 940 F.3d 804, 812 (2d Cir. 2019) ("Even if the plaintiff had been given notice and the court had explicitly converted the motion to one for summary judgment, we would still have to vacate because the district court's opinion relied on credibility determinations not permissible at any stage before trial.").

Separately, the District Court's apparent rationale that Plaintiffs may not allege *any* facts on information and belief because they know *some* aspects of a defendant's operations departs from settled law, which holds that a relator must "make[ ] plausible allegations … that lead to a strong inference that specific claims were indeed submitted and that information about the claims submitted are peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 86. Plaintiffs satisfied that standard here by alleging specific details of the eviCore's scheme, while alleging on information and belief facts to which they have no access, such as the particulars of eviCore's invoicing. *See* BACKGROUND Part D, *supra*; *see also United States v. Molina Healthcare of Ill., Inc.*, 10 F.4th 765, 774 (7th Cir. 2021) (rejecting argument that relator was required to allege details of contract negotiations on motion to dismiss: "how would [the relator] have had access to those documents or conversations? The obligation to set out the 'who, what, when, where,

and how' of the fraud does not require such granular detail."); *United States ex rel. Nedza v. Am. Imaging Mgmt.*, No. 15 C 6937, 2020 U.S. Dist. LEXIS 52415, at *36 (N.D. Ill. Mar. 26, 2020) ("Like specific coverage denials, it does not appear [plaintiff] had access to [defendant's] contract documents or billing materials, but nonetheless, the TAC sufficiently alleges the MA contract documents contained the certification provisions at issue and that the MA plans submitted monthly requests for capitation payments pursuant to the MA contracts.").

The District Court thus misapplied the applicable pleading standard under Fed. R. Civ. P. 9(b), which Plaintiffs amply satisfied. The District Court's dismissal of Plaintiff's FCA claims therefore warrants reversal.

III. THE COMPLAINT PLEADS THE OTHER ELEMENTS OF AN FCA CLAIM

Plaintiffs also adequately alleged the remaining elements of their FCA claims, as developed in the briefing below. But because the District Court declined to consider those elements (A-243 n.5), the appropriate course is to remand for further consideration. *See Schonfeld v. Hilliard*, 218 F3d 164, 184 (2d Cir. 2000) (when "grounds [for dismissal] were briefed by the parties below, but the district court elected not to address them. … It is our distinctly preferred practice to remand such issues for consideration by the district court in the first instance.").

CONCLUSION

For the foregoing reasons, the District Court's judgment should be reversed.

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Respectfully submitted,

/s/ David S. Stone
STONE & MAGNANINI LLP
400 Connell Drive, Suite 6200
Berkeley Heights, New Jersey 07922
(973) 218-1111

-and-

Stephen A. Weiss
Christopher Ayers
Diogenes P. Kekatos
SEEGER WEISS LLP
55 Challenger Road
Ridgefield Park, New Jersey 07660
(973) 639-9100

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Dated: July 11, 2022

Respectfully submitted,

/s/ David S. Stone
STONE & MAGNANINI LLP
400 Connell Drive, Suite 6200
Berkeley Heights, New Jersey 07922
(973) 218-1111

-and-

Stephen A. Weiss
Christopher Ayers
Diogenes P. Kekatos
SEEGER WEISS LLP
55 Challenger Road
Ridgefield Park, New Jersey 07660
(973) 639-9100