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States Court of Appeals
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8-25-2023

Victoria Druding v. Care Alternatives

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 22-1035

UNITED STATES OF AMERICA and STATE OF NEW
JERSEY ex rel
VICTORIA DRUDING; BARBARA BAIN; LINDA
COLEMAN; RONNI O'BRIEN

v.

CARE ALTERNATIVES

Victoria Druding, Barbara Bain, Linda Coleman, and
Ronni O'Brien,
Appellants

On Appeal from the United States District Court
for the District of New Jersey
(District Court No. 1-08-cv-02126)
Honorable Juan R. Sanchez, Chief District Judge

Argued on April 25, 2023

Before: KRAUSE, BIBAS, and RENDELL, *Circuit Judges*

(Filed: August 25, 2023)

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OPINION OF THE COURT

KRAUSE, *Circuit Judge*.

The False Claims Act (“FCA”), 31 U.S.C. § 3729, *et seq.*, is a flexible, far-reaching tool that empowers the federal government and private individuals acting in the government’s name, known as relators, to bring claims for fraud against the United States. At the same time, it is not “an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016). So when a government contractor submits a claim for payment but fails to disclose a statutory, regulatory, or contractual violation, that claim does not automatically trigger FCA liability. Instead, the Act requires that the contractor’s alleged violation be, among other things, “material” to the government’s decision to pay. *Id.* at 192-93.

And in *Escobar*, the Supreme Court identified various factors to assist courts in evaluating materiality.

In this case, the District Court granted summary judgment to the Defendant, Care Alternatives, Inc. (“Care Alternatives”), a New Jersey hospice provider, for lack of materiality based principally on the government’s continued reimbursement of Care Alternatives even after being made aware of its deficient documentation required by regulation. Because the District Court assigned dispositive weight to a single *Escobar* factor, government action, while overlooking the factors that could have weighed in favor of materiality—and despite an open dispute over the government’s “actual knowledge,” 579 U.S. at 195—we will vacate the District Court’s grant of summary judgment and remand for further proceedings consistent with this opinion.

I. Background

Defendant Care Alternatives is a for-profit hospice provider that operates in New Jersey. It employs teams of clinicians known as “Interdisciplinary Teams” (“IDTs”), consisting of registered nurses, chaplains, social workers, home health aides, and therapists. JA 6. These groups work alongside independent physicians who serve as hospice medical directors. The IDTs meet regularly to review patient care plans and discuss patients who are up for recertification of their need for hospice care.

The Relator-Appellants (“Relators”) are former employees of Care Alternatives, some of whom were clinicians who participated in IDTs. They brought this action under the False Claims Act alleging that Care Alternatives submitted claims for Medicare reimbursement despite inadequate documentation in the patients’ medical records supporting hospice eligibility, as required by 42 C.F.R. § 418.22(b)(2) (2011).

Before reviewing the specifics of Relators’ claims and the circumstances leading to this appeal, we will review the requirements that hospice providers must meet to qualify for Medicare reimbursement and the False Claims Act.

A. Medicare Hospice Benefit

In 1982, Congress created the Medicare Hospice Benefit, an amendment to the Social Security Act that authorized Medicare beneficiaries to receive coverage for hospice care. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 122, 96 Stat. 324, 356-63. Hospice care is considered palliative care, meaning it is “patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering.” 42 C.F.R. § 418.3 (2021). It aims to “mak[e] [a terminally ill] individual as physically and emotionally comfortable as possible.” 48 Fed. Reg. 56,008, 56,008 (Dec. 16, 1983). A patient who has been certified as eligible for hospice care and elects to receive the Hospice Benefit waives the right to Medicare payment for “curative” care that is designed to treat the individual’s condition. *See* 42 U.S.C. § 1395d(d)(2)(A)(ii).

For a patient to be eligible for Medicare hospice benefits, and for a hospice provider to be entitled to bill for such benefits, a patient must be certified as “terminally ill,” *see* 42 C.F.R. §§ 418.20, meaning “that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course,” *id.* § 418.3. There are two principal components of that certification: it must (1) be signed by at least one physician, and (2) be accompanied by “[c]linical information and other documentation that support the medical prognosis” of terminal illness in the medical record. *Id.* § 418.22(b).

To satisfy the first component, physician certification, an individual’s “attending physician” and the hospice’s “medical director” must “certify in writing . . . that the individual is terminally ill . . . based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s illness.” 42 U.S.C. § 1395f(a)(7)(A)(i). This certification must be obtained at the time a patient is admitted to hospice, *id.*, and renewed at ninety days and every sixty days thereafter, *id.* at § 1395f(a)(7)(A)(ii).

To satisfy the second component, medical documentation, “[c]linical information and other documentation that support the medical prognosis must

accompany the certification and must be filed in the [patient's] medical record with the written certification.” 42 C.F.R. § 418.22(b)(2); *see also id.* § 418.22(b)(3) (requiring certification to include a “brief narrative explanation of the clinical findings that support[] a life expectancy of 6 months or less”). As the Center for Medicare and Medicaid Services (“CMS”), the agency that administers the Hospice Benefit, has explained: “A hospice needs to be certain that [a] physician’s clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course. A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit[.]” 70 Fed. Reg. 70,532, 70,534-35 (Nov. 22, 2005).

B. False Claims Act

The False Claims Act “imposes significant penalties on those who defraud the Government.” *Escobar*, 579 U.S. at 180. The Act makes liable “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” to the government. 31 U.S.C. § 3729(a)(1)(A).

The government may bring FCA actions directly. *Id.* § 3730(a). Alternatively, as happened in this case, “a private person, known as a relator, may bring a *qui tam* civil action” in the government’s name. *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019); *see also* 31 U.S.C. § 3730(b). In such cases, the government may “intervene in the action” after investigating the relator’s allegations. *Cochise Consultancy, Inc.*, 139 S. Ct. at 1510 (citations omitted). If, as here, the government declines to intervene, the relator may still “pursue the action.” *Id.* (citation omitted). The relator is entitled to “a share,” generally between 15 and 30 percent, “of any proceeds from the action.” *Id.* (citations omitted).

To prevail on an FCA claim, the relator must prove that the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the government to make a payment. *Escobar*, 579 U.S. at 181-82; *United States ex rel*

Petratos v. Genetech Inc., 855 F.3d 481, 487 (3d Cir. 2017) (citations omitted). “Materiality,” the Court explained in *Escobar*, turns on a variety of factors such as: (1) whether the government has expressly designated the legal requirement at issue as a “condition of payment”; (2) whether the alleged violation is “minor or insubstantial” or instead goes to the “essence of the bargain” between the contractor and the government; and (3) whether the government made continued payments, or does so in the “mine run of cases,” despite “actual knowledge” of the violation. *See* 579 U.S. at 193 n.5, 194-95 (quotation and citations omitted). As this Court and our sister circuits have repeatedly recognized, this is a “holistic,” totality-of-the-circumstances inquiry.¹

C. Factual and Procedural History

¹ *See, e.g., United States ex rel. Int’l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315, 342 (3d Cir. 2021) (“A materiality inquiry under the FCA is a holistic, totality-of-the-circumstances examination[.]”); *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019) (“No one factor is dispositive, and our inquiry is holistic.”); *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 110 (2d Cir. 2021), *cert. denied*, 142 S. Ct. 2679 (2022) (same (quoting *Lemon*, 924 F.3d at 161)); *United States ex rel. Prather v. Brookdale Senior Living Cmty., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018) (“The analysis of materiality is holistic . . . None of these considerations is dispositive alone, nor is the list exclusive.”) (quotations and internal quotation marks omitted); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (citation omitted); *United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, 48 F.4th 1146, 1157 (10th Cir. 2022) (citation omitted); *United States ex rel. Janssen v. Lawrence Mem’l Hosp.*, 949 F.3d 533, 541 (10th Cir. 2020); *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1300 (11th Cir. 2021) (citation omitted); *United States ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1347 (11th Cir. 2021).

Relators brought this suit under the *qui tam* provision of the FCA. Pursuant to that provision, they filed their Complaint under seal in 2008 and provided the government with the information upon which they intended to rely so that the government could make an informed decision as to whether it would intervene and take over the case. 31 U.S.C. § 3730(b)(2).² They alleged that Care Alternatives submitted fraudulent reimbursement claims to CMS between 2006 and 2007, in violation of the FCA. Their theory is that although each claim had a physician certification of terminal illness, there was inadequate clinical documentation supporting that diagnosis, in violation of 42 C.F.R. § 418.22(b)(2). According to Relators, § 418.22(b)(2) is the “cornerstone” of the Medicare Hospice Benefit because without sufficient clinical documentation supporting a physician’s certification, there is no way “to ensure that the [physician’s] certification is accurate,” and thus, that hospice care goes to its intended beneficiaries. Reply Br. 12, 15.

In 2015, seven years after the Complaint was filed, the government notified the District Court that it would not intervene but that it nevertheless wished to remain an interested party in the proceedings. Relators opted to proceed independently and served the operative First Amended Complaint upon Care Alternatives.³

During discovery, the parties produced extensive evidence addressing whether Care Alternatives admitted patients with insufficiently documented need for hospice care. This included dueling expert opinions. Relators’ expert, Dr. Robert Jayes, M.D., prepared a report as to whether the

² As discussed below, the Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”) also issued a subpoena in November 2009 for the medical records of 112 patients and a variety of corporate policies, internal documents, and employee emails.

³ Care Alternatives moved to dismiss, and the Court granted the motion in part, dismissing Relators’ claims regarding altered documentation and violations of the federal Anti-Kickback statute, but not Relators’ FCA claims regarding inappropriate hospice certifications, which are now before us.

physician certifications were accompanied by supporting documentation. He examined the records of forty-seven patients and opined that the documents did not support hospice eligibility in thirty-five percent of those patients' hospice certification periods. In his view, any reasonable physician would have reached the same conclusion.

Care Alternatives' expert, Dr. Christopher Hughes, M.D., disagreed. For each certification that Dr. Jayes reviewed, Dr. Hughes opined that a physician could have reasonably determined that the prognosis for each patient was six months or less.

Discovery also included the depositions of several former Care Alternatives employees, including Relators, who testified to whether Care Alternatives admitted or recertified patients who did not have a documented need for hospice care and to Care Alternatives' awareness of these alleged violations.⁴ In addition, Relators produced an expert report prepared by Al Palentchar, a Certified Public Accountant, who calculated, based on Dr. Jayes' schedule of inadequately documented patient billings, that Care Alternatives had improperly charged over \$3.6 million to Medicare.

At the close of discovery, Care Alternatives moved for summary judgment, arguing that Relators could not make out the elements of an FCA claim. In the ruling that gave rise to the first appeal in this case, the District Court granted that motion based solely on failure to show falsity. *Druding v. Care Alts., Inc.*, 346 F. Supp. 3d 669, 685, 688 (D.N.J. 2018). It viewed the mere "difference of opinion" between experts regarding the accuracy of a patient's prognosis as insufficient to create a triable dispute of fact as to the element of falsity. *Id.* at 688 (citation omitted). It therefore concluded that: "there [wa]s no factual evidence" that certifying doctors made "knowingly false" certifications. *Id.* We reversed, explaining that "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *United States ex rel. Druding v. Care Alts., Inc.*, 952 F.3d 89,

⁴ Their testimony is summarized *infra* Section III.B.1.

97 (3d Cir. 2020) (citations omitted). So the District Court should have considered evidence (such as Dr. Jayes’ report) that was relevant to whether Care Alternatives complied with regulatory requirements, including that the physician’s certification be accompanied by “[c]linical information and other documentation that support the medical prognosis [of terminal illness].” *Id.* (quoting 42 C.F.R. § 418.22(b)(2)). Because there was substantial evidence of Care Alternatives’ noncompliance with this requirement, we held summary judgment on falsity to be improper and remanded for the District Court’s disposition of the other issues raised on summary judgment: scienter, causation, and materiality. *Id.* at 101.

On remand, the District Court found sufficient evidence of scienter,⁵ but granted summary judgment based on lack of materiality and, *a fortiori*, causation. Specifically, it found “no evidence” that Care Alternatives’ “insufficiently documented certifications . . . were material to the Government’s decision to pay.” JA 16. Its reasoning was that “[t]he Government could see what was or was not submitted to it by Care Alternatives along with its claims seeking payment” yet never “refused any of Care Alternatives’ claims, despite the inadequacy or missing supporting documentation or where compliance with 42 C.F.R. § 418.22 was otherwise lacking.” *Id.* at 17. And it faulted Relators for failing to present evidence that “the Government’s apparent disregard of the inadequacies in Care Alternatives’ billing documentation was not the result of its having concluded those inadequacies were immaterial to its decision to make those payments anyway,” or that “the Government ever stopped reimbursing Care Alternatives after it was made aware of the false, inadequately supported physician certifications.” *Id.* As a result, it concluded: “Relators have failed to create a genuine factual dispute as to the issue of materiality[.]” *Id.* at 18.

⁵ On that point, it concluded: “[t]he [] evidence clearly reflects knowledge on Care Alternatives’ part that its medical documentation did not always support the physician-signed certifications of hospice necessity and thus did not always comply with the Medicare/Medicaid regulations governing payment.” JA 14.

This appeal followed.

II. Jurisdiction and Standard of Review

We have jurisdiction based on 28 U.S.C. § 1291. The District Court had jurisdiction under 28 U.S.C. § 1331.

We exercise plenary review of a district court’s grant of summary judgment. *Reedy v. Evanson*, 615 F.3d 197, 210 (3d Cir. 2010) (citation omitted). Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” *Thomas v. Cumberland Cnty.*, 749 F.3d 217, 222 (3d Cir. 2014) (quoting Fed. R. Civ. P. 56(a)) (internal quotation marks omitted). When deciding a motion for summary judgment, “[a]ll reasonable inferences from the record must be drawn in favor of the nonmoving party” and the court “may not weigh the evidence or assess credibility.” *MBIA Ins. Corp. v. Royal Indem. Co.*, 426 F.3d 204, 209 (3d Cir. 2005).

III. Discussion

Relators contend that summary judgment was premature because a reasonable jury could have concluded that Care Alternatives’ submission of hospice reimbursement claims for patients with insufficiently documented need for hospice care was a “material” violation under the FCA. In Relators’ view, *Escobar*’s first and second factors—whether the legal requirement is a “condition of payment,” and whether the alleged violations were “[s]ubstantial,” respectively—weigh in favor of materiality, while *Escobar*’s third factor—government action—is neutral. *See* 579 U.S. at 193 n.5, 194-95. We consider these factors below.

A. Whether 42 C.F.R. § 418.22(b)(2) Was an Express Condition of Payment

The first factor that *Escobar* identifies as relevant to materiality is whether the government “expressly identif[ied] a provision as a condition of payment.” *Id.* at 194.

Here, it is undisputed that § 418.22(b)(2)'s documentation requirement is a condition of payment. Per CMS regulation, hospice providers may not bill CMS for their services without “[c]linical information and other documentation that support the medical prognosis [accompanying] the certification and [] filed in the medical record.” 42 C.F.R. § 418.22(b)(2).

The question for us is what import to assign this designation. To that end, we are guided by *Escobar*, which indicates “[w]hether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.” 579 U.S. at 190. It is *relevant* because the government’s decision to expressly designate a provision as a condition of payment may “signal[] the importance” of that provision. *Id.* at 191. But it is *not dispositive*, because the mere fact that the government has the “option to decline to pay if it knew of the defendant’s noncompliance,” *id.* at 194, does not mean that the government is *likely* to exercise that option, or that it routinely does so, *see id.* at 193 (“Under any understanding of the concept, materiality [l]ooks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”) (quotation and internal quotation marks omitted). Thus, for example, “[i]f the Government contracts for health services and adds a requirement that contractors buy American-made staplers,” a contractor who “submits a claim for those services but fails to disclose its use of foreign staplers” does not commit a material violation if the government routinely pays such claims. *Id.* at 195.

Equipped with this guidance, we conclude that the mere fact that § 418.22(b)(2) is identified as a condition of payment does not, in and of itself, support a finding of materiality; and thus, this designation does not necessarily preclude summary judgment. *See id.* at 194 (“Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance”). However, it is “‘certainly probative evidence of materiality.’” *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019) (quoting *United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1020 (9th Cir. 2018)). And here, Relators have adduced evidence that bears on the importance of § 418.22(b)(2)'s documentation requirement and the

substantiality of Care Alternatives' alleged violations.⁶ Under these circumstances, a jury should have been permitted to weigh § 418.22(b)(2)'s condition of payment status alongside *Escobar*'s other factors.

B. Whether Care Alternatives' Alleged Violations of 42 C.F.R. § 418.22(b)(2) Were "Minor or Insubstantial" or Instead Went to the "Essence of the Bargain"

Escobar's second factor asks whether the "noncompliance is minor or insubstantial," 579 U.S. at 194, or instead went to "the very essence of the bargain" between the contractor and the government, *id.* at 193 n.5 (quotation omitted). Care Alternatives argues that its purported violations of 42 C.F.R. § 418.22(b)(2) are insignificant because "[e]very patient" who is "part of this lawsuit[] had a certification of hospice eligibility, signed by an appropriate physician . . . and [n]o one is disputing that the staff at Care Alternatives provided good, compassionate care." Answering Br. 32-33 (quotation omitted). But the physicians' signatures and the overall quality of care provided by Care Alternatives is neither here nor there. Instead, *Escobar* spotlights whether the contractor's *alleged violations* are "minor or insubstantial."

⁶ *Cf. Farfield*, 5 F.4th at 344-46 (affirming denial of summary judgment where Davis-Beacon Act payroll requirement was condition of payment, which "support[ed] the District Court's materiality finding" along with a lack of "evidence of past relevant Government (in)action"; and evidence showing that compliance was "essential to the bargain"); *Bibby*, 987 F.3d at 1352 (reversing summary judgment where "both the requirement's designation as a condition of payment and its centrality to the government program favor materiality" despite "countervailing evidence of the VA's knowledge and its reaction to noncompliance" because "[t]o resolve the issue by weighing conflicting evidence was error") (citation omitted); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 504 (8th Cir. 2016) (reversing summary judgment where "conditioning [of payment], the significance of the requirement[,] and the government's acts show that the recordkeeping promise was material").

579 U.S. at 194. And here, those alleged violations are Care Alternatives' certifications of patients with insufficient clinical documentation to support a terminal diagnosis, as required by § 418.22(b)(2). So we will examine the importance of § 418.22(b)(2) and the magnitude of Care Alternatives' alleged violations.

1. Significance of 42 C.F.R. § 418.22(b)(2)

CMS has made clear that “[a] signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit.” 70 Fed. Reg. at 70,534-35. Why? Because “[a] hospice *needs to be certain* that [a] physician’s clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course.” *Id.* at 70,534 (emphasis added). Put differently, CMS never meant to give physicians unchecked authority to certify patients as hospice eligible. So § 418.22(b)(2)’s requirement that physicians’ signed certifications be supported by the patients’ medical records is an essential form of oversight.

More fundamentally, § 418.22(b)(2) protects the public fisc and the overall integrity of the Medicare hospice program. By requiring that “clinical information . . . support” a terminally ill prognosis, § 418.22(b)(2) helps ensure that hospice care goes to those who actually need it and protects Medicare funds from wrongfully claimed payments. *See Lemon*, 924 F.3d at 163 (finding it “apparent” that “false terminally-ill certifications may lead the government to make a payment which it would not otherwise have made” (quotation omitted)).⁷ Conversely, it ensures that patients who are *not* terminally ill do not receive hospice benefits, and therefore, that they remain eligible for curative care. *See* 42 U.S.C. § 1395d(d)(2)(A)(ii).

⁷ *See also* Report of Dr. Robert L. Jayes 1, *United States ex rel. Druding v. Care Alternatives*, No. 1:08-cv-02126 (D.N.J. 2021), ECF No. 135-6, Ex. 19 (Part I) (“Jayes Report”) (highlighting “the possibility of fraud in the Medicare Hospice Program”).

In sum, § 418.22(b)(2)'s documentation requirement “addresse[s] a foundational part of the Government’s” Medicare hospice program, and thus, “false certifications simply [are] not ‘minor or insubstantial’ violations.” *United States v. Luce*, 873 F.3d 999, 1007 (7th Cir. 2017) (quoting *Escobar*, 579 U.S. at 194).⁸

2. Severity of Care Alternatives’ Alleged Violations

Nor is § 418.22(b)(2) significant only in the abstract. Relators have put forward ample evidence that Care Alternatives’ actual violations of § 418.22(b)(2) were not “minor or insubstantial.” *Escobar*, 579 U.S. at 194. That evidence, “viewed in the light most favorable to [Relators],” *Reedy*, 615 F.3d at 209 (quotation omitted), shows that (1) Care Alternatives’ documentation deficiencies were pervasive; (2) Care Alternatives was aware of the gravity of its noncompliance; and (3) Care Alternatives’ patients were potentially ineligible, as a medical matter, for hospice care.

Beginning with the scope of Care Alternatives’ alleged violations, this is not a case about occasional noncompliance. Rather, as the District Court found, “there is [] significant evidence in the record . . . that Care Alternatives had longstanding problems with maintaining necessary and proper documentation.” JA 11. In addition to Relators’ expert, Dr. Jayes, who opined that forty-five percent of the files he reviewed did not support hospice eligibility, *Druding v. Care Alternatives, Inc.*, No. 08-2126, 2021 WL 5923883, at *3 (D.N.J. Dec. 15, 2021), Care Alternatives’ former CEO Sam Veltri observed that “‘it was a constant, constant fight to make sure the documentation was good,’ *i.e.* that it was ‘accurate,’ ‘clinical, ‘made sense,’ and ‘made its way to the charts,’” *id.* at *4. Indeed, as a 2007 internal audit revealed, Care Alternatives’ “maintenance of the clinical records [wa]s below standard,” due to, *inter alia*, “documentation issues and information missing that is required for reimbursement,

⁸ See also *Bibby*, 987 F.3d at 1348 (considering the “centrality” of compliance with a particular government regulation to the overall “goal” of the program) (quotation omitted); *Escobar*, 842 F.3d at 110 (same).

regulatory and accrediting standards.” JA 2110. The percentage of randomly audited charts containing all necessary data in 2007 was only 56.5% in the first quarter, 53.9% in the second quarter, 54.1% in the third quarter, and 43.6% in the fourth quarter. *Id.* at 13. In view of this evidence, a reasonable jury could find that Care Alternatives’ violations were not just isolated incidents but were part of a pattern of significant noncompliance. *Cf. United States ex rel. Int’l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.*, 5 F.4th 315, 347 (3d Cir. 2021) (contractor’s misclassifications of more than \$150,000, over the course of two years, on 105 separate occasions “were not minor or insubstantial”).

Care Alternatives’ leadership also clearly understood the importance of § 418.22(b)(2) compliance, which could further support a materiality finding. *See id.* at 345 (“Farfield’s clear appreciation that Davis-Beacon violations would ‘likely’ so affect the ‘behavior of the recipient of the alleged misrepresentation’” weighed in favor of materiality (quoting *Escobar*, 579 U.S. at 193)). For instance, Loretta Spoltore, a Care Alternatives administrator, testified that her “goal was [] to be a hundred percent compliant” because she “do[es]n’t look good in stripes.” JA 1682. Likewise, Martha Coppola, a Care Alternatives compliance officer, testified that “if you were surveyed” by CMS and the requisite chart documentation “was not there, it doesn’t matter if [staff members] were on their way up the turnpike to bring it, it wasn’t there, and that was a problem.” *Id.* at 292. And Veltri testified that he brought in an outside consultant, Toni Swick, to train employees on CMS documentation requirements.

This is also not a case where it is beyond dispute that the patients were, in fact, terminally ill. To be sure, Relators do not proceed under the theory that the physicians’ certifications of terminal illness were medically unreasonable. Their theory is that there was inadequate documentation supporting those certifications in the patients’ records—which could reflect *either* poor recordkeeping *or* lack of terminal illness (or both). Nor do Relators allege bad faith on the part of any of the certifying physicians. But they posit, and we

agree, that patients' terminal prognoses cannot be verified without adequate documentation.⁹

In this case, the uncertainty is hardly academic. For instance, Dr. Jayes' report discusses times when "[c]linical evidence contradict[ed] [the] hospice diagnosis," Jayes Report 5, and when "[s]ervices continu[ed] despite patient stabilization or clarification of erroneous admission information so that [the] patient no longer ha[d] a six month prognosis," *id.* at 6. The testimony of certain employees also raises doubts about patients' substantive eligibility, as Relators summarize. Some employees "testified that the medical records could not have supported hospice eligibility because these patients did not have the signs and symptoms that would meet the criteria necessary [to] make them eligible for hospice"; others testified that "they were directed by Care Alternatives to alter medical records, or to re-write medical records, in order to 'paint a picture' that the patients were actually hospice eligible." Opening Br. 13 (collecting testimony). Even Veltri, although he averred that he "[n]ever" sought to bring in patients who were inappropriate for hospice, JA 2205-06, expressed the view that a hospice "lives and dies as a company . . . on its census" and thus, "[i]t is imperative that we constantly, constantly get new patients in," *id.* at 1601.

Whether this testimony should be credited is outside our purview. *MBIA Ins. Corp.*, 426 F.3d at 209. But the point is this: a reasonable jury could conclude, based on the evidence

⁹ That uncertainty distinguishes this case from *United States ex rel. Spay v. CVS Caremark Corp.*, which involved an FCA suit against a CVS pharmacy that filled in "dummy Prescriber IDs" on CMS reimbursement forms in lieu of patients' actual physicians' IDs. 875 F.3d 746, 750-51 (3d Cir. 2017). In *Spay*, there was no question that "[t]he claims themselves were neither false nor fraudulent" and that CMS accepted this "workaround" as a "technical, formulaic way of preventing a computer program from denying legitimate claims." *Id.* at 765. So we upheld the District Court's grant of summary judgment for CVS based on, *inter alia*, lack of materiality. *Id.*

presented, that Care Alternatives’ alleged violations of 42 C.F.R. § 418.22(b)(2) were not isolated instances of incomplete notes or misplaced documents—that is, “minor or insubstantial” violations—but rather, that Care Alternatives’ violations went to the “essence of the bargain”: patients’ medical need for hospice care.¹⁰ *Escobar*, 579 U.S. at 193 n.5, 194 (quotation omitted).

For all of these reasons, *Escobar*’s substantiality factor could support a materiality finding.¹¹

C. Whether the Government’s Actions in the Wake of Relators’ Fraud Allegations Disprove Materiality

That leaves us with *Escobar*’s third factor, government action. As the Supreme Court explained:

[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

579 U.S. at 195.

¹⁰ We emphasize that this is not a medical malpractice case, as Appellants candidly acknowledged during oral argument. *See* Oral Arg. Tr. 82:22-86:22. But insofar as compliance with § 418.22(b)(2)’s documentation requirement cannot be divorced from issues surrounding substantive eligibility, a jury might consider that reality in assessing materiality.

¹¹ For purposes of appellate review, we acknowledge that some of *Escobar*’s factors “could support a materiality finding” not because the evidence definitively points towards materiality—it does not—but because on this record, a reasonable jury could conclude that Care Alternatives’ alleged violations were material.

The District Court concluded based solely on this factor that Care Alternatives' alleged violations were, as a matter of law, immaterial. Specifically, it reasoned: (1) the government continually reimbursed Care Alternatives despite knowledge of the inadequacies in its documentation, and (2) Relators produced "no evidence" explaining away "the Government's apparent disregard" of those inadequacies, which the District Court surmised was their burden on a motion for summary judgment. JA 16-17.

We perceive two errors with this approach, addressed below *seriatim*.

1. The Government's Alleged Knowledge

The District Court seemed to impute "actual knowledge" of Care Alternatives' inadequate documentation to the government based on the fact that "[t]he Government could see what was or was not submitted to it by Care Alternatives along with its claims seeking payment." JA 17. But CMS regulations do *not* require hospice providers to submit physician certifications and supporting clinical documentation with their claims for payment; instead, those documents are kept on file in the patients' medical records. 42 C.F.R. § 418.22(b)(2), (d). So CMS would not have obtained "actual knowledge" of Care Alternatives' insufficient documentation simply by reviewing its reimbursement claims.

Care Alternatives appears to concede this point. But it directs our attention to the fact that after Relators filed their Complaint (in April 2008, with service on the United States in September 2008, HHS-OIG and the DOJ conducted a joint investigation, including a November 2009 subpoena for 112 patient medical records and a variety of company policies, internal documents, and employee emails. Still, it is not clear that the government thereby acquired "actual knowledge" of Care Alternatives' alleged violations, or at least, of the full gravity of those alleged violations.

Presumably, the government would have uncovered significant deficiencies in Care Alternatives' documentation

controls,¹² though by that point, the disputed claims (from 2006 and 2007) were already paid.¹³ And if we credit—as we must at this stage—Relators’ testimony that Care Alternatives’ providers charted to “paint a picture” of hospice eligibility, *see* Opening Br. 13 (summarizing testimony), then the government would not have known that Care Alternatives was certifying patients who were potentially inappropriate for hospice care.

To be sure, the government’s inaction over the past fifteen years *is* evidence of immateriality.¹⁴ As Care Alternatives forcefully argues, the government has not availed itself of any of its myriad enforcement tools, including its ability to recoup prior payments, 42 C.F.R. § 405.371(a)(3).¹⁵ But whether that inaction is *dispositive* evidence of

¹² However, the United States continues to deny that there is *any* evidence of “actual knowledge” of § 418.22 violations. DOJ Amicus Br. 14, 17, 19.

¹³ *Escobar* indicates that timing is relevant. *See* 579 U.S. at 195 (indicating that whether “the Government *pays a particular claim in full* despite its actual knowledge that certain requirements were violated” is evidence of materiality (emphasis added)).

¹⁴ The government’s decision not to intervene, on the other hand, is “at best, of minimal relevance.” *Farfield*, 5 F.4th at 346. As we recognized in *Farfield*, “[if] relators’ ability to [meet] the element of materiality were stymied by the government’s choice not to intervene, this would undermine the purposes of the [False Claims] Act,” which is explicitly designed to permit private persons to litigate suits in lieu of the government. *Id.* (quotation omitted); *see also Prather*, 892 F.3d at 836; *Janssen*, 949 F.3d at 542 n.12.

¹⁵ The Supreme Court in *Escobar* focused on the government’s continued payment decisions rather than post-hoc prosecutions or other enforcement actions. *See* 579 U.S. at 195. But in light of *Escobar*’s holistic inquiry, we do not read this to suggest that the government’s post-hoc enforcement behavior is irrelevant to the materiality inquiry. *Cf. United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020) (questioning whether “post hoc enforcement actions are relevant to FCA materiality analysis at all”).

immateriality is another matter. And *Escobar* focuses on whether the government had “*actual knowledge*” of a violation when it made a payment, which is still only “very strong”—not dispositive—evidence of immateriality. 579 U.S. at 195 (emphasis added). In this case, we simply do not know what the government knew and when. *Cf. Spay*, 875 F.3d at 746 (“[Relator] does not contest that CMS employees knew that dummy identifiers were being used[.]”); *Petratos*, 855 F.3d at 490 (affirming summary judgment where Relator conceded “the Government would have paid the [disputed] claims with *full knowledge* of the alleged noncompliance” (emphasis added)). Like our sister circuits, we will not equate the government’s awareness of allegations of fraud with “actual knowledge” that fraud occurred.¹⁶ And we recognize that “the Government may not want to prematurely end a relationship with a contractor over unproven allegations.” *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 517 (6th Cir. 2022). So a reasonable jury could conclude that the government’s inaction is not conclusive.

2. Relators’ Burden

Nor was it, as the District Court held, “incumbent upon the Relators to present some evidence suggesting the government’s apparent disregard of the inadequacies in Care

¹⁶ *See, e.g., Prather*, 892 F.3d at 834 (“Without actual knowledge of the alleged non-compliance, the government’s response to the claims submitted by the defendants—or claims of the same type also in violation of 42 C.F.R. § 424.22(a)(2)—has no bearing on the materiality analysis.”); *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 517 (6th Cir. 2022) (“[T]he facts alleged in this case do not indicate that NASA had ‘actual knowledge’ that Wolf Creek did in fact submit falsely inflated quotes. Instead, the alleged facts show only that USN4U informed NASA of its allegations, not that NASA necessarily believed the allegations to be true.”); *AECOM*, 19 F.4th at 115 (“[I]t makes sense not to place much weight on the government’s response in the wake of [] litigation because, prior to discovery and a formal court ruling, the relator’s allegations are just that – allegations, and the government may not necessarily have knowledge of all the material facts.”).

Alternatives’ billing documentation was not the result of its having concluded those inadequacies were immaterial.” JA 17. As a general matter, relators are not required to conduct discovery on government officials to demonstrate materiality—an imposition that would find no support in *Escobar*’s holistic approach. And on a motion for summary judgment, it is the *moving party* who bears the burden of demonstrating the absence of a genuine issue of material fact—a burden that Care Alternatives has not met. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (citing Fed. R. Civ. P. 56(c)).

* * *

Thus, notwithstanding the government’s prolonged inaction in the wake of Relators’ fraud allegations, it was erroneous to treat this factor as determinative of immateriality. A jury must be permitted to weigh the government’s inaction alongside *Escobar*’s other factors.¹⁷

IV. Conclusion

For the foregoing reasons, we will reverse the District Court’s grant of summary judgment and remand for further proceedings consistent with this opinion.

¹⁷ Although materiality is a jury question in this case, summary judgment may be proper in others. *See Escobar*, 579 U.S. at 195 n.6 (rejecting assertion “that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment”).