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 DEFENDANT-APPELLEE

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Appellee eviCore healthcare MSI, LLC ("eviCore"), a nongovernmental party, states that eviCore is a wholly owned subsidiary of Evernorth Health, Inc. Evernorth Health, Inc. is wholly owned by Cigna Corporation.

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STATEMENT OF ISSUES ON APPEAL

1. Did the District Court properly dismiss the Second Amended Complaint ("SAC") for Relators' failure to plead their False Claims Act counts with the particularity required under Federal Rule of Civil Procedure 9(b)?

2. Did the District Court properly dismiss the SAC for failure to plausibly plead the "worthless services" theory of falsity under the False Claims Act?

STATEMENT OF THE CASE

I. INTRODUCTION

In a 40-page, well-reasoned opinion, the District Court properly dismissed all claims in the Second Amended Complaint ("SAC" or the "Complaint") that Plaintiff-Appellants SW Challenger, LLC, Jane Doe 1 and Jane Doe 2 (together, "Appellants" or "Relators") filed against eviCore healthcare MSI, LLC ("eviCore") for the pervasive failure to meet bedrock pleading requirements. Even though Relators chose not to amend the SAC to meet their pleading burden—despite requesting and receiving leave to do so by the District Court and after the District Court identified the SAC's pervasive failures—Relators instead ask this United States Court of Appeals to overturn the District Court's thorough decision dismissing all claims against eviCore. As Relators have had ample opportunity to plead their case, eviCore respectfully requests that this Court affirm the District Court's dismissal.

EviCore[1/] is an industry leader in medical benefits management. EviCore contracts with managed care health plan clients (including Medicare Advantage plans) nationwide to provide utilization management services, including prior authorization reviews, in which eviCore reviews requests for treatments or services

[1/] For ease of review, Appellee "eviCore" capitalizes its name in this brief where its name begins a sentence.

that physicians and other providers order for their patients to determine whether the proposed medical procedures are medically necessary or otherwise covered by the health plan. Relators are eviCore "insiders": they were eviCore clinical reviewers who conducted prior authorization reviews. They allege in the SAC that eviCore violated the False Claims Act ("FCA") and sixteen analogous state laws due to eviCore's allegedly deficient prior authorization services provided to its health plan clients. Without alleging any specific contract, identifying any contract provision or health plan prior authorization rules, or providing any instances of false claims, the SAC speculates that eviCore, under its prior authorization contracts with health plans, approved too many clinical services that providers ordered for their patients.

The Department of Justice ("DOJ"), through the U.S. Attorney's Office for the Southern District of New York, investigated Relators' allegations and declined to intervene in Relators' lawsuit, as did each State for which Relators alleged analogous state law violations (the "Qui Tam States"). Relators filed the SAC (their third complaint), and eviCore moved to dismiss it. The District Court, after an exhaustive analysis of the allegations, ordered complete dismissal of all federal and state causes of action.

The District Court correctly held that the SAC fails to plausibly and particularly allege: (1) facts supporting any specific alleged fraudulent conduct,

much less any specific alleged submission of false claims sufficient to satisfy the heightened pleading requirements of Rule 9(b); and (2) that eviCore submitted false claims to health plans, or caused health plans to submit false claims by performing prior authorization services that were "worthless." The SAC does not plausibly or particularly allege any other theory of liability under the FCA, either.

There are several reasons this Court should affirm the District Court's ruling.

First, even in the limited set of circumstances where pleading "on information and belief" is allowed under Rule 9(b), Relators must plead a strong inference that false claims were actually submitted, and also establish that information about those claims is peculiarly within eviCore's knowledge. As the District Court correctly concluded, the SAC falls short of this standard. Relators' conclusory argument in their opening brief that they pleaded facts in the SAC to support a "strong inference" of false claims lacks citations to the SAC. Relators thus do not show that the allegations in the SAC met this standard. In addition, and as the District Court found, Relators' inability to point to specific facts alleged in the SAC that, if proven, would demonstrate the "who, what, when, where" of any alleged specific false claim further demonstrates that the SAC lacks plausible, specific allegations.

Second, as the District Court concluded, the SAC also fails as a matter of law to plausibly allege another element of an FCA claim—falsity. Relators base their theory of "falsity" on assertions that eviCore's prior authorization services to health plans were "worthless." But they did not allege sufficient facts to establish that eviCore's services, which utilized clinical and demographic information, were based in current medical evidence, and adhered to the directives of their health plan clients, were so deficient that they were "the equivalent of no performance at all"—the standard for finding eviCore's prior authorization services "worthless."

In fact, their allegations in the SAC, as the District Court found, are confused and contradictory. The District Court correctly found that Relators' "auto-approval" allegations in each instance were limited or qualified and thus show that eviCore *did* provide prior authorization services. This precludes Relators' claim that eviCore's prior authorization services were entirely "worthless." As a result, the SAC does not come close to plausibly alleging that eviCore's services were entirely of "no value" to a health plan, much less, a federal payor, as required by the Second Circuit. The District Court recognized this pleading deficiency and properly dismissed the SAC on this ground as well.

Finally, the District Court correctly found that to the extent the SAC alleges claims based on eviCore's alleged approvals of unnecessary medical treatments, these claims also fail. The SAC alleges no other plausible theories of FCA liability

against eviCore. Relators apparently rely in this appeal on the potential theories of liability that *could* be alleged against contractors to health plans discussed in the Statement of Interest ("SOI") that DOJ filed in the District Court. In its SOI, DOJ expressly took no position on the merits of eviCore's motion to dismiss and submitted the filing to preserve legal theories in other cases involving the Medicare Advantage program. But pointing to theories that *could* potentially be alleged in a case against a sub-contractor to a health plan that participates in Medicare Advantage is a far cry from showing that plausible, specific facts *have* been alleged here against eviCore. The opening brief does not point to sufficient allegations in the SAC to establish that Relators have met their pleading burden on any FCA theory.

In conjunction with dismissing each of Relators' claims, the District Court granted Relators leave to amend as they requested—a fact that Relators omit from their opening brief.[2/] Despite being armed with a thoroughly reasoned decision explaining Relators' pleading deficiencies, as well as the Government's SOI that Relators now recite, Relators did nothing and they never attempted to amend their SAC. Because Relators apparently cannot plead sufficient facts and allegations to

[2/] This is the second time that Relators were granted leave to amend. After the Government declined to intervene in this action and the First Amended Complaint ("FAC") was unsealed, Relators requested leave to amend the FAC, which request for leave eviCore did not oppose, and the District Court granted. (*See* A-5-6, Dkt. Nos. 10-14).

support their causes of action, they asked the District Court to enter final judgment so they could appeal to the Second Circuit. Relators now ask the Second Circuit to do what they implicitly conceded they could not: revive the deficient SAC.

The Second Circuit should affirm the District Court's well-reasoned decision, and should not resuscitate Relators' deficiently-pleaded SAC especially where Relators made no effort to address the pleading deficiencies the District Court identified.

II. BACKGROUND

Relators allege two FCA causes of action under 31 U.S.C. §§ 3729(a)(1)(A) and (B). (A-242). Under these subsections, "an entity is liable when it either 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,' or 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" (A-243) (citing *United States v. Strock*, 982 F.3d 51, 58 (2d Cir. 2020)).

As the basis for their FCA counts, Relators contend that eviCore adopted prior authorization procedures to automatically approve certain categories of providers' treatment requests rather than perform individualized medical necessity reviews for such requests as purportedly required by governing regulations and eviCore's contracts with health plans. (*See* Brief for Plaintiffs-Appellants, ECF No. 51 (hereinafter, "Appellant Br.") at 32). Relators allege that this "auto-approval

scheme[]" led to false claims being submitted when: (1) eviCore's health plan clients submitted bills to the Centers for Medicare & Medicaid Services ("CMS") for medically unnecessary treatments that eviCore approved, or (2) eviCore billed the health plan for prior authorization reviews that were never performed or were performed in a "worthless fashion." *Id.*; (A-170, ¶ 168; A-171, ¶ 175).

Although Relators broadly challenge the sufficiency of eviCore's prior authorization services, as the District Court found, the SAC's allegations regarding eviCore's "typical [prior authorization] practice are sparse." (A-225). Indeed, the SAC does *not* identify any specific instances of medically unnecessary treatments that eviCore approved or allege facts showing that eviCore performed its services in an entirely "worthless fashion." (*See* A-246).

Additionally, for the first time on this appeal, Relators now also contend that eviCore's auto-approval practices led to the submission of false claims in a third manner, based on "false data" health plans submitted to CMS for computing capitation payments to MCOs. (Appellant Br. 32). This theory is not alleged anywhere in the SAC and, in a last-ditch effort, Relators argue that the District Court should have considered this FCA theory. *See id*.

The SAC fails to plausibly or particularly allege false claims under any of these theories and the District Court correctly dismissed Relators' causes of action.

A. Regulatory Background

1. Medicare and Medicaid Programs

The federal Medicare program is administered by CMS and provides health insurance to individuals who are 65 years or older or disabled, among others. (A-147, ¶¶ 64-65). Medicare beneficiaries elect to receive Medicare benefits through traditional fee-for-service Medicare or through a private health insurer that offers coverage under the Medicare Advantage program. (*See* A-147, ¶¶ 65, 67). Health plans that offer Medicare Advantage plans (referred to by Relators as Medicare managed care organizations or "MCOs")[3/] contract with CMS to manage the care of their beneficiaries. (A-133, ¶ 2).

MCOs receive payments from CMS, as administrators of the Medicare program, and from their beneficiaries. (A-134, ¶ 4). CMS pays an MCO a fixed amount per year to cover the anticipated cost of the medical services provided to its beneficiaries. (*See id.*; *see also* A-223). The fixed payment that MCOs receive from CMS for each member is based on the health status of each member in an MCO's plan, the demographic information of those beneficiaries, and other factors. (*See* A-134, ¶ 4). Thus, under the Medicare Advantage program, the fixed capitated rate an MCO receives is based on that MCO's beneficiaries' diagnoses

[3/] Relators' use the term "MCO" for both federal Medicare Advantage Organizations (MAOs) and state Medicaid managed care plans, and in this brief, eviCore uses Relators' term.

from the prior year—not the medical services that the beneficiary actually receives throughout the current year. (*See* A-223). If the cost of a beneficiary's medical services exceeds the fixed rate that CMS pays the MCO for that beneficiary, the MCO incurs the loss. So the MCO bears the risk and cost if unnecessary medical services for its beneficiaries are approved.[4/]

The Medicaid program, a joint federal and state program, provides health care to indigent and disabled individuals. (A-149, ¶ 73). While federal law sets the parameters for operating the states' Medicaid Programs, each state implements and administers its own state specific regulations for that state's Medicaid Program. (*See* A-149-50, ¶¶ 75-80). Like with federal Medicare, private health insurers can contract with state Medicaid agencies to administer health benefits for beneficiaries under state Medicaid managed care programs. (A-150, ¶ 82).

2. Prior Authorization Services

MCOs use various methods to reduce the costs of care for their beneficiaries, including prior authorization. (*See* A-223). Prior authorization involves review of treatments or services that health care providers order for their patients, to determine whether the health plan will pay for that treatment or service. (*See* A-

[4/] *See* 63 FR 34968, 35003 (June 26, 1998) ("We will pay [MCOs] for enrollees in coordinated care plans on a capitated basis . . . Because [MCOs] offering coordinated care plans will not be paid for each additional service they provide, we believe that there is no risk of over-utilization of services.").

154-55, ¶ 88; *see also* A-223-24). Medicare Advantage does not require health plans to implement any prior authorization review and, in some instances, prohibits it.[5/] If an MCO decides to use prior authorization services, it must not limit medically necessary services.[6/] In other words, because MCOs are financially "at risk," as described above, they could have a financial incentive to limit care. The Social Security Act, as well as CMS regulations and guidance, are thus designed to prevent MCOs from inappropriately interfering with the provider-patient relationship and *denying* medically necessary services. *See, e.g.*, 42 C.F.R. § 422.566(d). This regulation does not reflect a CMS concern that MCOs or their prior authorization vendors would approve too many services that health care providers order for their patients.[7/]

[5/] For example, MCOs may not require prior authorization for emergency or urgently needed services (42 C.F.R. § 422.111(b)(5)(ii)) and plans designed as *preferred provider organizations* may not require prior authorizations for plan-covered medically necessary services provided by non-contracted providers. *See* Medicare Managed Care Manual ("MMCM"), Chapter 4, Section 110.4.

[6/] *See* MMCM, Chapter 4, Section 110.1.1 ("Plans may not implement utilization management protocols that create inappropriate barriers to needed care. Prior authorization and referral are two utilization management approaches frequently used by plans…."); *see also* 42 C.F.R. §422.752(a)(1).

[7/] For example, the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") recently published a report analyzing MCO denials of prior authorization requests and explained, "[a] central concern about the capitated payment model used in Medicare Advantage is the potential incentive for [MCOs] to deny beneficiary access to services and deny payments to providers in an attempt to increase profits." OIG, OEI-09-18-00260, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About*

B. Factual Background

EviCore[8/] contracts with health plan clients nationwide to provide utilization management services, including prior authorization reviews. (*See* A-135, ¶ 10). When MCOs decide to contract with eviCore for prior authorization services, the MCOs establish plan-specific requirements in their contracts with eviCore. (*See, e.g.*, A-158, ¶ 107; A-224). For example, health plans sometimes require eviCore to "approve, partially approve, or deny" requests within a specific time period, or direct eviCore to approve some services for certain periods of time, to ensure that patient care is not denied. (*See id*. ¶ 106; A-157, ¶ 103). But the SAC does not even identify either (1) any specific MCO contracts that governed eviCore's utilization management or prior authorization services, or (2) the terms or requirements for prior authorization review in any specific MCO contracts. (A-224).

EviCore's prior authorization process begins when a provider submits to eviCore a request for medical service or treatment that the provider ordered for their patient. (A-154-55, ¶ 88).[9/] Providers can submit a request over the phone, via

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Beneficiary Access to Medically Necessary Care (April 2022), available at https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[8/] Relators' references to eviCore's predecessor CareCore National are irrelevant. As the District Court properly concluded, the claims in this action "relate to eviCore, *not* CareCore, and stem from alleged wrongdoing during a later, distinct time period." (A-242) (emphasis in original).

[9/] In the Medicare Program, providers certify to the government that the service or treatment that they provided to the beneficiary was "medically necessary." *See, e.g.*, CMS Health Insurance Claim Form (CMS-1500), available at

fax, or online through a web portal on eviCore's website. (A-155, ¶ 89). Regardless of the method, the provider must submit certain clinical and demographic information necessary for eviCore to make an approval determination, which proceeds into eviCore's electronic decision-making system, known as its "pathways." (A-155, ¶ 89; A-165, ¶ 139). If the provider submits a request online, the provider will enter clinical and demographic information about the patient into the pathway system. (A-156, ¶ 94). If the provider submits the request over the phone or by fax, a member of eviCore's intake staff will enter the information in the same manner. (A-156, ¶ 95). EviCore's system considers clinical and demographic information when makings prior authorization decisions. (A-155, ¶ 89).

EviCore may approve prior authorization requests in one of three ways. First, eviCore may approve a case "as requested" based on a health plan's direction and business rules. (A-138, ¶ 22; A-154, ¶ 86). MCOs provide utilization review

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https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1188854. This form states that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment" and that the "services on the [claim] form were medically necessary." *Id*. Under Medicare Advantage, providers also certify that the services that they provide to MA members are medically necessary. This certification is through the provider's claims submission, in the participating provider agreement between the MCO and the provider, or both. *See* 42 C.F.R. §§ 424.30, 424.32; *see also* 42 C.F.R. § 422.500(b) (defining "Clean claim" as a claim that conforms with the requirements for claims under original Medicare).

criteria and rules to eviCore that are used to evaluate prior authorization requests for their beneficiaries. (A-154, ¶ 86). Although health plan directives were sometimes called "auto-approvals," they are more accurately described as requests that eviCore approves at the direction of, or "as requested" by the health plan. (*See, e.g.*, A-138, ¶ 22; A-162, ¶¶ 125-26).

Second, eviCore may approve providers' requests based on the clinical and demographic information submitted by the provider into eviCore's decision-making logic, or pathway. (*See generally* A-155). The clinical pathway used by eviCore for specialized therapy cases is known as CorePath. (A-155, ¶ 90). CorePath is not an "automatic" approval or artificial intelligence; rather the CorePath pathway functions like a flow chart, asking the provider condition-specific clinical questions to obtain information to evaluate whether a recommended service should be approved. (A-155, ¶¶ 89-90; A-156, ¶¶ 94-95). If the information submitted meets the criteria for approval, the CorePath system will provide a real-time approval decision to the provider who may treat the patient immediately. Thus, this process is not "automatic," it is focused on a logic-based review of the information submitted by the treating provider. (*See* A-155, ¶¶ 89-90; A-156, ¶ 94).

Third, if eviCore does not approve the case through its electronic pathways, the request is routed to an eviCore clinical reviewer (such as a physical or

occupational therapist) who will review the clinical information provided to eviCore and can request more information about the requested service from the provider. (A-156, ¶ 96). Based on the clinical information provided and health plan requirements, eviCore's clinical reviewers can approve the services requested. (A-154, ¶ 86). Only a physician reviewer, or other licensed medical professional, may *deny* services, per state and CMS regulations.[10/] If eviCore denies a prior authorization request, the provider and patient are notified that the health plan will not pay for the provider's recommended services, and barring a successful appeal of eviCore's denial, the patient either will not receive the requested care, or must pay for the services herself. (*See* A-137, ¶ 18).

C. Procedural History

Relators have filed three complaints. They filed their initial complaint, under seal, on or about March 20, 2019. (A-5, Dkt. No. 1; A-11). They then filed a First Amended Complaint on May 21, 2020. (A-5, Dkt. No. 2; A-91). Following an investigation while the complaints were under seal, DOJ notified the District Court that neither DOJ nor the Qui Tam States intended to intervene in this FCA action. (A-212-13). The District Court then unsealed the case on June 10, 2020. (A-122). Relators moved to amend again, eviCore did not oppose, and once granted, Relators filed the SAC on September 23, 2020. (A-6, Dkt. No. 15; A-129).

[10/] *See* 42 C.F.R. § 422.566(d).

On November 23, 2020, eviCore moved to dismiss the SAC arguing, among other things, that the SAC fails to allege plausible, particularized allegations as required by Rules 8(a) and 9(b) in FCA actions. (A-7, Dkt. No. 21). Relators opposed the motion to dismiss and sought leave to amend the SAC if the District Court granted dismissal. (A-8, Dkt. No. 31).

On March 1, 2021, DOJ filed its SOI related to eviCore's motion to dismiss. (A-8, Dkt. No. 39). In the SOI, the Government took no position on the sufficiency of Relators' allegations or eviCore's motion to dismiss. (*See* Appellant Br. 24 (citing SOI at 2)). Rather, the SOI sought to protect DOJ's view of allegations that "*could* give rise" to false claims within the Medicare Advantage program to preserve its enforcement interests. (*See* Appellant Br. 24 (quoting SOI at 7-8) (emphasis in original)); (A-239).

On August 13, 2021, the District Court issued a Decision and Order granting eviCore's motion to dismiss the SAC. (A-259). The District Court dismissed the SAC on two grounds: (1) Relators failed to "plead their claims with sufficient particularity to satisfy Rule 9(b)," and (2) Relators "failed to adequately plead falsity" as required under the FCA. (A-242-43). As one basis for finding the lack of particularity, the court found that Relators' allegations were "confused and contradictory" and "fall short of alleging a 'detailed scheme' from which fraudulent claims can be 'easily' inferred." (A-249-50). The court also found the

SAC "falsity" allegations failed, finding "that falsity has not been alleged here because the services eviCore provided were not so 'worthless' that they were 'the equivalent of no performance at all.'" (A-245).

About six months after the District Court's Order, and Relators having not further prosecuted their case, the court requested a status update from the parties. (A-9, Dkt. No. 45). Relators told the court that they would not amend the SAC; instead they asked the court to enter final judgment so they could appeal the dismissal order. (A-260). The court then entered final judgment for eviCore on February 10, 2022. (A-262). On March 14, 2022, Relators filed a Notice of Appeal. (A-263).

Relators only appeal the District Court's decision relating to their FCA causes of action (Counts I and II). (*See* Appellant Br. 2). Relators do not appeal the District Court's dismissal of the remaining twenty counts against eviCore in the SAC, including alleged violations of the reverse false claims section of the FCA (Count III), conspiracy to violate the FCA (Count IV), violations of analogous state false claims statutes (Counts V-XX)[11/] and retaliation against Jane Doe 1 and Jane Doe 2 (Counts XXI- XXII). *See id.*

[11/] The District Court dismissed the state law counts because it declined to exercise supplemental jurisdiction over the state-law claims. (A-256-57).

SUMMARY OF THE ARGUMENT

This Court should affirm the District Court's well-reasoned dismissal of Appellants' claims against eviCore in their entirety for at least three reasons.

First, the SAC fails to allege fraud with particularity. (A-242). The District Court properly dismissed Relators' FCA counts for failure to plead fraud with particularity as required by Rule 9(b). (A-242-43). Indeed, the District Court correctly concluded that the SAC does not identify "a single request for payment for prior authorization services" nor "who made such requests, when, or where" sufficient to meet the "heightened pleading standard of Fed R. Civ. P. 9(b)." (A-248). The District Court also correctly refused to allow Relators to plead on "information and belief" to satisfy Rule 9(b) because Relators' "confused and contradictory" allegations do not "detail specific and plausible facts from which systematic falsification can be easily inferred." (A-249) (internal quotations omitted).

Nor did Relators establish that information regarding the specific purported claims were "*only* within [eviCore's] knowledge." (A-250-51) (emphasis in original); *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 97 (2d Cir. 2017) (stating relator may allege the submission of false claims on information and belief only where relator (1) "make[s] allegations that lead to a strong inference that specific claims were indeed submitted," and (2) "plead[s] that

the particulars of those claims were peculiarly within the opposing party's knowledge."). Relators made no attempt to cure their pleading deficiencies or allege additional, detailed facts to meet Rule 9(b)'s requirements.

Second, the SAC fails to plausibly allege that eviCore performed worthless services for the MCOs that caused false claims to be submitted to MCOs or CMS. The District Court properly applied the Second Circuit's standard for "worthless services" under *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). The District Court correctly found that the SAC fails to allege that eviCore's prior authorization services were of no value to the MCOs or CMS under this standard. (A-245-47) (finding that "falsity has not been alleged here because the services eviCore provided were not so 'worthless' that they were 'the equivalent of no performance at all'"). Even accepting Relators' allegations as true, the District Court found that insofar as the SAC challenged the sufficiency of eviCore's services, the SAC failed to allege that its prior authorization services were worthless to the MCOs or a federal payor. (A-246).

Third, the SAC does not plausibly allege any other theory of liability against eviCore under the FCA. The District Court correctly concluded that to the extent Relators' claims are premised on approvals of medically unnecessary treatments, these claims "fare no better." (A-248). And Relators' attempt now on appeal to use

the Government's SOI to rewrite the factual allegations and theories in their deficient SAC fails.

STANDARD OF REVIEW

The Second Circuit "review[s] *de novo* a district court's grant of a motion to dismiss a *qui tam* action." *Vierczhalek v. Medimmune Inc.*, 803 F. App'x 522, 525 (2d Cir. 2020) (summary order). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotations omitted). This Court need not accept legal conclusions as true. *Id*.

Complaints alleging violations of fraud under the FCA, as here, must also comply with the heightened pleading requirements of Rule 9(b), which require that fraud be pleaded with particularity—a higher standard than is required for other types of claims. *See United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 247 (2d Cir. 2019) (summary order); *United States ex rel. Takemoto v. Nationwide Mut. Ins. Co.*, 674 F. App'x 92, 95 n.1 (2d Cir. 2017) (summary order) ("This court has generally held FCA claims to the higher pleading standard of Rule 9(b), which requires that plaintiffs state with particularity the specific statements or conduct giving rise to the fraud claim.") (internal quotations omitted).

ARGUMENT

I. THE COMPLAINT DOES NOT ALLEGE FRAUD WITH PARTICULARITY.

A. The District Court Properly Dismissed Relators' False Claims Act Counts for Failure to Plead Fraud with Particularity as Required by Rule 9(b).

The SAC fails to satisfy Rule 9(b), and this Court can affirm the District Court's dismissal on this basis alone. *Qui tam* complaints filed under the FCA must satisfy Rule 9(b). *See, e.g.*, *Chorches*, 865 F.3d at 83. Rule 9(b) is "rigorously enforced" in the Second Circuit. *Gelbman*, 790 F. App'x at 247 (summary order). To satisfy this particularity standard an FCA complaint must identify the false or fraudulent statement, who made it, when and where the statement was made, and why the statement was fraudulent. *Id*. For causes of action pleaded on personal knowledge, the complaint must allege specific false claims that were submitted (for example, by identifying the invoice or billing submissions alleged to be false), when the purportedly false records were presented, and the individuals involved in the billing. *See id*.; *see also Wood ex rel. United States v. Applied Research Assocs.*, 328 F. App'x 744, 750 (2d Cir. 2009) (summary order). The District Court correctly found that the SAC fails to meet this demanding standard. (A-247-48).

There is a limited exception to this general rule. The Second Circuit permits a relator to allege the submission of false claims based on information and belief, but only in the limited circumstances where the relator: (1) "make[s] allegations

that lead to a strong inference that specific claims were indeed submitted;" *and* (2) "also plead[s] that the particulars of those claims were peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 86. Allowing a relator to base allegations on information and belief "must not be mistaken for license to base claims of fraud on speculation and conclusory allegations." *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990). Rather, these stringent requirements ensure that "those who *can* identify examples of actual claims *must* do so at the pleading stage." *Chorches*, 865 F.3d at 86 (emphasis in original). As the District Court found, the SAC also fails to meet this limited exception.

1. The SAC Fails to Allege with Particularity that eviCore Submitted or Caused MCOs to Submit False Claims.

As the District Court recognized, the SAC does not allege particular facts showing any specific submission of purportedly false claims sufficient to satisfy Rule 9(b). (*See* A-247-48). Relators apparently concede this point and focus their argument on appeal on the limited exception to Rule 9(b) in which Relators may plead on information and belief.[12/] (*See* Appellant Br. at Section II). This is unsurprising because the District Court was right: "the SAC does not identify *any* records of requests for payment from eviCore to any MCOs for utilization management or prior authorization services." (A-247-48) (emphasis in original).

[12/] EviCore addresses this argument in Section I.A.2, below.

The SAC alleges that eviCore submitted false claims or made false statements to MCOs and caused MCOs to submit false claims to CMS for prior authorization services that "eviCore either never rendered, or performed in a worthless fashion." (A-171, ¶175; *see also* A-170, ¶170). Yet the SAC never identifies a single eviCore invoice sent to a specific MCO client for prior authorization services, let alone an invoice for services that violated eviCore's unidentified contracts with an MCO or violated any unspecified MCO rules regarding prior authorizations. (*See* A-248). There is also not a single allegation concerning who submitted the invoices, when they were submitted, or what payment any MCO made to eviCore or sought from CMS for prior authorization reviews. *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704 (ERK), 2009 U.S. Dist. LEXIS 43438, at *11 (E.D.N.Y. May 22, 2009) (Rule 9(b) "requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud."); *Applied Research Assocs.*, 328 F. App'x at 750 (summary order) (affirming dismissal where complaint did not allege a single false "record or billing submission" or "when a purportedly false claim was presented for payment by a particular defendant at a specific time"). The District Court recognized these pleading deficiencies concluding, "Relators have not identified a single request for payment for prior authorization services, nor have Relators identified who made such requests, when, or where." (A-248).

To the extent that Relators allege that eviCore's prior authorization approvals caused the submission of false claims where MCO's "bill[ed] for medically unnecessary treatments authorized by eviCore," Relators' conclusory allegations fare no better. (Appellant Br. 47; A-248). Relators do not identify a single medical treatment or service that eviCore approved but should have denied, a single bill to an MCO (or from an MCO to CMS) for such treatment or service, who submitted the claim, when it was submitted, or what payment was sought from an MCO or CMS. (A-248) ("Relators do not identify any approvals, much less do they allege who approved the unnecessary services, where, or when."). As the District Court found, the lack of any specific allegation that eviCore submitted *any* false or fraudulent claims is fatal to Relators' FCA claims under Rule 9(b)'s heightened pleading standard. (A-247).

2. The SAC Also Fails to Meet Either Prong of the Limited Exception under *Chorches* to Satisfy Rule 9(b).

Unable to point to specific allegations identifying the actual submission of false claims, Relators contend they are "not required to point to specific invoices" because they alleged "a scheme that *inevitably* led to many false claims being submitted." (Appellant Br. 47) (emphasis in original). Under the standard the Second Circuit articulated in *Chorches*, a complaint may satisfy Rule 9(b)'s particularity requirement by making plausible allegations: (1) "creating a strong

inference that specific false claims were submitted to the government;" and (2) "that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 86.

On the first prong of the analysis, the District Court was right: the SAC fails to make "plausible allegations creating a strong inference that specific false claims were submitted." (A-249); *Chorches*, 865 F.3d at 86. As the District Court correctly concluded, "Relators here do not provide allegations that 'detail specific and plausible facts' from which systematic falsification can be 'easily' inferred." (A-249). Relators' allegations about eviCore's typical prior authorization practices are "sparse" and the facts Relators do allege "are confused and contradictory." (A-225; A-249). Put simply, the District Court found that Relators' conclusory allegations that eviCore's prior authorization processes were fraudulent, failed as a matter of law. (*See* A-249).

As the District Court explained, whether a procedure is approved and thus covered by a health plan is dependent on that "particular MCO's internal rules." (A-224). Nowhere in the SAC do Relators identify either "any specific MCO contracts at issue here that governed eviCore's utilization management or prior authorization services," or any specific rule that eviCore allegedly violated when approving some unknown treatment request. (A-224).

In fact, the SAC cannot establish any systematic "auto-approval" practice in which treatment requests were indiscriminately approved, because Relators' allegations show the opposite: eviCore's software requires providers to submit "demographic and clinical information" about their patient before the system makes an approval determination and, at least in many cases, eviCore's pathways were developed based on "current medical evidence, literature, and guidelines." (A-249-50) (citing SAC ¶¶ 89, 142). Moreover, Relators' allegations that at "various times" for "certain categories" of requests "in specific jurisdictions, for specific populations, and/or under specific healthcare plans" were automatically approved (A-138, ¶¶ 22-23) does not establish a scheme that "inevitably" led to false claims being submitted. (*See* Appellant Br. 47; A-250). As the District Court found, "[a]t best" these allegations establish "a discrete and haphazard set of auto-approval processes," and the allegations fall short of the *Chorches* standard. (A-250).

Even if Relators could plausibly allege that eviCore's prior authorization procedures were deficient—which they cannot—their allegations are far from the detailed scheme alleged in *Chorches*, and fail to create a strong inference that specific false claims were actually submitted to CMS in this case. (*See* A-249). In *Chorches*, relator Fabula alleged details about the specific ambulance runs that he was instructed to falsify, including the patient name, address, and reason for the

ambulance call such that defendants were on notice of the specific claims at issue. *Chorches*, 865 F.3d at 84. He also specifically alleged that he was "directed, under threat of being put on unpaid leave, to change and falsely certify" specific electronic records for reimbursement and that he "did as he was ordered." *Id*. The allegations in *Chorches* further led to a reasonable inference that alleged false claims were actually submitted to the Government because relator Fabula, directly alleged statements by his supervisors' that the falsified records were intended to be submitted to the Government. *See id*. at 85.

Relators here provide no such detail. Relators do not cite a single allegation in the SAC to support their conclusory argument that the SAC "disclosed extensive information about the auto-approval practices at issue so as to place eviCore on full notice of the claims alleged." (Appellant Br. 47). Nowhere in the SAC do Relators allege a specific treatment or service that eviCore approved but should have denied, or explain why the requested treatment or service was not medically necessary.[13/] Unlike the detailed allegations in *Chorches*, Relators do not identify any patient or provider name, address, or treatment ordered for a patient, or

[13/] The only specific prior authorization request alleged in the entire SAC is a reference to an email stating that an eviCore clinical reviewer had to approve 200 physical therapy visits for an ankle sprain. (A-159, ¶ 111). Relators do not allege that this treatment was medically unnecessary for that specific patient and do not contend that eviCore violated any MCO contractual provision or rule provided to eviCore.

whether such member was covered by Medicare Advantage or Medicaid. *See Chorches*, 865 F.3d at 84. Although the SAC does allege that eviCore "directed" Relators to "auto-approve" or "approve as requested" certain categories of services (A-138, ¶ 22), the SAC never identifies a specific instance where Relators believed a request was medically unnecessary and approved it anyway, nor that the requested service was for a patient covered by a Government-sponsored health plan. *See Chorches*, 865 F.3d at 85. The SAC provides no basis to infer that any treatment request approved through eviCore's prior authorization process should have been denied, or that eviCore authorized unnecessary treatment for Medicare Advantage or Medicaid members. Thus the District Court properly found that the SAC lacked specific facts to support a strong inference of fraud. (A-250); *see also Gelbman*, 790 F. App'x at 248 (summary order) (affirming dismissal where complaint failed to "adduce specific facts supporting a strong inference of fraud" because relators never alleged how defendant's computer system was allegedly rigged or who carried out the rigging, and the court was "left to speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government").

Even if the SAC "adduce[d] specific facts supporting a strong inference of fraud"—which it does not—Relators would fail to satisfy the second prong of *Chorches*, in any event. *See* 865 F.3d at 82. Relators cannot establish this prong

either, because the relevant information about the alleged false claims was not solely within eviCore's knowledge. (A-250); *Chorches*, 865 F.3d at 86 (requiring under the second prong, Relators plead that the particulars of the alleged claims were "peculiarly within the opposing party's knowledge"). This exception does not apply when, as here, "relators are 'insiders' with access to the information on which their claims are based": there is no excuse for pleading on "information and belief" when Relators could have accessed the information at issue. *See United States ex rel. NPT Assocs. v. Lab. Corp. of Am. Holdings*, No. 1:07-cv-05696, 2015 U.S. Dist. LEXIS 155601, at *21 (S.D.N.Y. Nov. 17, 2015). Relators were clinical reviewers who conducted prior authorization reviews—the very review function at issue.

Relators argue on appeal that "the details of those claims (e.g., the invoices and eviCore's contracts with MCOs offering MA plans) are 'peculiarly within eviCore's knowledge.'" (Appellant Br. 45). But, as the District Court recognized, the SAC belies this argument. (A-250-51). Indeed, the SAC shows that Relators were both eviCore employees and clinical reviewers with "personal knowledge and experience" regarding eviCore's alleged auto-approval activities, including "personal contact" with employees and executives involved with and directing its prior authorization procedures as well as other clinical reviewers working at eviCore. (A-251; A-142-43, ¶¶ 43, 44; *see also* A-138, ¶ 24). Despite alleging that

as clinical reviewers, Relators' "primary job responsibilities include[d] reviewing physical therapy and occupation therapy treatment requests" and that eviCore directed its "clinical reviewers" to "auto-approve" or "approve as requested" the services in question in this case, the SAC lacks a single example of a treatment request that Relators were directed to improperly "auto-approve" or "approve as requested." (*See, e.g.*, A-143, ¶ 44; A-138, ¶ 22). The District Court was correct and Relators cannot credibly allege that they lack access to the relevant facts and details that might support their claims. (A-251) (finding "Relators do not credibly allege that all specific facts regarding the scheme were exclusively known to eviCore").

Indeed, the SAC alleges that Relators *did have* access to eviCore's review criteria and rules: "eviCore's [c]linical [r]eviewers are trained in the use of utilization review criteria and rules provided to eviCore by MCOs." (A-154, ¶ 86). It is implausible that Relators, two clinical reviewers tasked with both following rules established by the MCOs and with developing and improving review guidelines for prior authorization determinations, would not have access to the specific facts they would need to allege regarding their claims. (*See, e.g.*, A-165, ¶¶ 139-140). In addition, Relators assert that Jane Doe 1 "was assigned to health plans that were 'auto-approvals'" and in her role was involved in "updating and developing pediatric guidelines." *Id*. The SAC does not allege that clinical

reviewers, like Relators, were restricted from or otherwise prohibited from reviewing eviCore policies, or health plan contracts or rules, or why such access would have been restricted. Similarly, the SAC fails to allege that Relators had no access to relevant eviCore bills submitted to the MCOs. As a result, the limited exception to Rule 9(b)'s stringent requirements is inapplicable here.

For this second prong of the *Chorches* standard, Relators' lack of allegations are in sharp contrast to the detailed allegations in *Chorches*. There, the Second Circuit held that relator Fabula sufficiently established that he did not have access to specific false claims. *See Chorches*, 865 F.3d at 82. The complaint in *Chorches* specifically alleged that the relator and other EMTs and paramedics "were prohibited from making unauthorized entrances into the administrative building of [defendant] in New Haven where all the billing was taking place" and that they "were restricted to the 'garage' and the 'window' where they punched in and punched out each day," such that any "information about [defendant's] submissions to Medicare . . . [was] not accessible by any paramedics or EMTs such as [relator]." *Id.*

By contrast, the SAC here lacks any similar allegations and cannot establish that eviCore exclusively had knowledge about the details regarding the contracts and invoices on which the SAC is based or that Relators could not access that information. *Id.*; *see also Gelbman*, 790 F. App'x at 248 (summary order)

(concluding relator failed to establish relevant bills were "peculiarly within [defendants'] knowledge" where relator was an "Information Specialist working on Medicaid reimbursement" at the state agency "responsible for submitting Medicaid claims to the federal government"); *United States ex rel. O'Toole v. Cmty. Living Corp.*, 2020 U.S. Dist. LEXIS 85443, at *27 (S.D.N.Y. May 14, 2020) (explaining where relator's own allegations show she had access to corporate records and relevant documents during employment, conclusory allegations "without substantiation" that facts were peculiarly within opposing party's knowledge are insufficient). For these reasons, the District Court properly found that Relators did not establish that "all specific facts regarding the scheme were exclusively known to eviCore," and this Court should affirm the District Court's dismissal. (*See* A-250-51).

B. Relators Made No Attempt to Cure Their Pleading Deficiencies or Meet the Requirements of Rule 9(b) Following Dismissal.

Relators fail to mention in their brief that, in opposing eviCore's motion to dismiss, they asked the District Court for leave to further amend the SAC because "Relators have not yet had the benefit of an opinion from the Court applying the law to the facts alleged and setting forth factual deficiencies that must be addressed in order for Relators' complaint to be viable." (Relators' Opposition to Defendant's Motion to Dismiss, 19-cv-2501-VM, A-8, Dkt. No. 31, at 24; *see also*

A-259). In its lengthy Order detailing the SAC's pleading deficiencies, the District Court granted this request. (A-259) (stating that "[n]ow that Relators are apprised of their pleading failures, the Court grants leave to further amend the SAC."). Relators, however, never amended their complaint to attempt to correct the pleading deficiencies the District Court set forth. (*See* A-9 at Dkt. Nos. 44 & 45). Instead, they did nothing for *six months*. *Id*.

Finally, when the District Court requested a status update from the parties, Relators told the court that they would not file another amended complaint. (A-9, at Dkt. Nos. 45 & 46). Relators asked the court to enter final judgment to permit Relators to appeal its dismissal order. (A-260) (Order stating, "[t]he Court granted leave for the Relators to further amend the SAC…Relators notified the Court they do not intend to replead and request final judgment be entered…"). Relators' failure to replead suggests that they do not have additional facts sufficient to establish the requirements of Rule 9(b) and that further amendment would be futile.

Fraud is a serious allegation, and Rule 9(b) provides meaningful protection against meritless claims of fraud. *See, e.g.*, *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 169 (2d Cir. 2018) (describing purpose of Rule 9(b) "to protect defendants in fraud cases from 'frivolous accusations'"); *United States ex rel. Corp. Compliance Assocs. v. Hosp. for Special Surgery*, 2014 U.S. Dist. LEXIS

109786, at *50 (S.D.N.Y. Aug. 7, 2014) (quoting *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004) (Rule 9(b) "serves to 'provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit.'")). This Court should affirm the District Court's dismissal because Relators apparently are unable to replead in a manner sufficient to address the SAC's shortcomings and satisfy Rule 9(b)'s heightened pleading standard.

II. THE COMPLAINT FAILS TO ALLEGE THAT EVICORE SUBMITTED, OR CAUSED MCOS TO SUBMIT, FALSE CLAIMS BY PERFORMING WORTHLESS SERVICES.

A. The District Court Properly Applied the Second Circuit's Standard for "Worthless Services" under *Mikes*.

Not only does the SAC fail to plausibly and particularly allege the actual submission of any alleged false claims to an MCO (or by an MCO to CMS), the SAC also fails to allege a basis for the falsity of any claims.[14/] There are generally two types of false claims under the FCA: (1) legally false claims (involving a false representation of compliance with a federal statute, regulation or prescribed contractual term); and (2) factually false claims (involving an incorrect description of goods or services provided or a request for reimbursement for good or services

[14/] "[F]raud under the FCA has two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." *Chorches*, 865 F.3d at 83 (quoting *United States ex rel. Hagerty v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016)).

never provided at all). *See, e.g.*, *United States ex rel. Gelbman v. City of New York*, No. 14-CV-771, 2018 U.S. Dist. LEXIS 169435, at *13 (S.D.N.Y. Sep. 30, 2018) (citing *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 696-97 (2d Cir. 2001), *abrogated on other grounds by Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176 (2016)); (A-244).

A "worthless services" claim is derivative of a factually false claim—where services were not provided—because it seeks reimbursement for services that were so deficient that it was as if the services were not provided at all. *Mikes*, 274 F.3d at 703; *see also Chesbrough v. VPA. P.C.*, 655 F.3d 461 (6th Cir. 2011) ("If [defendant] 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."). As explained by the Second Circuit, "a worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the [FCA] irrespective of any certification." *Mikes*, 274 F.3d at 702.

Despite Relators' contention that the District Court "collapsed" Relators' FCA claims into a "judicially created category of 'worthless services,'" (Appellant Br. 33, 39)[15/], a worthless services theory is *precisely what Relators alleged in the*

[15/] Relators' brief does not explain where in the District Court's decision or how the District Court allegedly "improperly collapsed Plaintiffs' allegations into the judicially created category of a 'worthless services' claim." (Appellant Br. 33).

SAC. Relators repeatedly contend throughout the SAC that eviCore's prior authorization services were worthless. (*See, e.g.*, A-164, ¶ 131) ("As a result of eviCore's scheme, CMS and the Qui Tam States paid MCOs and their subcontractor, eviCore, millions of dollars to perform prior authorization reviews which either never happened or were undertaken in a sub-standard, worthless fashion."). And the SAC expressly alleges that the false claims counts are based on eviCore's "worthless prior authorization services." (*See* A-170, ¶ 170) (alleging in Count I, eviCore submitted false claims to MCOs "for worthless prior authorization services"); (A-171, ¶ 175) (alleging in Count II, MCOs submitted false claims to CMS for "prior authorization services that eviCore either never rendered, or performed in a worthless fashion").

The District Court properly assessed Relators' worthless services allegations under *Mikes*, which is binding precedent in this Circuit on the worthless services standard. The *Mikes* doctrine is long-standing and straightforward: services are "worthless" where "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 (emphasis added). Challenges to the "quality" of the services or allegations that services "did not conform" with certain rules or requirements is not the equivalent of no performance at all and are not worthless services. *United States v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710 (NAM/DEP), 2011 U.S. Dist. LEXIS

4862, at *62 (N.D.N.Y. Jan. 19, 2011); *see also Mikes*, 274 F.3d at 703. The SAC does not make plausible, specific allegations that eviCore's prior authorization services under its contracts with MCOs were so deficient that eviCore failed to provide *any* services or that they were the equivalent of no performance at all. (*See* A-246).

As a result, and as the District Court correctly found, Relators did not meet the demanding standard to allege worthless services. *Id*. In reaching this conclusion, the District Court pointed to various allegations in the SAC that contradict Relators' conclusory allegations that eviCore's services were worthless; Relators' own allegations show that eviCore's prior authorization services could not possibly be "worthless," and thus equivalent to no performance at all. In fact, Relators allege that eviCore's

- automation software and electronic pathways, like CorePath, require "demographic and clinical information" and were developed by knowledgeable clinical reviewers using medical evidence (A-249-50) (citing SAC ¶ 89, 142);
- "approve as requested" protocols in 2018 are "admittedly limited to only 'the first three requests,'" and not to additional requests (A-245) (citing SAC ¶ 26);
- instructions to clinical reviewers about approvals were limited to "*certain providers, therapies, and populations*," not all requests (A-246) (emphasis in original) (citing SAC ¶ 99); and
- approvals for the specific plan Blue Cross Blue Shield of Texas were limited to "*pediatric* treatment requests" due to "provider noise." (A-246) (emphasis in original) (citing SAC ¶ 102).

Relators here fail to plausibly allege as to any MCO contract, much less all MCO contracts, that *all* prior authorization services performed by eviCore were "worthless." In fact, the SAC would have to allege that eviCore improperly "auto-approved" all claims that should have been denied under the terms of a contract with an MCO, yet does not even identify a single example of an "auto-approved" prior authorization request that should have been denied because it was medically unnecessary. And in any event, as the District Court recognized, eviCore's automated review processes are based on patient-specific information, and the treating provider must submit "demographic and clinical information" before an approval notice will be provided to the beneficiary and her provider. (*See* A-249-50). Indeed, as the SAC alleges, knowledgeable clinical reviewers developed the criteria within the software—which determines when a treatment can be approved—"based on current medical evidence, literature, and guidelines." (A-250). Such services that use clinical information and that were developed using medical evidence, literature, and guidelines cannot be "the equivalent of no performance at all" and are not "worthless." (*See id*.; A-246).

B. The District Court Properly Held that a Worthless Services Claim Must Allege eviCore's Prior Authorization Services Were of No Value to the MCOs.

Relators' misleading contention that eviCore argued and the District Court applied a so-called "bundle theory" of worthless services should be rejected. (*See*

Appellant Br. 40). Relators neither cite any briefing where eviCore made a bundling argument nor point to any portion of the District Court's Order where the District Court purportedly applied a "bundle theory" to dismiss the SAC. *See id*. There is also no allegation in the SAC that eviCore provided "a bundle" of services to MCOs.[16/] Relators' bundling argument also fails to address the clear standard under *Mikes*: an alleged service or treatment is "worthless" *only* if the service has no value to the federal payor but the provider of the service seeks payment for the service. *See, e.g., Mikes,* 274 F.3d at 702. Relators would have to plausibly allege—which they have not done—that eviCore provided no value with respect to all services delivered under a specific contract, or at least a specific invoice under a specific contract. *See id*. It is not enough for Relators to allege that eviCore "provided services that were worth some amount less than the services paid for." *See United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d

[16/] In referring to "bundling" Relators may be referencing FCA cases alleging worthless services claims in nursing home facilities where multiple services, such as "feeding, turning, or bathing" are provided to patients on a flat "room and board" rate. Even in that context, courts have rejected worthless services claims which challenge the level or amount of some, but not all, of multiple services provided. *See United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002). Courts have held in those cases that such allegations do not establish that "for all practical purposes, the patients were receiving no room and board services or routine care *at all*" and do "not fit within the worthless services category." *See, e.g., id.* (emphasis added). In any event, the SAC makes no allegation that eviCore provided to MCOs multiple "bundled" services, so Relators' argument is misplaced.

699, 710 (7th Cir. 2014) (applying *Mikes*, explaining a "diminished value" of services theory does not satisfy a worthless services claim because "[s]ervices that are 'worth less' are not 'worthless'").

The District Court correctly analyzed the value of eviCore's prior authorization services provided to the MCOs. (*See* A-246). Relators allege only that eviCore, which provides prior authorization services to millions of beneficiaries across health plans nationwide, performed "auto-approvals" on a discrete subset of prior authorization reviews, related to certain providers, treating certain populations, during certain periods of time. *See id.* As the District Court explained, these discrete allegations do not establish that eviCore performed no services at all for MCOs, or that eviCore's prior authorization services were worthless from the perspective of a federal payor. *See id.* Even if eviCore's approval processes were not "entirely satisfactory or appropriate" in Relators' view, "[i]nsofar as eviCore provided *some* legitimate prior authorization and utilization managements services, those services were not 'the equivalent of no performance at all.'" *Id*. (emphasis in original).

Relators also mischaracterize the cases on which they rely. In any event, these cases do not support their argument. For example, Relators cite *Chesbrough v. VPA. P.C.*, 655 F.3d 461 (6th Cir. 2011), but this case contradicts their argument; the Sixth Circuit affirmed dismissal for defendants, just as the Second

Circuit should do here. (*See* Appellant Br. 41-42). In that case, relators (the Chesbroughs), alleged that certain "nondiagnostic" (i.e., unreadable) radiology tests were of such bad quality a diagnosis could not be interpreted, such that they were worthless and thus "false." *See Chesbrough*, 655 F.3d at 468. While the Sixth Circuit agreed theoretically that the five x-ray studies that were nondiagnostic *could* constitute "worthless services" if such tests had no medical value, this conclusion is consistent with the District Court's proper application of *Mikes*. *See Chesbrough*, 655 F.3d at 468. Relators simply did not allege that eviCore's services had no value to MCOs or CMS.

Unlike the five individual claims for nondiagnostic tests in *Chesbrough* where each had no medical value and thus would have been entirely "worthless," here, as the District Court found, Relators cannot allege that claims for payment by eviCore to its MCO clients—the invoices or requests for payment from eviCore to an MCO—for prior authorization services were worthless to those MCOs. (A-245-46); *see also Chesbrough*, 655 F.3d at 468; *United States ex rel. Kolchinsky v. Moody's Corp.*, No. 12cv1399, 2018 U.S. Dist. LEXIS 41117, at *14 (S.D.N.Y. Mar. 13, 2018) (concluding relator failed to demonstrate defendant's ratings service was worthless where he acknowledges only some of defendant's ratings were erroneous).

Moreover, that court affirmed dismissal in its entirety for defendants and found that the Chesbroughs failed to establish that any alleged "nondiagnostic" tests were actually submitted to the government for payment. *Chesbrough*, 655 F.3d at 472. The Court should also affirm dismissal here.[17/]

The Eleventh Circuit decision that Relators cite is also inapplicable. In *United States v. Houser*, 754 F.3d 1335 (11th Cir. 2014), a criminal case under the health care fraud statute (not the FCA), the Eleventh Circuit concluded that defendant's conviction based on the "worthless services concept" rested on the fact that defendant submitted claims for services that "had not been rendered" to patients "*at all*." *Houser*, 754 F.3d at 1343, 1347 (emphasis in original). As

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[17/] Similarly here, as described in Section I, *supra*, this Court can affirm dismissal based on Relators' failure to allege the submission of false claims with particularity under Rule 9(b) alone. As the Sixth Circuit explained:

> "The mere existence of a few allegedly 'nondiagnostic' tests does not support a strong inference that claims for those tests were submitted to the government. Assuming that the five tests alleged by the [relators] to be nondiagnostic constituted 'worthless services,' it is not necessarily true that [defendant] billed the government for these tests. To conclude that a claim was presented requires a series of assumptions. First, one must assume that the tests were performed on Medicare or Medicaid patients, and could therefore have been billed to the government. . . . One must then assume that [defendant] submitted bills for useless tests. . . [relators] argue that [defendant], as a for-profit company, must have billed for the services it performed. But [defendant] might have absorbed the expense of the five nondiagnostic tests itself."

Chesbrough, 655 F.3d at 472.

explained above, Relators cannot allege that eviCore provided no prior authorization services "at all" under a contract with an MCO. *See id.*

Moreover, the Eleventh Circuit's analysis is instructive where the court contrasted the facts of *Houser* with an FCA case, *United States ex rel. Swan v. Covenant Care*, 279 F. Supp. 2d 1212 (E.D. Cal. 2002). In *Swan*, the court, applying *Mikes*, rejected a worthless services claim where defendant billed all of its routine nursing services at a single per diem rate. *Swan*, 279 F. Supp. 2d at 1221 ("[Defendant] does not bill the government separately for individual acts of patient care such as feeding, turning, or bathing."). Despite allegations challenging the level of care and amount of services provided to defendant Covenant Care's patients, that court held that because relator Swan did not allege that defendant's neglect of its patients was so severe "that, for all practical purposes, the patients were receiving no room and board services or routine care at all," relator failed to establish that any bill to the government was worthless. *Id*. Relators' allegations here—challenging the adequacy or amount of prior authorization services eviCore provided—are similar to *Swan* and do not meet the "worthless services" standard, either. (*See* A-246).

Finally, Relators argue that the District Court erred by "applying the standards of 'ex post critiques of how providers executed a procedure[ ]' to

Plaintiffs' claims about 'ex ante coverage decisions.'" (Appellant Br. 43).[18/] But this argument, drawn from a discussion of the meaning of the term "medical necessity" (not "worthless services") in *Mikes*, is illogical and irrelevant. The District Court did not refer to "ex post critiques" anywhere in its decision or dismiss Relators' causes of action on that basis. Relators' red-herring distinction about the meaning of the phrase "medical necessity" does not apply at all to the allegation that eviCore performed "worthless" prior authorization services.

Relators further conflate two separate and legally distinct concepts in arguing that the District Court misapplied *Mikes* in dismissing Relator's *worthless services* allegations because, according to Relators, their "allegations that eviCore failed to provide contracted-for pre-authorization medical necessity reviews directly implicate the *medical necessity* standard of the Medicare statute." (Appellant Br. 43) (emphasis added). But the definition of "medical necessity" has

[18/] The concept Relators rely on is taken directly from a discussion in *Mikes* about construing the term "medically necessary." *See Mikes*, 274 F.3d at 698. In *Mikes*, the court found that relator's allegation that spirometry tests were not performed correctly, and thus claims for these services were false, "do[es] not implicate the standard set out in the [reimbursement] form that the procedure was dictated by medical necessity." *Id*. In other words, a procedure may be medically necessary but it may be poorly executed. The court further explained that "[m]edical necessity ordinarily indicates the level – not the quality – of the service." *Id*. So the court found that the "phrase 'medically necessary'– as applying to ex ante coverage decisions but not ex post critiques of how providers executed a procedure – would also conform to our understanding of the phrase 'reasonable and necessary' as used in the Medicare statute." *Id*. This is unrelated to the District Court's Order.

nothing to do with whether Relators alleged that eviCore provided worthless services to MCOs and federal payors, their theory in the SAC. As is clear from the case law discussed above, worthless services turns on one relevant inquiry: whether a service had no value at all to an MCO or federal payor. *See Mikes*, 274 F.3d at 702. Whether a medical treatment or service will be covered by a health plan (i.e., "ex ante coverage determinations") and how a *provider*—not eviCore—executed a medical procedure (i.e., "ex post critiques") have no bearing on the District Court's decision that Relators failed to allege that eviCore's prior authorization services were totally worthless.[19/]

For these reasons, the Court should affirm the District Court's decision dismissing the SAC.

III. THE SAC DOES NOT PLAUSIBLY ALLEGE ANY OTHER THEORY OF LIABILITY UNDER THE FALSE CLAIMS ACT.

The District Court correctly concluded that the SAC fails to allege an FCA cause of action. Relators argue that the District Court failed to analyze other purportedly asserted theories of fraud. (*See* Appellant Br. 32, 35). But the SAC

[19/] The distinction Relators try to rely on had nothing to do with the analysis of worthless services in *Mikes*. The *Mikes* court only referenced the deficient performance of services (i.e., "ex post critiques") when analyzing *express false certification*, an entirely distinct FCA legal issue from worthless services. *See Mikes*, 274 F.3d at 697-98. There are no allegations in the SAC that eviCore made any false certifications of medical necessity to the Government (providers represent that a treatment or services is medically necessary). *Id*. at 698; *see also* Appellant Br. 43.

relies on only one theory, and expressly alleges that the false claims counts are based on eviCore's "*worthless* prior authorization services." (*See* A-170, ¶ 170, A-171, ¶175) (emphasis added). Relators now argue that "whatever the precise legal theory of liability, Plaintiffs alleged facts describing FCA violations by eviCore." (Appellant Br. 38). Relators' own admission that their theory of liability is not clear demonstrates that Relators have not articulated a plausible, particular theory of FCA liability.

Because there are no specific allegations in the SAC to which Relators can point, their brief on appeal instead restates potential theories of fraud summarized in DOJ's SOI. (*See, e.g.*, Appellant Br. 32). Relators now contend—*for the first time on appeal*—that they asserted facts supporting these theories of liability, which were not alleged in the SAC, and which they did not try to add to any amended complaint. These theories are merely a regurgitation of *potential* theories of false claims included in the Government's SOI that *could* apply to subcontractors to MCOs, like eviCore. (Appellant Br. 32).

Appellants identify three possible theories of false claims purportedly in DOJ's SOI: (i) MCO bills for medically unnecessary treatment[20/]; (ii) eviCore bills

[20/] Relators mischaracterize the Government's SOI with respect to this theory. In their Brief, Appellants state, "as the Government described in its [SOI], eviCore's auto-approval schemes led to false claims being submitted . . . including (i) *MA plans* submitting bills for medically unnecessary treatments authorized by eviCore." (Appellant Br. 32) (emphasis added). However, the SOI actually states

for medical necessity reviews not performed; and (iii) MCO submission of false data to CMS for capitation payments. (Appellant Br. 32). The SAC does not allege particular facts under any of these three theories and the District Court's dismissal should be affirmed.

In regards to their first theory of alleged false claims that Relators parrot from the SOI—MCO bills for medically unnecessary treatments—the District Court *did* consider whether the SAC alleged false claims based on the submission of bills for medically unnecessary treatment and concluded that such claims could not satisfy Rule 9(b). (A-248) (stating that "[t]o the extent Relators' claims are premised on eviCore's alleged approvals of unnecessary medical treatments, these claims fare no better. Relators do not identify any approvals, much less do they allege who approved the unnecessary services, where, or when."). The SAC fails to identify a single specific instance where a prior authorization request was approved when it should have been denied because it was medically unnecessary or because it violated health plan rules for approval. (*See* Section I.A.1, *supra*). Nowhere in the SAC do Relators identify a bill for medically unnecessary treatment that was submitted to a federal payor, who submitted it, and when. (*See id*.; A-248).

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that improper approvals could result in a potential claim where a "*healthcare provider* bill[s] a [MA] plan for the medically unnecessary treatment" allegedly authorized by eviCore—not the MA plan. (Appellant Br. 24 (quoting SOI at 2) (emphasis added)).

With respect to Relators' second theory from the SOI— eviCore bills for medical necessity reviews not performed—this theory appears to simply rephrase Relators' "worthless services" claim. (*See, e.g.*, A-171, ¶ 175 (alleging MCOs submitted false claims to CMS for "prior authorization services that eviCore either never rendered, or performed in a worthless fashion")). As discussed in Section II above, the District Court fully analyzed this theory and found that the SAC does not identify a single eviCore invoice for prior authorization services not performed, nor who submitted the invoice, to what MCO, when. (*See* A-248). As the District Court correctly concluded, this theory also fails. *Id*.

Finally, as to the third type of theoretical false claims Relators recite from the SOI—MCO submission of false data to CMS for capitation payments—the SAC does not allege this theory at all. The SAC does not make a single reference to MCOs' capitated payments, what data is submitted to CMS for such payments, how that data relates to eviCore's services, or why such data was false. The SOI *does not* assert that the SAC alleged, much less plausibly so and with particularity, any of these theories and the District Court did not have to consider theories of fraud, such as this theory, not alleged in the SAC. *See United States v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710 (NAM/DEP), 2011 U.S. Dist. LEXIS 4862, at *62 (N.D.N.Y. Jan. 19, 2011).

Reciting theories that *could* apply to other cases, but which Relators never plausibly or particularly alleged in *this case* does not somehow resuscitate a plainly deficient complaint. Nor is it proper to raise these issues for the first time in this appeal.[21/] Relators were offered an opportunity to replead their claims, and could have done so. Yet after six months of consideration, Relators did not, and apparently could not, address the pleading deficiencies the District Court correctly identified. The District Court's dismissal should be affirmed.

CONCLUSION

The District Court correctly dismissed all claims against eviCore. For the reasons discussed above, this Court should affirm the District Court's Order.

Dated: October 7, 2022

Respectfully submitted,

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[21/] *See, e.g.*, *McCarthy v. DeJoy*, No. 20-3600, 2022 U.S. App. LEXIS 4613, at *4 (2d Cir. Feb. 22, 2022) ("It is a well-established general rule that an appellate court will not consider an issue raised for the first time on appeal, unless considering the issue is necessary to avoid a manifest injustice.") (internal quotations omitted).

CERTIFICATE OF COMPLIANCE

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Dated: October 7, 2022

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