

No. _____

In the Supreme Court of the United States

BROOKDALE SENIOR LIVING
COMMUNITIES, INC., ET AL.,

Petitioners,

v.

UNITED STATES OF AMERICA,
EX REL. MARJORIE PRATHER,

Respondent.

*On Petition for Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit*

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This Court has affirmed False Claims Act (FCA) liability, 31 U.S.C. § 3729 *et seq.*, under a theory of “implied false certification.” See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016). For that expanded theory of fraud liability to apply, however, the contractor’s violation must be material to the government’s decision to pay the claim, and the contractor must know it is material. *Id.* at 1996, 2002. Despite that holding, the Sixth Circuit held that a relator’s failure to plead any facts regarding an alleged regulatory violation’s effect on the government’s past payment of claims “has no bearing on the materiality analysis” and that scienter can be established even where the relator does not allege that the defendant knew that the regulatory violation was material to the government’s decision to pay claims. That decision directly conflicts with published decisions in other circuits regarding the proper enforcement of the FCA’s materiality and scienter elements.

The questions presented are:

1. Whether the failure to plead facts relating to past government practices in an FCA action can weigh against a finding of materiality.
2. Whether an FCA allegation fails when the pleadings make no reference to the defendant’s knowledge that the alleged violation was material to the government’s payment decision.

PARTIES TO THE PROCEEDING

Pursuant to Supreme Court Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Sixth Circuit. The petitioners here, and appellees below, are Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC. The respondent here, and appellant below, is the United States of America ex rel. Marjorie Prather.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Petitioners Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC (collectively, “Brookdale”) provide the following disclosure.

Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Innovative Senior Care Home Health of Nashville, LLC (d/b/a Innovative Senior Care Home Health), and ARC Therapy Services, LLC (d/b/a Innovative Senior Care) are all owned by Brookdale Senior Living Inc. Brookdale Senior Living Inc. has no parent corporation. No publicly traded corporation owns 10% or more of the stock of Brookdale Senior Living Inc.

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JURISDICTION

The Sixth Circuit issued its opinion on June 11, 2018. The court denied Brookdale’s petition for rehearing *en banc* on August 22, 2018. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This petition involves provisions of the False Claims Act, 31 U.S.C. §§ 3729-30, as well as other statutes and regulations governing home health services, 42 U.S.C. § 1395f(a)(2)(C), 42 U.S.C. § 1395n(a)(2)(A), 42 C.F.R. § 424.22 (eff. Feb. 18, 2011). The relevant provisions are reproduced at Pet. App. 110–120.

INTRODUCTION

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, “imposes significant penalties on those who defraud the Government.” *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016). In *Escobar*, this Court confirmed that FCA liability may attach under a theory of implied false certification where a government contractor submits claims for payment while falsely representing that it has complied with its statutory, regulatory, or contractual obligations. *Id.* at 1999. Such liability, however, is limited to those misrepresentations that are “material

to the Government’s payment decision” *Id.* at 2002. The Court noted that the materiality standard is “rigorous,” “demanding,” and is focused on the actual effect that the violation has on the government’s payment of claims, as opposed to whether the government would be “entitled to refuse payment were it aware of the violation.” *Id.* at 2003–04, 2004 n.6.

Likewise, the FCA imposes a “rigorous” scienter requirement. *Id.* at 2002. It requires that a relator allege facts showing that the defendant “knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” *Id.* at 1996. The Court recognized that the rigorous materiality and scienter requirements serve gatekeeper functions for screening viable FCA claims and that strict enforcement of those requirements can effectively address “concerns about fair notice and open-ended liability.” *Id.* at 2002.

In the instant case, the Sixth Circuit reverts the state of the law with respect to the FCA’s materiality and scienter requirements to pre-*Escobar* standards. Although the relator was afforded leave to amend her complaint specifically to address the materiality requirement articulated in *Escobar*, the relator alleged no facts about the government’s past payment practices or enforcement efforts with respect to the alleged regulatory violation or any factual allegations about whether and why the alleged violation would cause the government to deny a claim for payment. Nonetheless, the Sixth Circuit held that the relator’s pleading no allegations about past government action “has no bearing on the materiality analysis.” Pet. App. 22–23.

Although courts routinely consider what allegations are lacking from a complaint when addressing a defendant's motion to dismiss, particularly when analyzing allegations under Rule 9(b)'s heightened standard to plead fraud with particularity, the Sixth Circuit held that to consider the absence of allegations in this context would be to "dr[aw] a negative inference" in favor of the defendant. Pet. App. 21. Instead, the court held that the rigorous and demanding materiality requirement was satisfied because the court determined that the regulation (1) was labeled a condition of payment and (2) was a "mechanism of fraud prevention." Pet. App. 27.

Through this holding, the Sixth Circuit aligns itself with the Ninth Circuit, which similarly found that relators had sufficiently pled materiality where there was "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 907 (9th Cir. 2017), *petition for cert. filed*, 2017 WL 6812110 (Dec. 26, 2017) (No. 17-936).

The Sixth and Ninth Circuits stand in stark contrast to three other circuits that recognize that allegations of past government action—or the lack thereof—are relevant to the holistic, multi-factor materiality analysis required under *Escobar*. The latter circuits appropriately heed this Court's guidance in *Escobar* that the government's actual behavior, as opposed to its abstract legal rights to deny a claim, is critical to evaluating whether a party has defrauded the government intentionally. In particular, and in direct contrast to the opinion below, the Third Circuit

has held that the relator's failure to plead any past government payment denials based on the underlying violation, any previous successful claims based on that violation, or any previous court decision upholding the relator's theory of liability "militates against a finding of materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017).

The Sixth Circuit's holding, on the other hand, incentivizes relators to choose not to plead any allegations about past government payment practices or enforcement efforts, thereby effectively removing that factor from the materiality analysis at the pleading and motion to dismiss stage. That perverse incentive directly contradicts this Court's instruction in *Escobar* that the materiality analysis is not too fact-intensive to consider on a motion to dismiss and allows a relator or the government to satisfy the materiality requirement merely by pleading that the regulation at issue is a condition of payment and could be used to prevent fraud. *See Escobar*, 136 S. Ct. at 2004 n.6. That low standard is not the one that this Court set forth in *Escobar* for implied certification cases.

Regarding scienter, the Sixth Circuit found that the scienter requirement was adequately pled by allegations that implied Brookdale was "on notice that [its] claim-submission process was resulting in potential compliance problems" and "acted with 'reckless disregard' with respect to [its] compliance with 42 C.F.R. § 424.22(a)(2)." Pet. App. 29–30. The Sixth Circuit departed from the scienter requirement established in *Escobar* and now directly conflicts with the D.C. Circuit, which has held that scienter requires showing "that the defendant knows (1) that it violated

a contractual obligation, and (2) that its compliance with that obligation was material to the government's decision to pay." *United States v. Sci. Applications Intern. Corp.*, 626 F.3d 1257, 1271 (D.C. Cir. 2010) (SAIC).

This Court's review is warranted to resolve the direct, irreconcilable, and growing circuit split with respect to two separate issues and to provide government contractors with certainty regarding their potential FCA liability for submitting claims for payment that do not involve any affirmative misrepresentation by the contractor. Allowing the Sixth Circuit's opinion to stand sanctions using the FCA as an all-purpose anti-fraud statute where materiality is satisfied merely because the underlying regulation is labeled a condition of payment and can be said to act as a "mechanism of fraud prevention." Pet. App. 27. This precedent also permits an FCA claim to move forward even where the defendant reasonably believed that the violation at issue was minor or insubstantial and not material to the government's decision to pay claims.

STATEMENT

Petitioners Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit.

1. The FCA was originally enacted in 1863 to prevent contractors during the Civil War from submitting fraudulent or false claims for payment to the U.S. Government. See *United States v. Bornstein*, 423 U.S. 303, 309 (1976). The FCA imposes liability on a person who, among other possible violations, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” or, in relevant part, who “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]” 31 U.S.C. §§ 3729 (a)(1)(A), (a)(1)(G).

Suits may be filed directly by the government or by private citizen “relators,” who file under the FCA’s *qui tam* provisions. 31 U.S.C. §§ 3730(a), (b)(1). A suit under the FCA can represent a financial windfall for relators, who may be rewarded with a portion of any money recovered from the suit—between 15 and 30 percent of the proceeds of the action, plus attorneys’ fees and costs. 31 U.S.C. § 3730 (d)(1)–(2).

Damages under the FCA are “essentially punitive in nature.” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784–85 (2000) (noting that the FCA’s treble damages provision “reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers”).

2. This case involves the provision of home health services between 2010 and 2012. Medicare beneficiaries who are homebound are eligible to receive certain medically necessary services, such as skilled nursing and therapy services, at home. 42 U.S.C. §§ 1395k(a)(2)(A), 1395x(m). To qualify for home health services, Medicare beneficiaries must (1) be

homebound, (2) be under the care of a physician, (3) need intermittent skilled nursing care, physical therapy, or speech language pathology services, (4) be under a plan of care established and periodically reviewed by a physician, and (5) have a face-to-face encounter with a physician during the relevant time period. 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A); 42 C.F.R. § 409.42. CMS will pay for home health services only if a physician certifies that the eligibility requirements have been met. 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A).

Home health services are unique in that they are a form of care that is not provided in an institutional or medical setting but in the patient's home. Thus, the physician is involved throughout a patient's receipt of services but is not present alongside the home health agency personnel who provide care, as a physician would be for inpatient or outpatient hospital services. Home health regulations take into account the flexibility required by this arrangement, allowing the initiation of care and initial billing of services on verbal physician orders, 42 C.F.R. § 409.43(d), and requiring a completed, signed, and dated plan of care only "[b]efore the claim for each episode for services is submitted for the final percentage prospective payment." 42 C.F.R. § 409.43(c)(3).

At issue in this case is the timing of the physician certification of eligibility for home health services. The government first promulgated regulations regarding the physician certification in 1967. *See* Federal Health Insurance Program for the Aged Certification and Recertification, 32 Fed. Reg. 668, 670 (Jan. 4, 1967) (to be codified at 20 C.F.R. pt. 405); Federal Health

Insurance for the Aged Certification and Recertification, 32 Fed. Reg. 9537, 9539 (Jun. 12, 1967) (to be codified at 20 C.F.R. pt. 405). Those initial regulations stated that the certification should be obtained at the time the plan of care is established or “as soon thereafter as possible.” *Id.*

That requirement has not changed since 1967. The current regulations also require that the physician meet face-to-face with the patient within the required timeframe. 42 C.F.R. § 424.22(a)(1). The regulations still require that the physician certification be “obtained at the time the plan of care is established or as soon thereafter as possible.” *Id.* § 424.22(a)(2).¹

A home health agency is not required to submit the physician certification when it bills Medicare, nor does CMS request the timing of the certification on its claim form. Instead, home health agencies retain supporting records and present them when requested. 42 C.F.R. § 424.22(c). CMS maintains several layers of audits, inspections, and reviews through contractors and related agencies to ensure compliance with regulations. *See, e.g.* 42 U.S.C.A. § 1395ddd(a)–(b) (establishing the Medicare Integrity Program, including reviews and audits of home health agencies); 42 U.S.C. §§ 1395h,

¹ This timing requirement stands in contrast to physician certification requirements for other services, like inpatient admissions, which have a “hard” deadline for completion. 42 C.F.R. § 424.13(b) (specifying a certain number of days required for the certification, no later than 20 days into the hospital stay). It is also in contrast with now-repealed regulations for “presumed coverage” for home health services that required a written and signed certification before the first billable visit. *See* 42 C.F.R. § 405.1633 (eff. Jul. 9, 1975).

1395u(a), 1395kk-1 (authorizing administration and payment of claims under Medicare Part A and Part B and the use of Medicare administrative contractors). The Office of the Inspector General for the Department of Health and Human Services (HHS-OIG), for example, routinely publishes detailed reports and findings relating to the post-payment review of claims at home health companies and sets priorities for enforcement actions. *See, e.g.* HHS-OIG, A-02-14-01005, MEDICARE COMPLIANCE REVIEW OF HOME HEALTH VNA FOR 2011 AND 2012, (Jul. 14, 2016); HHS-OIG, SEMIANNUAL REPORT TO CONGRESS (2018).

3. Relator Prather worked as a utilization review (“UR”) nurse for Brookdale Senior Living Inc. from September 2011 through November 2012. Pet. App. 72. Relator alleges that until September 2011, each Brookdale home health agency submitted its own claims directly to Medicare. Third Am. Compl. ¶ 76, ECF No. 98. In September 2011, however, Brookdale centralized billing for most agencies to its corporate office in Tennessee. *Id.* At that time, there was a backlog of about 7,000 unbilled Medicare claims, worth approximately \$35 million. Pet. App. 73. Relator was hired as a UR nurse to assist in reviewing the held claims for “items that needed to be completed before the claim could be released for final billing to Medicare,” which included that orders were signed, face-to-face documentation was complete, and therapy reassessments had been done. Pet. App. 73–74.

Relator does not allege that Brookdale ever submitted a final claim for payment without a signed physician certification. Relator does not allege that Brookdale ever backdated physician certifications to

misrepresent the timing of the signature. Nor does Relator allege that a physician ever certified a patient's eligibility to receive home health services that were not medically necessary. Relator's sole theory of liability is that from 2011 through 2012 Brookdale sometimes submitted bills for home health services where the physician's signature on the certification was not obtained at the time the plan of care was established or "as soon thereafter as possible." Pet. App. 81–82.

On a previous appeal in this case, the Sixth Circuit determined that this theory sufficiently pled the falsity of the home health claims. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 765 (6th Cir. 2016) (*Prather I*). Although no court or government agency had defined "as soon thereafter as possible" in the fifty-year history of the regulation, the Sixth Circuit held in a 2-1 decision that a delay in completing the certification is permitted "only if the length of the delay is justified by the reasons the home-health agency provides for it." *Prather I*, 838 F.3d at 765. The Sixth Circuit did not rely on any government payor decisions, opinions, or enforcement actions in making this determination. Based on statutory interpretation and the court's own finding that a deadline "makes it more difficult to defraud Medicare," the Sixth Circuit held that Relator sufficiently pled a violation of the regulation, satisfying the falsity element of an FCA claim where a home health agency violates this timing-and-explanation requirement. *Id.* at 764–66.

The United States earlier had declined to intervene in the *qui tam* in April 2014. Pet. App. 10. Despite filing Statements of Interest with the district court and

an Amicus Brief with the Court of Appeals, the Department of Justice has refused to take a position on the materiality of the timing-and-explanation requirement created by the Sixth Circuit panel. Likewise, CMS has taken no position on the pending litigation, has not cited to the decision in any pending appeals, and has taken no action to apply the regulation according to the interpretation from the Sixth Circuit.

4. On remand from the first appeal, Brookdale indicated its intention to move to dismiss the Second Amended Complaint in light of this Court's recent decision in *Escobar*. The district court granted leave for Relator to file a Third Amended Complaint to comply with that decision. With respect to materiality, Relator added the conclusory allegation that "[t]he United States, unaware of the falsity of the claims that Defendants submitted, and in reliance on the accuracy thereof, paid Defendants and other health care providers for claims that would otherwise not have been allowed." Pet. App. 21. Relator did not allege that the Government had ever denied payment to Brookdale or any other home health agency for violating the timing-and-explanation requirement in the fifty-year history of the regulation. Relator did not allege that the Government had ever required any explanation or justification for delays in obtaining the physician signature. Nor did Relator plead any facts to establish why or how the Government would have altered its payment decision had it been aware of a delay in obtaining the physician's signature before submitting a claim for medically necessary home health services.

The United States District Court for the Middle District of Tennessee granted Brookdale’s motion to dismiss. Pet. App. 104. The district court considered “all of the factors identified in *Escobar* as relevant to the question of materiality.” Pet. App. 103. First, the district court held that while the provision at issue was an express condition of payment, that was “not dispositive to liability under the FCA.” Pet. App. 93. Next, the district court considered Brookdale’s argument that Relator “fails to allege that the government has ever denied a claim based on a violation of the timing requirements of § 424.22.” Pet. App. 93.

In analyzing the past government action factor, the district court rejected the United States’ argument that “CMS’s failure to act is relevant only where it is shown that CMS approved payment with actual knowledge of the alleged misrepresentations” Pet. App. 93–94. The district court observed that “the timing requirement . . . has been part of the Medicare regulations for fifty years, and home health care is a huge industry making up a significant portion of the millions of Medicare claims submitted every year.” Pet. App. 95. Thus, considering “the sheer volume of claims, the relator’s inability to point to a single instance where Medicare denied payment based on violation of § 424.22(a)(2), or to a single other case considering this precise issue,” the district court concluded that this factor “weighs strongly in favor of a conclusion that the timing requirement is not material.” Pet. App. 95.

After reviewing relevant Medicare regulations and guidance, the district court further concluded that while “the physician certification itself is clearly an essential and material component of the bargain between home health providers and Medicare,” Relator “has not pointed to facts in the record, including conduct on the part of CMS, legal precedent, or relevant Medicare guidance supporting a conclusion that the timing requirement is likewise material.” Pet. App. 103. The district court stated that while the Sixth Circuit might believe the timing requirement to be a mechanism of fraud prevention, “numerous CMS publications from the relevant time period” indicate that it is not. Pet. App. 101.

5. A divided panel of the Sixth Circuit again reversed. The panel majority held that the timing-and-explanation requirement was material because it is an “express condition of payment” and is “a mechanism of fraud prevention.” Pet. App. 27. Crucially, the panel majority held that where the Relator failed to plead facts about whether or how any violation of this regulation had ever affected past government payment decisions, the past government action factor of the materiality analysis could not be considered and could not weigh against finding materiality.

Finally, the panel majority held that Relator adequately pled scienter because her “factual allegations support the inference that the defendants were on notice that their claim-submission process was resulting in potential compliance problems.” Pet. App. 30.

Judge McKeague dissented, writing that “[t]wo years ago, the majority invented a more stringent timing-and-explanation requirement out of whole cloth” and now “decides both that this requirement (created by the court in 2016) was somehow material to the government’s decision to pay claims in 2011 and 2012, and that the defendants knew, seven years ago, that it was material—even though Prather identifies no authority in support of that position.” Pet. App. 32.

Even accepting the majority’s “timing-and-explanation requirement,” Judge McKeague reasoned that to satisfy the materiality requirement, Relator must “plead facts connecting the defendant’s insufficient justifications to Medicare’s decision to pay.” Pet. App. 45. In other words, Judge McKeague would have required Relator to “explain, with particularity, if and how the specific violation would have influenced the government’s payment decision.” Pet. App. 45–46. Judge McKeague noted that Relator did not identify “*any* governmental statements disapproving of Brookdale’s alleged excuses, neither as a per se matter or in the context of these particular delays.” Pet. App. 53.

Describing materiality under *Escobar* as the “lodestar by which the courts separate the careless from the nefarious,” Judge McKeague underscored that enforcing this requirement at the pleading stage is critical for enforcing the notice-providing function of Rule 9. Pet. App. 45. If Relator cannot explain how a specific violation would have influenced the government’s payment decision, “Brookdale is left to guess about how it has allegedly defrauded the government.” Pet. App. 46.

Judge McKeague concluded that “[w]ithout concrete evidence of the government’s payment history or any helpful regulatory guidance,” the relator must provide additional factual allegations regarding why the regulatory violation was material. Pet. App. 55. However, where the timing-and-explanation requirement “sprung, fully formed, from the minds of two federal judges” it is unsurprising that the relator had “no history, commentary, or guidance she can use to demonstrate materiality.” Pet. App. 59.

For similar reasons, Judge McKeague observed that the majority misapplied the FCA’s scienter requirement. Judge McKeague “struggle[d] to see how Brookdale can be held responsible for recklessly disregarding such a specific requirement when nothing—absolutely nothing—in the existing law required it to provide affirmative justifications for late signatures during the billing process.” Pet. App. 61. Relator’s allegations regarding scienter also failed, Judge McKeague reasoned, because allegations relating to general compliance issues had “no relationship to the signatures” and therefore did not show “that Brookdale knew omitting the explanations would influence the government’s payment decisions or that it recklessly disregarded that possibility.” Pet. App. 60–61.

REASONS FOR GRANTING THE PETITION**I. THE DECISION BELOW CONFLICTS WITH THREE OTHER CIRCUITS' APPLICATIONS OF THE FCA'S MATERIALITY REQUIREMENT AND FURTHER WIDENS AN EXISTING CIRCUIT SPLIT.**

Before this Court's decision in *Escobar*, multiple circuit courts had determined that the implied false certification theory of liability was not viable under the FCA. *See United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711–12 (7th Cir. 2015); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010). Those courts stated that regulatory violations should not be enforced under the FCA and instead are “for the agency—not a court—to evaluate and adjudicate.” *Sanford-Brown, Ltd.*, 788 F.3d at 712. Those courts were concerned that the FCA would be used as a “blunt instrument to enforce compliance” with all regulations. *Id.* (quoting *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001)); *see also Steury*, 625 F.3d at 268.

In *Escobar*, this Court held that implied false certification is a viable theory but that it may only apply if the underlying statutory, regulatory, or contractual violation is material to the government's payment decision. *Escobar*, 136 S. Ct. at 2002. In doing so, the Court recognized that the materiality standard plays a significant role in cabining potential liability under the FCA and preventing its transformation into an “all-purpose antifraud statute” or “a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Id.* at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

This Court rejected that materiality was too fact intensive for courts to dismiss FCA cases at the pleading stage, instead stating that the standard is a “familiar and rigorous one.” *Id.* at 2004 n.6.

The Court stated that it is not sufficient to find materiality where the government “would have the option to decline to pay if it knew of the defendant’s noncompliance.” *Id.* at 2003. Instead, the “rigorous” and “demanding” materiality analysis focuses on the actual behavior of the government in light of statutory, regulatory, or contractual violations. *Id.* at 2003, 2004 n.6. The Court explained that materiality “cannot be found where noncompliance is minor or insubstantial.” *Id.* at 2003. It noted that “the Government’s decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive.” *Id.* Proof of materiality may include “evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” *Id.*

This case asks the inverse—whether a court may consider in its materiality analysis the failure to plead facts regarding the government’s response to the mine run of cases involving noncompliance with the particular statutory, regulatory or contractual requirement.

In short, the Sixth Circuit approach precludes courts from considering a relator’s failure to plead what this Court specifically identified as proof of materiality. *Escobar*, 136 S. Ct. at 2003. The Sixth Circuit erred by holding that the failure to plead past government action concerning a regulation that has existed nearly

as long as the Medicare program itself can have no bearing on the materiality analysis. The analysis envisioned in *Escobar* is turned on its head where a court considers only the abstract legal rights to deny a claim and forecloses analyzing the actual action *or inaction* of the government in light of a potential violation.

This holding has deepened an already existing circuit split regarding the application of *Escobar* at the pleading stage. The Sixth Circuit's holding that the lack of any allegations about past government action "has no bearing on the materiality analysis," Pet. App. 22–23, is directly opposed to the Third Circuit, which held that "where a relator does not plead that knowledge of a violation could influence the Government's decision to pay, the misrepresentation likely does not 'have a natural tendency to influence payment' as required by the statute." *Petratos*, 855 F.3d at 490 (internal alterations omitted) (quoting 31 U.S.C. § 3729(b)(4)). "At a minimum, this would be 'very strong evidence' that the misrepresentation was not material." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003). To support its finding of immateriality, the court in *Petratos* explicitly considered that the relator "fail[ed] to plead that CMS 'consistently refuses to pay' claims like those alleged [here]." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003).

The Sixth Circuit's analysis is in contrast to the published opinions of at least three other circuits and goes even further than the Ninth Circuit, which employs a similarly permissive pleading standard for materiality.

A. Three circuits recognize that the actual behavior of the government is critical to the materiality analysis at the pleading stage.

The majority of circuit courts applying *Escobar*, including the First, Third, and Fourth Circuits, have held that pleading facts showing that the government's payment decision would be affected by the violation in question is critical to the materiality analysis at the pleading stage. This is true both for cases where the underlying conduct is known to the government, but also where it is not known. These courts reject a reading of *Escobar* that might significantly expand FCA liability to situations where the government may have the "option to decline" payment for the underlying violation or where the government has signaled no interest in the issue. *Escobar*, 136 S. Ct. at 2003. These courts instead require relators to plead some facts showing that the government would not have paid the claims at issue had it known of the underlying deficiencies.

In *Petratos*, the relator alleged that Genentech, a drug manufacturer, concealed information about one of its cancer drugs that would have revealed severe side effects. *See* 855 F.3d at 485. Like in *Prather*, there were no allegations that the government knew about the underlying misrepresentations until after the suit was filed. The Third Circuit affirmed dismissal of the suit on materiality grounds.

In addressing the pleadings, the court noted that "there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured." *Id.* at 490

(alterations in original) (quoting the findings of the district court). The court stated that “where a relator does not plead that knowledge of a violation could influence the Government’s decision to pay, the misrepresentation likely does not ‘have a natural tendency to influence payment’ as required by the statute.” *Id.* at 490 (internal alterations omitted) (quoting 31 U.S.C. § 3729(b)(4)). “At a minimum, this would be ‘very strong evidence’ that the misrepresentation was not material.” *Id.* (quoting *Escobar*, 136 S. Ct. at 2003).

The court rejected the relator’s argument that he sufficiently pled materiality by alleging that the defendants’ misstatements caused individual physicians to prescribe medications that they otherwise would not have. Such evidence of causation cannot substitute for allegations of materiality, which asks “whether the government’s payment decision is affected” *Id.* at 492. Like the district court in this case, the Third Circuit held that the relator’s failure to plead past government payment denials of similar claims or to identify “a single successful claim” under the relator’s theory of liability “or a court decision upholding such a theory” weighed against finding materiality. *Id.* at 490.

The First Circuit similarly rejected an argument that false statements were material where they “could have” influenced the government’s FDA approval of the drug at issue, requiring that the relator plead facts showing that underlying misrepresentations are “material to the government’s payment decision itself.” *D’Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016). In *D’Agostino*, the relator could not claim that FDA

approval for certain devices was “fraudulently obtained” where he failed to plead that the FDA took any action, either to investigate, audit, or withdraw approval for certain devices after learning of misrepresentations by the defendants. *Id.* at 8. In denying the relator’s request to amend his complaint as futile, the First Circuit stated that the relator “may well misconstrue” materiality under *Escobar* and “[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so.” *Id.* at 7–8.

The First Circuit reaffirmed that view in a similarly situated case also resting on alleged false statements to the FDA. *See United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 36 (1st Cir. 2017), *cert. denied*, (Apr. 16, 2018) (No. 16-1442). In that case, the relator alleged that DePuy Orthopaedics made material false statements to the FDA that influenced CMS’s decision to pay for certain medical devices. The First Circuit specifically considered the relator’s failure to plead facts regarding subsequent actions by the FDA. Where there was “no allegation that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations,” this was “very strong evidence that those requirements are not material.” *Id.* at 35. This evidence was particularly “compelling” when the FDA “armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position.” *Id.*

These courts have rightly focused their materiality analyses on the actual behavior of the government. In a case in the Fourth Circuit, the relator alleged that the defendant failed to provide adequate security services at Al Asad Airbase in Iraq. *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 175 (4th Cir. 2017), *cert. dismissed*, 138 S. Ct. 370 (2017). The relator alleged that “Triple Canopy brought in guards from Uganda who were unable to meet . . . marksmanship requirement[s]” and falsified scorecards indicating that they did. *Id.* at 175–76. The government intervened and filed its own complaint. *See id.* at 176.

The Fourth Circuit found that the government’s complaint successfully stated a claim and that the government had pled materiality sufficiently. *See id.* at 178. In addition to finding the omissions material due to “common sense” and Triple Canopy’s covering up the misrepresentations, the court also relied on the government’s actions. *Id.* The court found highly relevant to the materiality analysis that the government “did not renew its contract” and then “immediately intervened” in the underlying action. *Id.* at 179.

These courts understood that the failure to plead facts about past government action with respect to the alleged violation can and often should weigh against finding materiality. Because the materiality analysis is holistic and no one factor is dispositive, pleading past government action is not a requirement for pleading materiality. But allegations of past government action—or the lack thereof—at least should be relevant to the materiality analysis. Considering whether an FCA complaint includes such allegations comports with this

Court's decision in *Escobar* and ensures reasonable limits on FCA liability.

B. The Ninth and Sixth Circuits' materiality analysis conflicts with the analysis adopted by the First, Third, and Fourth Circuits.

The Sixth Circuit now joins the Ninth Circuit in refusing to consider as relevant to the materiality analysis a complaint's lack of allegations of any past government action with respect to the alleged violation at issue. A court's refusal to consider that pleading failure in determining materiality allows a relator or the government to ignore or disregard the past government action factor at the pleading stage simply by electing not to plead any such allegations. By focusing solely on the potential legal rights of government entities to deny payment, as opposed to their action or inaction in the face of regulatory non-compliance, these circuits have created a separate and lower standard that cannot be reconciled with the analyses of the First, Third, and Fourth Circuits as discussed above.

In *Campie*, the Ninth Circuit reversed the lower court's dismissal of the relators' implied false certification claims. *See* 862 F.3d at 895. The relators alleged that Gilead bought unapproved ingredients from an unapproved manufacturing facility for certain HIV drugs, which allegedly resulted in the submission of false claims. *See id.* at 899.

In analyzing materiality, the Ninth Circuit rejected Gilead's argument that the claims were not material because past government actions showed that the FDA

continued to approve the drugs despite knowing of the violations. *See id.* at 906. The court acknowledged that “[a]lthough it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us.” *Id.* at 907. The relators had elected not to plead facts relating to the government’s payment practices, but the Ninth Circuit did not consider that lack of allegations as part of its materiality analysis. The relators stated a viable claim because they alleged “more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations” *Id.* In other words, the Ninth Circuit determined that the regulatory violation could constitute fraud, even where the FDA had declined to do so.

The Sixth Circuit, citing *Campie* in its analysis, goes even further. It states categorically that where a relator elects not to plead facts relating to the government’s past actions with respect to the underlying violation, the lack of such allegations “has no bearing on the materiality analysis.” Pet. App. 22–23. As such, district courts in the Sixth Circuit now may not consider a relator’s or the government’s failure to plead facts relating to past government actions. That holding applies to all FCA cases even where, as here, the regulation at issue has existed for decades, and public information about the government’s enforcement actions during that time period—or lack thereof—is readily available. In the Sixth Circuit, if a relator or the government chooses not to plead past government actions—which they now are highly incentivized not to do—the court’s materiality analysis is limited to whether a regulation is designated a

“condition of payment,” Pet. App. 16, and whether the court deems the regulation to go to the “essence of the bargain,” Pet. App. 23, between the government and the defendant or can act as a “mechanism of fraud prevention.” Pet. App. 27. This returns the Sixth Circuit to the standard for pleading materiality that was in place prior to *Escobar*. See, e.g., *United States ex rel. Hobbs v. Medquest Assocs., Inc.*, 711 F.3d 707, 717 (6th Cir. 2013) (holding that false certification liability turns on whether the regulation in question is a “condition of payment” or a “condition of participation”).

Courts have recognized *Campie*’s incompatibility with the majority view that a lack of allegations about past government action can be relevant to the materiality analysis. The First Circuit observed that the Ninth Circuit’s decision in *Campie* “offers no rebuttal at all to [the] observation that six jurors should not be able to overrule the FDA.” *Nargol*, 865 F.3d at 36 (citing *D’Agostino*, 845 F.3d at 8). The court further stated that “it offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything. Instead, it decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solutions can be envisioned, even in theory.” *Id.*

Extensive disagreement among circuits as to whether the failure to plead facts regarding past government action with respect to the underlying violation can weigh against a finding of materiality presents a compelling reason for this Court to grant review.

II. THE DECISION BELOW CONFLICTS WITH THIS COURT’S DECISION IN *ESCOBAR* AND DEEPENS A CIRCUIT SPLIT AS TO WHETHER THE FCA’S SCIENTER ELEMENT REQUIRES THAT THE DEFENDANT POSSESS KNOWLEDGE OF MATERIALITY.

Like the FCA’s materiality requirement, the FCA’s rigorous scienter requirement “help[s] to ensure that ordinary [violations of statutory, regulatory, or contractual requirements] are not converted into FCA liability.” *SAIC*, 626 F.3d at 1271. “[C]oncerns about fair notice and open-ended liability ‘can be effectively addressed through strict enforcement of the Act’s materiality and scienter requirements.’” *Escobar*, 136 S. Ct. at 2002 (quoting *SAIC*, 626 F.3d at 1270).

In *Escobar*, this Court held that FCA liability in implied false certification cases turns on “whether the defendant *knowingly* violated a requirement that the defendant *knows* is material to the Government’s payment decision.” *Id.* at 1996 (emphasis added). The FCA defines “knowing” and “knowingly” as “actual knowledge,” “deliberate ignorance,” or “reckless disregard.” 31 U.S.C. § 3729(b)(1)(A). Thus, to establish scienter under the FCA, a relator must show that the defendant knew (1) that it violated a legal requirement and (2) that that requirement was material to the government’s payment decision.

Despite the language in the *Escobar* opinion, circuits have split deeply regarding the proper standard for adequately pleading knowledge under the FCA. Because the Sixth Circuit did not require Relator to show that Brookdale knew its compliance with the timing-and-explanation requirement was material to

the government’s decision to pay, the Sixth Circuit is in conflict with the D.C. and Eleventh Circuits about whether the FCA’s scienter requirement requires the plaintiff to establish the defendant’s knowledge of materiality. The Sixth Circuit instead joins five circuits in not requiring allegations that establish knowledge of materiality. This Court’s review is warranted to clarify how the rigorous scienter requirement should be enforced.

A. Circuit courts have split deeply regarding whether the FCA requires that the defendant possessed knowledge of materiality.

Prior to *Escobar*, circuit courts analyzing scienter under the FCA generally required a relator or the government to allege only that the defendant possessed knowledge of its legal violation. *See, e.g., United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 259–60 (5th Cir. 2014) (“To meet the ‘requisite scienter’ requirement, the United States must plead that Bollinger acted with knowledge of the falsity of the statement”); *United States ex rel. Hill v. City of Chicago*, 772 F.3d 455, 456 (7th Cir. 2014) (“[W]ithout knowledge of falsity there cannot be a knowingly false claim”). In fact, the First Circuit explicitly rejected the argument that a defendant must possess knowledge of materiality to establish FCA scienter. *See United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 312–13 (1st Cir. 2010) (“Unum’s claim that the FCA requires that a defendant have knowledge that a claim was materially false is a misreading of the statute and of *Allison Engine*.”).

There was one exception. In *SAIC*, which this Court cited approvingly in *Escobar*, the D.C. Circuit held that “[e]stablishing knowledge under [§ 3729(a)(1)(A)] on the basis of implied certification requires the plaintiff to prove that the defendant knows (1) that it violated a contractual obligation, and (2) that its compliance with that obligation was material to the government’s decision to pay. If the plaintiff proves both, . . . then it will have established that the defendant sought government payment through deceit, surely the very mischief the FCA was designed to prevent.” *SAIC*, 626 F.3d at 1271.

Since *Escobar* was issued, the Eleventh Circuit has joined in holding that the FCA’s “scienter requirement means that a plaintiff must show that the defendant had actual knowledge of or recklessly disregarded a condition’s materiality.” *United States ex rel. Marstellar v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018) (remanding case to district court for reconsideration in light of *Escobar*).

However, in addition to the Sixth Circuit, five other courts of appeals applying the FCA’s scienter requirement since *Escobar* have failed to require the plaintiff to show knowledge of materiality. See *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 657 (5th Cir. 2017) (“[T]he relator must demonstrate that the defendant ‘acted with knowledge of the falsity of the statement’” (quoting *Bollinger Shipyards*, 775 F.3d at 259–60)); *United States ex rel. Sheet Metal Workers Int’l Ass’n, Local Union 20 v. Horning Invs., LLC*, 828 F.3d 587, 593 (7th Cir. 2016) (“[T]he defendant must ‘have acted with actual knowledge, or with deliberate ignorance or reckless

disregard to the possibility that the submitted claim was false.” (quoting *United States v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013)); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016) (“Fraudulent inducement requires a plaintiff to show . . . the defendant knew the statement was false”); *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1176 (9th Cir. 2016) (scienter satisfied by allegation that the defendant “failed to make simple inquiries which would alert him that false claims are being submitted”); *United States ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018) (“Dr. Polukoff adequately alleges that Dr. Sorensen performed unnecessary PFO closures on patients and then knowingly submitted false certifications to the federal government that the procedures were necessary”).

Thus, the majority of appellate courts conducting the scienter analysis since *Escobar* have ignored *Escobar*’s directive that a defendant must know that its violation is material to the government’s payment decision. This Court must intervene to directly address that FCA scienter in an implied certification case requires the plaintiff to show that the defendant possessed knowledge of materiality.

B. The Sixth Circuit’s interpretation of the scienter requirement conflicts with *Escobar* because it requires an FCA plaintiff to establish only that the defendant possessed knowledge of falsity.

In concluding that the scienter requirement was satisfied, the panel majority relied on allegations that Relator and other UR nurses “were instructed to review the claims only cursorily” and “raised concerns about the defendants’ compliance with Medicare regulations,” and that Brookdale knew some physicians might not sign certifications after patient discharge. Pet. App. 29. “All these factual allegations,” the panel majority reasoned, “support the inference that [Brookdale was] on notice that [its] claim-submission process was resulting in potential compliance problems.” Pet. App. 30. Because Brookdale allegedly failed to investigate that noncompliance, the panel majority found that Brookdale “acted with ‘reckless disregard’ as to the truth of their certification of compliance and to whether these requirements were material to the government’s decision to pay.” Pet. App. 30–31.

The panel majority’s scienter analysis conflicts with *Escobar* because it does not require any independent showing that the defendant possessed knowledge of materiality. To the contrary, the panel majority found scienter satisfied despite the complete lack of any factual allegation that Brookdale actually knew or was on notice that noncompliance with the signature-and-timing requirement would affect the government’s payment decision. Thus, for the panel majority, FCA scienter was satisfied merely by the allegation that

Brookdale was “put on notice that [it] may be violating regulations.” Pet. App. 31 n.11.

Interpreted this way, the scienter requirement cannot effectively address concerns about fair notice and open-ended liability in implied false certification cases because it allows a plaintiff to impose FCA liability on a defendant regardless of the defendant’s understanding of the consequences of its noncompliance. Under the panel majority’s analysis, defendants can be held liable under the FCA for violations they reasonably believe only to be “minor or insubstantial,” or when they have no knowledge “that the Government consistently refuses to pay claims in the mine run of cases based on [such] noncompliance.” *Escobar*, 136 S. Ct. at 2003. This is not the type of behavior the FCA is meant to punish. “[B]illing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations.” *Id.* at 2002.

Judge McKeague explained in his dissent why the panel majority’s scienter analysis led to an over-expansion of FCA liability in this case. “The timing-and-explanation requirement did not exist until we decided *Prather I* in 2016 [B]efore *Prather I*, no one had any reason to think that this regulation required HHAs to submit explanations for late signatures I struggle to see how Brookdale can be held responsible for recklessly disregarding such a specific requirement when nothing—absolutely nothing—in the existing law required it to provide affirmative justifications for late signatures during the

billing process.” Pet. App. 61. Had the panel majority required Relator to show Brookdale’s knowledge of materiality, the district court’s dismissal would have been upheld because Relator offers no such allegations in her complaint.

III. THE SIXTH CIRCUIT’S ERRONEOUS READING OF *ESCOBAR* RAISES ISSUES OF EXCEPTIONAL IMPORTANCE TO ALL GOVERNMENT CONTRACTORS.

A. Wresting regulatory authority from the governing agencies stands to create substantial potential liability for all government contractors.

Where the materiality analysis centers on the abstract legal rights of the payor rather than on the government agency’s actions in practice, relators and courts are able to substitute their judgment as to what constitutes fraud, as seen in the opinion below. Refusing to consider as relevant to materiality whether the relator offers any allegations about the government’s actual payment practices threatens to widely expand potential liability under the FCA and undermine protections embedded in the formal regulatory structure.

In establishing the “timing-and-explanation” requirement for physician certification documents as material for home health claims, the Sixth Circuit relied on the designation of the regulation as a condition of payment, the court’s previous analysis that the regulation was a mechanism for “fraud prevention,” and the fact that a physician certification was mentioned in name only in some OIG reports. Pet.

App. at 25, 27. Critically, the Sixth Circuit deemed irrelevant whether any of the publicly available OIG reports analyzing home health claims, ALJ or federal court opinions analyzing claims denials, or any other adjudications relating to home health claims could provide Relator with any facts to support whether the government ever has or likely would deny claims based on the timing of the physician's certification. The absence of such facts is unsurprising, however, since the requirement "sprung, fully formed, from the minds of two federal judges" and not from CMS. Pet. App. at 59.

Now, 12,000 home health agencies across the country are left to determine whether this new requirement applies to the more than \$18 billion in home health claims paid by Medicare each year. *See* MedPac, Health Care Spending and the Medicare Program 111 (June 2018). As this requirement did not come through notice-and-comment rule making, the agencies have no mechanism for obtaining guidance or clarification on the requirement. Instead, they stand to be potentially liable for fraud.

Home health agencies will be forced to choose whether to follow the consistent, decades-long practice of obtaining the certification before submitting the final bill for services or to follow the "timing-and-explanation" requirement as it has now been established in the Sixth Circuit.

However, the potential liability is far broader than just for home health agencies. If all that is required to establish materiality under the FCA is a condition of payment label and a court's pronouncement that the regulation is a "mechanism of fraud prevention," there

is virtually no limitation on potential liability for government contractors or on the type of regulation that might be used to support such liability.

The Sixth and Ninth Circuits' approach returns the materiality analysis to a pre-*Escobar* standard and transfers regulatory authority from government agencies to relators and courts. Judge McKeague's admonition to "[l]eave rulemaking to the legislators and administrators" is well taken. Pet. App. 60.

B. The Sixth Circuit's holding creates a double standard for pleading materiality in intervened and non-intervened actions.

Refusing to consider a relator's failure to plead facts regarding the government's actual behavior in light of the alleged underlying violation also creates a double standard for pleading materiality in cases where the United States intervenes as opposed to cases where it declines to intervene. Had the United States intervened in this case, or in *Campie*, a court would expect the United States to plead facts about whether it has ever denied payment based on the violations at issue or instituted any enforcement actions based on such violations. As noted above, courts have considered as part of the materiality analysis the government's actions taken after learning of the violations. *See Triple Canopy*, 857 F.3d at 179.

By refusing to consider the absence of such allegations in this case, the Sixth Circuit adopted a lower, watered-down standard for a relator to plead materiality in a declined case. That holding risks

creating two separate bodies of case law depending on whether the government intervenes in the action.

Moreover, a materiality analysis that does not consider the actual behavior of the government when a relator elects to plead no facts about such actions or inactions incentivizes relators to omit adverse facts, including that the government has never enforced a particular regulation in the manner that the relator alleges gives rise to fraud. In also invites relators to base FCA claims on trivial regulations that have never been the basis for claim denials or enforcement actions with full confidence that that fact cannot even be considered at the pleading stage or stop relators from reaching the discovery phase on their claims.

C. The government is already using the Sixth Circuit’s decision to advocate for a watered-down pleading standard for fraud claims and a rejection of the materiality analysis at the pleading stage.

Finally, the importance of this case is underlined by the government’s behavior in its wake. In multiple statements of interest and briefs as amicus curiae, where the government has officially declined intervention in the case but maintains an “interest” in the outcome of the litigation, it has advocated for a materiality standard that seeks to move the law back to pre-*Escobar* standards. See Statement of Interest of the United States at 2, *United States ex rel. Roshan v. E. Tex. Med. Ctr., et al.*, No. 6:16-cv-1128 (E.D. Tex. Oct. 5, 2018) (*Roshan SOI*); Brief for the United States of America as Amicus Curiae Supporting Appellant,

United States ex rel. Ruckh v. Salus Rehab., LLC, 2018 WL 3621854 at *20 (11th Cir. Jul. 20, 2018).

In *Roshan*, the Department of Justice cited *Prather* for the proposition that FCA materiality requires only that the relator adequately plead “any one of the *Escobar* materiality factors” in order to survive a motion to dismiss. *Roshan SOI* at 4. Thus, the government’s position is that a relator may plead only that the provision is a condition of payment and that that pleading satisfies the materiality standard.

Further, it appears that the government is taking the position that the decisions in *Prather* and *Campie* suggest that “the holistic nature of the materiality inquiry can render it inappropriate for resolution as a matter of law.” *Ruckh*, 2018 WL 3621854 at *20. That argument is at odds with the clear language of *Escobar*, which expressly rejected any assertion that a rigorous materiality analysis is “too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment.” 136 S. Ct. at 2004 n.6.

It is clear that the Department of Justice intends to use *Prather* as a key weapon in seeking to return the materiality analysis to pre-*Escobar* standards where regulatory violations are material just because the government says they are. This Court’s intervention is required to prevent further deterioration of the materiality standard.

CONCLUSION

The petition for a writ of certiorari should be granted.

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Respectfully submitted,

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November 20, 2018

APPENDIX

APPENDIX

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COUNSEL

ARGUED: Patrick Barrett, BARRETT LAW OFFICE, PLLC, Nashville, Tennessee, for Appellant. Brian D. Roark, BASS, BERRY & SIMS PLC, Nashville, Tennessee, for Appellees. Megan Barbero, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus Curiae. **ON BRIEF:** Patrick Barrett, BARRETT LAW OFFICE, PLLC, Nashville, Tennessee, Michael Hamilton, PROVOST UMPHREY LAW FIRM, LLP, Nashville, Tennessee, for Appellant. Brian D. Roark, J. Taylor Chenery, Angela L. Bergman, BASS, BERRY & SIMS PLC, Nashville, Tennessee, for Appellees. Megan Barbero, Charles W. Scarborough, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus Curiae.

MOORE, J., delivered the opinion of the court in which DONALD, J., joined. McKEAGUE, J. (pp. 22–43), delivered a separate dissenting opinion.

OPINION

KAREN NELSON MOORE, Circuit Judge. Brookdale Senior Living Communities employed Marjorie Prather to review Medicare claims prior to their submission for payment. Many of these claims were missing the required certifications from physicians attesting to the need for the medical services that the defendants had provided. These certifications need to “be obtained at the time the plan of care is established or as soon thereafter as possible.” 42 C.F.R. § 424.22(a)(2). But the defendants were allegedly obtaining certifications months after patients’ plans of care were established.

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In July 2012, Prather filed a complaint pleading violations of the False Claims Act under an implied false certification theory. The district court dismissed her complaint, holding that Prather did not allege fraud with particularity or that the claims were false. This panel reversed the district court in part, holding that Prather had pleaded two of her claims with the required particularity and that the claims submitted were false. *United States ex rel. Prather v. Brookdale Senior Living Cmities., Inc. (Prather I)*, 838 F.3d 750, 775 (6th Cir. 2016). In doing so, we interpreted the phrase “as soon thereafter as possible” in 42 C.F.R. § 424.22(a)(2) to mean that a delay in certification is “acceptable only if the length of the delay is justified by the reasons the home-health agency provides for it” and held that the reason alleged for the defendants’ delay was not justifiable. *Id.* at 765.

On remand, the district court granted Prather leave to file her Third Amended Complaint (“complaint”) in light of the Supreme Court’s clarification of the materiality element of a False Claims Act claim in *Universal Health Services., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S. Ct. 1989 (2016). The defendants moved to dismiss again on the grounds that Prather did not plead sufficiently the materiality and scienter elements of her two alleged False Claims Act violations. The district court granted that motion, and Prather now appeals. For the reasons set forth below, we **REVERSE** the district court’s dismissal of Prather’s complaint and **REMAND** for proceedings consistent with this opinion.

I. BACKGROUND

A. Legal Background

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, imposes civil liability that is “essentially punitive in nature” on those who defraud the U.S. government. *Escobar*, 136 S. Ct. at 1996 (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000)). Here, Prather is asserting a theory of liability under the False Claims Act known as “implied false certification.” Under this theory, “liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s non-compliance with a statutory, regulatory, or contractual requirement.” *Id.* at 1995. This misrepresentation through omission “renders the claim ‘false or fraudulent’ under § 3729(a)(1)(A).” *Id.* “A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision in order to be actionable under the False Claims Act.” *Id.* at 1996.

The claims and alleged misrepresentations at issue in this case arise in the context of Medicare and home-health services. Medicare Parts A and B provide coverage for certain home-health services. *Prather I*, 838 F.3d at 755 (citing 42 U.S.C. §§ 1395c and 1395k(a)(2)(A)). These services include: “skilled nursing services, home health aide services, physical therapy, speech-language pathology services, occupational therapy services, and medical social services.” *Id.* (internal quotation marks and brackets denoting alterations omitted). “Medicare Part A or Part B pays

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for home health services only if a physician certifies and recertifies' the patient's eligibility for and entitlement to those services." *Id.* (quoting 42 C.F.R. § 424.22).

These certifications are projections about the patient's medical need and plan of care, and Medicare payments for the care provided are made on a prospective system of 60-day periods, known as an "episode of care." *Id.* at 756. Payments for each episode are made in two parts. The initial payment—the "request for anticipated payment" or "RAP"—is a percentage of the total expected reimbursement. *Id.* (citing 42 C.F.R. § 484.205(b)). The second payment—the "residual final payment"—is disbursed at the end of the episode. *Id.* (citing 42 C.F.R. § 484.205(b)).

"The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan." 42 C.F.R. § 424.22(a)(2). This regulation "permits a home-health agency to complete a physician certification of need after the plan of care is established, but . . . such a delay [is] acceptable only if the length of the delay is justified by the reasons the home-health agency provides for it." *Prather I*, 838 F.3d at 765.¹ If the required certification was not obtained in

¹The dissent attempts to re-litigate the issues decided in *Prather I*, including efforts to muddy the holding of that decision. Dissent Op. at 22, 30–31, 39–40. Both 42 C.F.R. § 424.22(a)(2) and our corresponding interpretation are not hard to understand. Certifications are timely in two situations. First, they are timely

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compliance with the timing requirement in 42 C.F.R. § 424.22(a)(2), the RAP and final payment claims are “impliedly false.” *Id.* at 766–67.

B. Factual Background

Prather, the relator in this case, “was employed by Brookdale Senior Living, Inc. as a Utilization Review Nurse from September of 2011 until November 23,

if they were “obtained at the time the plan of care is established.” 42 C.F.R. §424.22(a)(2). This is a binary rule: either the certification was obtained at the time the plan of care was established or it was not. Second, certifications are timely if they were signed as soon as possible after the plan of care is established. *Id.* This is a standard. Although the dissent is unhappy that it is a standard and not a rule, Dissent Op. at 30, this was how the regulation was written and neither we, the parties, nor the U.S. government can pretend this away. *Prather I*, 838 F.3d at 765 n.6. The strength, and weakness, of standards is that they are fact-specific in their application. Thus, whether a certification complies with the standard that it be signed “as soon thereafter as possible,” 42 C.F.R. § 424.22(a)(2), depends on the reason it was not completed at the time the plan of care was established. Imagine if the certification is signed one day after the plan of care is established. The reason? The certifying physician had to leave work early the day before because of a family emergency, and therefore delayed signing the certification. In this hypothetical, the length of the delay—one day—is plausibly justified by the reason for the delay—a personal emergency. Now imagine another certification that is signed months after the plan of care was established. In this case, the reason is because the home-healthcare provider is incompetent with its paperwork. This appears to be a situation in which the delay of several months is not justified by the excuse. This is a commonsense approach to which we continue to adhere.

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2012.”² R. 98 (Third. Am. Compl. ¶ 10) (Page ID #1462). Defendant Brookdale Senior Living, Inc., along with defendants Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC, “are interconnected corporate siblings who operate senior communities, assisted living facilities, and home health care providers.” *Id.* ¶ 3 (Page ID #1460).

Prather alleges that it was the defendants’ policy to “enroll[] as many of their assisted living facility residents as possible in home health care services that were billed to Medicare,” *id.*, even when these treatments “were not always medically necessary or did not need to be performed by nurses who billed to Medicare.” *Prather I*, 383 F.3d at 765; R. 98 (Third. Am. Compl. ¶¶ 70, 105, 110) (Page ID #1477, 1486, 1488). This “aggressive solicitation of their senior community and assisted living facility residents ultimately generated thousands of Medicare claims that were ‘held’ because they did not meet basic Medicare requirements” R. 98 (Third Am. Compl. ¶ 3) (Page ID #1460). “In September of 2011, there was a large backlog of about 7,000 unbilled Medicare claims worth approximately \$35 million.” *Id.* ¶ 77 (Page ID

² These facts are drawn from Prather’s complaint and attached exhibits. R. 98 (Third. Am. Compl.) (Page ID #1459–96). Because of the case’s procedural posture—it is before us on an appeal from the district court’s grant of a motion to dismiss—we presume all factual allegations in the complaint to be true. Furthermore, as this court and the parties are familiar with the basic factual allegations in this case, we recite only those alleged facts that are relevant to the issues currently being litigated before us.

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#1478). To facilitate the processing of these claims, the defendants initiated the “Held Claims Project,” and Prather was hired to work on this specific assignment. *Id.* ¶ 77–80 (Page ID #1478–49).

Prather’s job responsibilities included:

(1) pre-billing chart reviews in order to ensure compliance with the requirements and established policies of Defendants, as well as state, federal, and insurance guidelines; (2) working directly with the Regional Directors, Directors of Professional Services, and clinical associates to resolve documentation, coverage, and compliance issues; (3) acting as resource person to the agencies for coverage and compliance issues, (4) reviewing visits utilization for appropriateness pursuant to care guidelines and patient condition; and (5) keeping Directors of Professional Services apprised of problem areas requiring intervention.

Id. ¶ 80 (Page ID #1479).

The Held Claims Project team “used a ‘billing release checklist’ to identify items that needed to be completed before [a] claim could be released for final billing to Medicare.” *Id.* ¶ 82 (Page ID #1480). The checklist and corresponding documents for each claim were then given to the billing office. *Id.* Once the billing office had all the documentation required, it submitted the bill to Medicare. *Id.*

One of the required documents frequently missing was the physician certification. Initially, Prather and the other project members “sent attestation forms to doctors for them to sign to correct the problem of

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missing signatures,” but they “only received a few signed and completed forms back from the doctors.” *Id.* ¶ 86 (Page ID #1481). Beginning in May 2012, to facilitate the process of gathering the required certifications, “Defendants paid physicians to review outstanding held claims and sign orders for previously provided care.” *Id.* ¶ 98 (Page ID #1483). Additionally, team members visited physicians in order to obtain certifications. *Id.* ¶ 104 (Page ID #1818–19). Prather also alleges that the defendants repeatedly “billed RAPs without having physician certifications, and then re-billed them immediately after the RAPs were canceled in order to keep the funds received through the RAPs, while still lacking the required physician certifications.” *Id.* ¶ 99 (Page ID #1484).

Prather alleges that she, and the other employees in the Held Claims Project, “raised concerns” about “compliance problems” with supervisors. *Id.* ¶ 91–92 (Page ID #24). But the defendants told the utilization review nurses to ignore problems they found and only cursorily to review the documentation. *Id.* ¶ 23, 91, 94–95 (Page ID #1481–83). In response to Prather’s repeated comments to her supervisors that she was discovering compliance issues, she was told that the defendants could “just argue in our favor if we get audited.” *Id.* ¶ 114 (Page ID #1489).

To support her allegations that the defendants failed to comply with the timing requirement in 42 C.F.R. § 424.22(a)(2), Prather included five examples in her complaint and incorporated by reference two exhibits containing spreadsheets listing information about hundreds of other untimely certifications. In the examples in her complaint, Prather describes physician

certifications obtained from a few months to nearly a year after an episode of care began. *Id.* ¶ 104–13 (Page ID #1485–89). In her attached Exhibit A, Prather identifies 489 claims submitted to Medicare for which she alleges “Defendants did not obtain the required physician certification of need until after the episode was complete and/or the patient was discharged.” *Id.* ¶ 115–17 (Page ID #1489–90); R. 98-1 (Third Am. Compl. Ex. A) (Page ID #1497–1520). Similarly, in Exhibit B, Prather identifies 771 claims that were allegedly submitted to Medicare with physician certifications of the required face-to-face encounter that were not obtained “until after the patient had been discharged and/or the episode was complete.” R. 98 (Third Am. Compl. ¶ 118–20) (Page ID #1491); R. 98-2 (Third Am. Compl. Ex. B) (Page ID #1521–54).

C. Procedural History

Prather filed her complaint in this lawsuit under seal in July 2012 asserting multiple False Claim Act violations and state-law claims. R. 1 (Sealed Compl. at 28–45) (Page ID #28–45). In April 2014, the United States declined to intervene, and Prather’s complaint was unsealed and served on the defendants. R. 23 (Notice of Election to Decline Intervention) (Page ID #103–04); R. 24 (Apr. 10, 2014 Dist. Ct. Order) (Page ID #107–08). Before the defendants had responded to the initial complaint, Prather filed her First Amended Complaint. R. 52 (First Am. Compl.) (Page ID #178–211). The defendants subsequently moved to dismiss for failure to comply with Federal Rule of Civil Procedure 9(b), R. 56 (First Mot. to Dismiss at 1) (Page ID #217), and the district court granted the motion

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without prejudice, R. 71 (Mar. 31, 2015 Dist. Ct. Op.) (Page ID #889–922).

In June 2015, Prather filed her Second Amended Complaint. R. 73 (Second Am. Compl.) (Page ID #924–57). She alleged three claims: (1) the presentation of false claims to the United States government in violation of 31 U.S.C. § 3729(a)(1)(A); (2) the making or use of material false records or statements in the submission of claims to the government in violation of 31 U.S.C. § 3729(a)(1)(B); and (3) the wrongful retention of overpayments in violation of 31 U.S.C. § 3729(a)(1)(G). *Id.* at 29–32 (Page ID #952–55). The defendants again moved to dismiss for failure to comply with Federal Rule of Civil Procedure 9(b). R. 78 (Second Mot. to Dismiss at 1) (Page ID #1028). The district court granted the motion with respect to all three counts. R. 89 (Nov. 5, 2015 Dist. Ct. Op.) (Page ID #1358–1402).

Prather appealed, and this panel reversed the district court’s “dismissal of Prather’s claims regarding the submission of false or fraudulent claims for payment and the fraudulent retention of payments,” but affirmed the “dismissal of Prather’s claim regarding the use of false records.” *Prather I*, 838 F.3d at 775. The briefs in *Prather I* were filed prior to the Supreme Court’s decision in *Escobar*, so we did not address any potential impact that decision may have had on Prather’s complaint. *Id.* at 761 n.2. On remand to the district court:

the defendants stated their intent to file a motion to dismiss the Second Amended Complaint for failure to meet the standards set forth in *Escobar*. Because the Second Amended

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Complaint was filed before *Escobar* was issued, the court afforded the relator an opportunity to amend her complaint again, specifically to attempt to satisfy the pleading obligations identified in that case.

United States ex rel. Prather v. Brookdale Senior Living Cmities., Inc., 265 F. Supp. 3d 782, 787 (M.D. Tenn. 2017).

Prather filed her Third Amended Complaint in March 2017. R. 98 (Third. Am. Compl.) (Page ID #1459–96). She asserted two claims: (1) the presentation of false claims to the United States government in violation of 31 U.S.C. § 3729(a)(1)(A); and (2) the wrongful retention of overpayments in violation of 31 U.S.C. § 3729(a)(1)(G). *Id.* ¶ 121–31 (Page ID #1492–94). The defendants moved again to dismiss the complaint. R. 102 (Third Mot. to Dismiss) (Page ID #1571–73). The defendants argued that Prather had failed to plead adequately the required elements of materiality and scienter under *Escobar*. *Id.* at 1 (Page ID #1571). The district court granted the defendants’ motion to dismiss with prejudice, holding that Prather had not sufficiently pleaded materiality. *Prather*, 265 F. Supp. 3d at 801; R. 113 (June 22, 2017 Dist. Ct. Order) (Page ID #2142); R. 114 (Dist. Ct. J.) (Page ID #2143). It did not reach the issue of scienter. *Prather*, 265 F. Supp. 3d at 801.

Prather’s timely appeal from the district court’s judgment is now before the same panel that heard her original appeal in *Prather I*.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 9(b)'s requirement that fraud be pleaded with particularity applies to complaints alleging violations of the False Claims Act, because “defendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts.” *Prather I*, 838 F.3d at 760 (quoting *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)). “To satisfy Rule 9(b), a complaint of fraud, ‘at a minimum, must allege the time, place, and content of the alleged misrepresentation on which [the plaintiff] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.’” *United States ex rel. Marlar v. BWXY-12, L.L.C.*, 525 F.3d 439, 444 (6th Cir. 2008) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc. (Bledsoe I)*, 342 F.3d 634, 643 (6th Cir. 2003)). If the complaint “alleges ‘a complex and far-reaching fraudulent scheme,’ then that scheme must be pleaded with particularity and the complaint must also ‘provide[] examples of specific’ fraudulent conduct that are ‘representative samples’ of the scheme.” *Id.* at 444–45 (alteration in original) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys. (Bledsoe II)*, 501 F.3d 493, 510 (6th Cir. 2007)).

“This Court reviews *de novo* a district court’s dismissal of a complaint for failure to state a claim, including dismissal for failure to plead with particularity under [Rule] 9(b).” *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017) (alteration in original) (quoting *United States ex rel. Eberhard v. Physicians Choice Lab. Servs., LLC*, 642 F. App’x 547, 550 (6th Cir. 2016)),

cert. denied, No. 17-1399, 2018 WL 1697046 (U.S. May 29, 2018). We “must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains ‘enough facts to state a claim to relief that is plausible on its face.’” *Bledsoe II*, 501 F.3d at 502 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. ANALYSIS

To plead a claim under the False Claims Act, the plaintiff must sufficiently allege that: (1) the defendant made a false statement or created a false record; (2) with scienter; (3) that was “material to the Government’s decision to make the payment sought in the defendant’s claim”; and (4) that the defendant submitted to the U.S. government causing it to pay the claim. *United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 408 (6th Cir. 2016) (quoting *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 509 (6th Cir. 2010)); *see also United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir. 2017), *petition for cert. filed*, 86 U.S.L.W. 3361 (U.S. Dec. 26, 2017) (No. 17-936). In *Prather I*, we resolved in Prather’s favor the issue of whether Prather had sufficiently pleaded facts supporting the first element. 838 F.3d at 762. The parties are now contesting whether Prather sufficiently pleaded the second and third elements: scienter and materiality. Appellant Br. at 12; Appellees Br. at 14–15. These two elements are integral to both of Prather’s alleged claims and therefore Count One and Count Two of Prather’s complaint rise or fall together. *Prather*, 265 F. Supp. 3d at 801. Because the district court

addressed only materiality and not scienter, we will discuss the two elements in that order.

A. Materiality

“[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision in order to be actionable under the False Claims Act.” *Escobar*, 136 S. Ct. at 2002. The Act defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). In *Escobar*, the Supreme Court clarified this materiality requirement and emphasized that the “standard is demanding.” 136 S. Ct. at 2003.

“[M]ateriality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.’” *Escobar*, 136 S. Ct. at 2002 (second alteration in original) (quoting 26 SAMUEL WILLISTON & RICHARD A. LORD, A TREATISE ON THE LAW OF CONTRACTS § 69:12 (4th ed. 2003)). Something is material if a reasonable person “would attach importance to [it] in determining his choice of action in the transaction” or “if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter ‘in determining his choice of action,’ even though a reasonable person would not.” *Id.* at 2002–03 (alteration in original) (quoting RESTATEMENT (SECOND) OF TORTS § 538 (AM. LAW INST. 1977)).

The analysis of materiality is “holistic.” *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). Relevant factors

include: (1) “the Government’s decision to expressly identify a provision as a condition of payment”; (2) whether “the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement” or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and (3) whether the “noncompliance is minor or insubstantial” or if it goes “to the very essence of the bargain.” *Escobar*, 136 S. Ct. at 2003 & n.5. None of these considerations is dispositive alone, nor is the list exclusive. *Id.* at 2001–04.

1. Express Condition of Payment

“A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.” *Escobar*, 136 S. Ct. at 2003. But such a designation is a relevant factor in determining materiality. *Id.*

The parties vigorously dispute whether the timing requirement in 42 C.F.R. § 424.22(a)(2) is an express condition of payment for RAPs and residual final payments.³ Appellant Br. at 25–27; Appellees Br. at 28–35; Appellant Reply Br. at 4–6. The district court concluded that the timing requirement was an express

³ The relevant “provision[s] . . . do[] not distinguish between requests for final payment and requests for anticipated payment” in stating the conditions of payment, *Prather I*, 838 F.3d at 766 (citing 42 C.F.R. § 424.10(a)), and thus we will not do so here either.

condition of payment for both, *Prather*, 265 F. Supp. 3d at 796, and we agree.

Medicare Parts A and B condition payment for services on a physician's certification regarding the necessity of such services. 42 U.S.C. §§ 1395f(a)(2) & 1395n(a)(2); 42 C.F.R. § 424.10. Thus, "[i]n order for home health services to qualify for payment under the Medicare program," 42 C.F.R. § 409.41 mandates that "[t]he physician certification and recertification requirements for home health services described in [42 C.F.R.] § 424.22" be met. 42 C.F.R. § 409.41(b). The timing requirement at issue in this case is located in 42 C.F.R. § 424.22.

Prather argues that this analysis answers the question. Section 409.41(b) expressly conditions payment on meeting the certification requirements in § 424.22. Section 424.22(a)(2) contains the timing requirement for the certification Prather alleges the defendants violated. Thus, Prather argues, § 424.22(a)(2) must be an express condition of payment. Appellant Br. at 26.

Not so fast argue the defendants. Section 409.41(b) directs the reader to the requirements "described in § 424.22." So the reader must then look to the language in § 424.22 itself. Appellees Br. at 30. Section 424.22 states: "Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate." The defendants argue that this language limits the broader language of 42 C.F.R. § 409.41 by making only the requirements in 42 C.F.R. § 424.22(a)(1) and (b)(2) express conditions of payment. Appellees Br. at 29.

The defendants are correct that § 409.41(b) incorporates the requirements in § 424.22, and thus it is necessary to examine the latter section to understand the scope of the former. For example, if § 424.22 contained a provision that stated “certifications may be submitted via U.S. mail” then § 409.41(b) could not be read as to make it an express condition of payment that the certification must be submitted via U.S. mail merely by reference to § 424.22 as a whole. But the defendants’ reading of the introductory clause in § 424.22 is overly crabbed.

The prefatory language states that payment requires the physician to certify (or recertify) the contents specified in § 424.22(a)(1) and (b)(2). Section 424.22(a), entitled “[c]ertification,” then explains in further detail what a certification requires. Thus, § 424.22(a) gives meaning to the word “certifies” in the introductory clause. The required certification is not a certification unless it complies with all provisions of § 424.22(a), both (a)(1) and (a)(2). And § 424.22(a)(2) states that the certification “*must* be obtained at the time the plan of care is established or as soon thereafter as possible and *must* be signed and dated by the physician who establishes the plan.”⁴ *Cf. Ebeid ex*

⁴ The opposite conclusion would produce results that are antithetical to common sense. Under the defendants’ approach, it is not an express condition of payment that the certification be signed and dated by the physician who establishes the plan of care. But an unsigned and undated document stating that the patient is eligible for a home-health benefit is not a certification. *See Certification*, BLACK’S LAW DICTIONARY (10th ed. 2014) (“1. The act of attesting; esp., the process of giving someone or something an official document stating that a specified standard has been satisfied.”); *Attest*, BLACK’S LAW DICTIONARY (10th ed. 2014) (“1. To

rel. United States v. Lungwitz, 616 F.3d 993, 1000–01 (9th Cir. 2010) (holding that 42 C.F.R. § 424.22(d), which limits which physicians may certify or recertify the need for home-health services, is an express condition of payment), *cert. denied*, 562 U.S. 1102 (2010).

Consequently, we agree with the district court that the timing requirement in 42 C.F.R. § 424.22(a)(2) is an express condition of payment. Thus, this factor weighs in favor of the conclusion that a misrepresentation with respect to this requirement is material.⁵ *Escobar*, 136 S. Ct. at 2003.

bear witness; testify . . . 2. To affirm to be true or genuine; to authenticate by signing as a witness.”).

⁵ The dissent seeks to reduce the weight of this factor by discussing the mechanisms by which a home healthcare provider would disclose violations of 42 C.F.R. § 424.22(a)(2). Dissent Op. at 32–37. In doing so, it loses sight of the woods for the trees. The implied false certification theory of liability is premised on the notion that parties submitting claims to the government must not “fail[] to disclose noncompliance with material statutory, regulatory, or contractual requirements.” *Escobar*, 136 S. Ct. at 2001. Thus, a provider who has committed a material violation cannot submit a claim in silence—regardless of whether its claim form has a box for reporting violations. An inquiry, therefore, into how mechanically providers could report violations is not helpful in determining materiality.

2. Past Government Action⁶

Another relevant factor in determining materiality is the government's past response to claims violating the same requirement. As the Supreme Court explained:

[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on non-compliance with the particular statutory, regulatory, or contractual requirement. Conversely, if 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.

Escobar, 136 S. Ct. at 2003–04.

⁶ The United States filed an amicus brief and appeared at oral argument taking a position only on this “past-government-action prong” of the materiality analysis. Amicus Br. at 4. It argued that the district court erred in its evaluation of this factor. *Id.* The United States appeared, as it is authorized to do so, to speak only on this issue. 28 U.S.C. § 517; FED. R. APP. P. 29. The dissent’s implied criticism of the United States’ counsel taking only a limited position in this case is not well-founded. Dissent Op. at 26, 32. The legislative branch has created the scheme that gives the executive branch the ability to “attend to the interests of the United States,” 28 U.S.C. §517, as it—not we—may choose.

Prather made no allegations regarding the government's past practice with respect to claims that the government knew did not comply with 42 C.F.R. § 424.22(a)(2). Rather, she only alleged facts regarding the government's reactions to claims submitted by the defendants: "The United States, unaware of the falsity of the claims that Defendants submitted, and in reliance on the accuracy thereof, paid Defendants and other health care providers for claims that would otherwise not have been allowed." R. 98 (Third. Am. Compl. ¶ 125) (Page ID #1493). Without allegations regarding past government action taken in response to known non-compliance with 42 C.F.R. § 424.22(a)(2), this factor provides no support for the conclusion that the timing requirement is material.

In its analysis, the district court went one step further and drew a negative inference from the absence of any allegations about past government action. It held that Prather's "inability to point to a single instance where Medicare denied payment based on violation of § 424.22(a)(2), or to a single other case considering this precise issue, weighs strongly in favor of a conclusion that the timing requirement is not material." *Prather*, 265 F. Supp. 3d at 797. This is one step too far.

Although a relator in a *qui tam* action faces a demanding standard at the motion-to-dismiss stage with respect to pleading materiality, she is not required to make allegations regarding past government action. The Supreme Court was explicit that none of the factors it enumerated were dispositive. *Escobar*, 136 S. Ct. at 2003. Thus, it would be illogical to require a relator (or the United States) to plead allegations about

past government action in order to survive a motion to dismiss when such allegations are relevant, but not dispositive. *Escobar*, 842 F.3d at 112 (“We see no reason to require Relators at the Motion to Dismiss phase to learn, and then to allege, the government’s payment practices for claims unrelated to services rendered to the deceased family member in order to establish the government’s views on the materiality of the violation. Indeed, given applicable federal and state privacy regulations in the healthcare industry, it is highly questionable whether Relators could have even accessed such information.”); *see also Campie*, 862 F.3d at 907 (holding that although discovery may reveal “that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us” and the relator had sufficiently alleged facts supporting that the requirement at issue was material).

Furthermore, we “must construe the complaint in the light most favorable to the plaintiff.” *Bledsoe II*, 501 F.3d at 502. Inferring from the absence of allegations regarding past government action, as the district court did, that this means the timing requirement is not material is an inference adverse to the relator and in favor of the defendant. This improperly inverts the pleading standard.

Prather alleges that the government did not know that the claims the defendants submitted were false. R. 98 (Third. Am. Compl. ¶ 125) (Page ID #1493). 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.

3. Essence of the Bargain

Another factor relevant to materiality is whether the “non-compliance is minor or insubstantial” or if it goes “to the very essence of the bargain.” *Escobar*, 136 S. Ct. at 2003 & n.5. The defendants concede that the physician certification does go to the essence of the bargain between themselves and the government—and therefore is material—but argue that the timing of the certification does not. Appellees Br. at 35. In response, Prather makes two arguments for why the timing requirement goes to the essence of the bargain. She first argues that the timing requirement is necessary to prevent fraud. Appellant Br. at 32–34; Appellant Reply Br. at 6–10. Prather next contends that the federal government’s guidance as to the importance of the certification’s timeliness demonstrates materiality. Appellant Br. at 35–37; Appellant Reply Br. at 10–14.

In *Prather I*, we discussed the timing requirement’s connection to fraud prevention when interpreting the phrase “as soon thereafter as possible” in 42 C.F.R. § 424.22(a)(2). 838 F.3d at 764. We noted that the timing requirement

makes it more difficult to defraud Medicare. Absent a deadline, a home-health agency might be able to provide unnecessary treatment absent a doctor’s supervision and take the time to find doctors who are willing to validate that care retroactively. A deadline allowing only a short—and justified—delay between the beginning of care and the completion of the

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physician certification could make such a scheme difficult to pull off.

Id. at 764.⁷ Whether the party on the other side of a transaction complied with the regulations aimed at preventing unnecessary or fraudulent certifications is a fact that a reasonable person would want to know before entering into that transaction.⁸ *Escobar*, 136 S. Ct. at 2002–03; *cf. United States v. Luce*, 873 F.3d 999, 1007–08 (7th Cir. 2017) (holding material a

⁷ Prather does not allege that the dates on the certifications were fraudulently backdated. Thus, a government agent reviewing each claim could determine that the physician certifications were not obtained in accordance with 42 C.F.R. § 424.22(a)(2) by looking at the underlying documentation and comparing the dates of the episode of care with the date on the physician certification. But merely because the government had an alternate way to assess the timeliness of the certifications does not negate the materiality of the defendants’ alleged misrepresentation about their compliance with § 424.22(a)(2). *See* 31 U.S.C. § 3729(b)(4) (defining material as ‘having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property’); *United States ex rel. Miller v. Weston Educational, Inc.*, 840 F.3d 494, 505 (8th Cir. 2016) (“To the extent Heritage asserts that its statements, even if false, did not cause any actual harm, this is not an element of materiality.”).

⁸ The dissent suggests that concern about fraud is illusory in this context. Dissent Op. at 38. But in her complaint, Prather points to evidence that “untimely and/or forged physician certifications on plans of care” are a key focus for the Inspector General for the Department of Health and Human Services. R. 98 (Third. Am. Comp. ¶ 47) (citing OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410, 42,414 (Aug. 7, 1998)); *see also infra*. Reasonable people want to know if a party has complied with regulations addressing an area of historical concern. *Escobar*, 136 S. Ct. at 2002–03.

misrepresentation that none of the officers of a loan-originating company were currently subject to criminal proceedings on a certification that “addressed a foundational part of the Government’s mortgage insurance regime, which was designed to avoid the systemic risk posed by unscrupulous loan originators”).

In her complaint, Prather referred to numerous guidance documents issued by the Department of Health and Human Services that she argues shows that the timing requirement goes to the essence of the bargain between the defendants and the government. R. 98 (Third Am. Compl. ¶ 47–52) (Page ID #1471–73); Appellant Br. at 35–36. Although this guidance was over ten years old at the time of the alleged false claims, it does provide some support for Prather’s assertion that the timing requirement is material. Prather references three publications issued by the Office of Inspector General for the Department of Health and Human Services which emphasize the timing requirement for physician certifications and highlight ‘untimely and/or forged physician certifications on plans of care’ as an “area[] of special concern.” *OIG Compliance Program Guidance for Home Health Agencies*, 63 Fed. Reg. 42,410, 42,414 (Aug. 7, 1998); *OIG Special Fraud Alert on Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services*, 64 Fed. Reg. 1813, 1814 (Jan. 12, 1999); *OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., OEI-02-00-00620, THE PHYSICIAN’S ROLE IN MEDICARE HOME HEALTH 2–4* (2001). Prather also cites 2015 guidance from the Centers for Medicare and Medicaid Services, which states: “It is not acceptable for HHAs to wait until the end of a 60-day episode of

care to obtain a completed certification/recertification” R. 86-2 (Medicare Benefit Policy Manual (2015) § 30.5.1—Physician Certification at 32) (Page ID #1270). This specific manual was not in effect at the time of the defendants’ alleged conduct, but it provides some support for Prather’s allegation that the government has consistently emphasized the importance of the timing requirement and its longstanding policy has been to mandate that home-healthcare providers complete the physician certification prior to the end of the episode of care.⁹ R. 98 (Third Am. Compl. ¶ 51) (Page ID #1473).

The defendants argue that the government’s decision not to intervene in this case indicates that the timing requirement is not material. Appellees Br. at 37–38. This argument is unpersuasive. In *Escobar* itself, the government chose not to intervene, and the Supreme Court did not mention this as a relevant factor in its materiality analysis. 136 S. Ct. at 1998. On

⁹ The dissent claims that this manual’s relevance is undercut by our decision in *Prather I*. Dissent Op. at 38–39. But the dissent is conflating this case with *Prather I* and the two ways Prather has utilized this evidence. In *Prather I*, Prather pointed to the manual to support her argument that certifications could never be timely if signed after the end of the episode of care. We rejected this argument as contrary to the plain language of the regulation. *Prather I*, 838 F.3d at 765 n.6. In the case currently before us, Prather points to this manual as evidence that the government has consistently emphasized the importance of the timing requirement, thus making it more likely that the requirement is material to the government’s decision to pay these kinds of claims. This second inference is the one that is relevant to this case, and it supports the conclusion that Prather has pleaded sufficiently the materiality element.

remand, the First Circuit held that the relators had sufficiently pleaded materiality, without reference to the government's declination of intervention. *Escobar*, 842 F.3d at 112. Furthermore, the False Claims Act is designed to allow relators to proceed with a *qui tam* action even after the United States has declined to intervene. 31 U.S.C. § 3730(d)(2). If relators' ability to plead sufficiently the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the Act. See Trevor W. Morrison, *Private Attorneys General and the First Amendment*, 103 MICH. L. REV. 589, 600–01 (2005) (describing how the False Claims Act is structured such that it encourages private citizens to pursue enforcement actions on behalf of the government).

* * *

After considering the factors implicated in this case that *Escobar* identified as indicative of materiality, we conclude that Prather has sufficiently alleged the required materiality element. The timing requirement in 42 C.F.R. § 424.22(a)(2) is an express condition of payment. Furthermore, Prather alleges that the government paid the claims submitted by the defendants without knowledge of the non-compliance, thus making the government's payment of the claims irrelevant to the question of materiality. Lastly, § 424.22(a)(2) is a mechanism of fraud prevention, which the government has consistently emphasized in its guidance regarding physician certifications.

B. Scienter

The defendants also argue that Prather failed to plead sufficiently the element of scienter. Appellees Br. at 41. The district court did not reach this issue in its decision. *Prather*, 265 F. Supp. 3d at 801.

“False Claims Act liability for failing to disclose violations of legal requirements” will not attach unless “the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” *Escobar*, 136 S. Ct. at 1996. The Act “defines ‘knowing’ and ‘knowingly’ to mean that a person has ‘actual knowledge of the information,’ ‘acts in deliberate ignorance of the truth or falsity of the information,’ or ‘acts in reckless disregard of the truth or falsity of the information.’” *Id.* (quoting 31 U.S.C. § 3729(b)(1)(A)). “Knowing” and “knowingly” does not require “proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(B). And, at the motion-to-dismiss stage, a plaintiff need only allege the scienter element generally. FED. R. CIV. P. 9(b).

“[A]n aggravated form of gross negligence (i.e. reckless disregard) will satisfy the scienter requirement for an FCA violation.” *United States ex rel. Wall v. Circle C Constr., L.L.C.*, 697 F.3d 345, 356 (6th Cir. 2012) (alteration in original) (quoting *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008)). Congress added the “reckless disregard” prong to the definition of knowledge in the False Claims Act “to target that defendant who has ‘buried his head in the sand’ and failed to make some inquiry into the claim’s validity.” *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (quoting S. Rep. 99-345, at 21 (1986)),

reprinted in 1986 U.S.C.C.A.N. 5266, 5286). This inquiry must be “reasonable and prudent under the circumstances.” *Id.* (quoting S. Rep. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5286).

In her complaint, Prather alleges sufficient facts that support the reasonable inference that the defendants acted with “reckless disregard” with respect to their compliance with 42 C.F.R. § 424.22(a)(2). First, Prather alleges that she and the other nurses employed to review claims were instructed to review the claims only cursorily. R. 98 (Third Am. Compl. ¶ 87) (Page ID #1481). Those working for the Held Claims Project were told that they needed to release claims more quickly. *Id.* ¶ 88 (Page ID #1481–82). To that end, Prather and her co-workers were instructed not to review the content of much of the documentation. *Id.* ¶ 94–95 (Page ID #1483).

Second, Prather alleges that both she and the other nurses raised concerns about the defendants’ compliance with Medicare regulations, but were told to ignore any problems. *Id.* at ¶ 91–92 (Page ID #1482). Prather states that her concerns were repeatedly dismissed and she was told that “there is such a push to get the claims through.” *Id.* ¶ 92, 96 (Page ID #1482, 1483). Additionally, Prather was told on multiple occasions that “[w]e can just argue in our favor if we get audited” as a solution to any compliance issues. *Id.* ¶ 114 (Page ID #1489).

Lastly, Prather alleges facts demonstrating that the defendants knew that their practices with respect to claims were potentially in violation of governing regulations. The defendants sent an email acknowledging that not all physicians would be

“comfortable” with signing untimely certifications and that the defendants could not “force” them to sign. *Id.* ¶ 98 (Page ID #1484). Drawing all inferences in favor of Prather, as we must, this email suggests that the defendants knew that their conduct was, at least, perilously close to noncompliance such that doctors might refuse to be complicit in the defendants’ billing practices.¹⁰ Furthermore, Prather alleges that a supervisor in the billing office alerted the employees that the defendants’ practice of cancelling and re-submitting RAPs because of a lack of physician certifications might prompt an audit from Medicare. *Id.* ¶ 100 (Page ID #1484–85).

All these factual allegations support the inference that the defendants were on notice that their claim-submission process was resulting in potential compliance problems. Once the defendants had been informed by the employees explicitly hired to review these claims that there may be compliance issues, they had an obligation to inquire into whether they were actually in compliance with all appropriate regulations, including 42 C.F.R. § 424.22(a)(2). According to Prather, however, the defendants did not conduct such an inquiry and instead repeatedly pushed their employees to ignore problems, which they knew might trigger an audit, in a rush to get the claims submitted. In doing so, the defendants acted with “reckless disregard” as to the truth of their certification of

¹⁰ Contrary to the dissent’s suggestion, Dissent Op. at 41–42, awareness that coercing physicians to sign certifications would be a separate unlawful act does not negate this scienter.

compliance and to whether these requirements were material to the government's decision to pay.¹¹

These factual allegations suffice, at the motion-to-dismiss stage, to demonstrate scienter. Discovery may reveal that the defendants did conduct an inquiry into their compliance with 42 C.F.R. § 424.22(a)(2) that was “reasonable and prudent under the circumstances.” *Williams*, 696 F.3d at 530 (quoting S. Rep. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5286). But, at this stage in the litigation, Prather has alleged sufficient facts supporting the inference that the defendants deliberately ignored multiple employees' concerns about their compliance with relevant regulations, and instead pressured their employees only cursorily to review claims for compliance problems so that they could be quickly submitted for reimbursement.

IV. CONCLUSION

Prather has sufficiently pleaded that the defendants misrepresented their compliance with the material

¹¹ The dissent constructs a strawman and complains that we are saying that Prather alleges that the defendants violated a requirement that did not exist at the time of the conduct at issue. Dissent Op. at 41. This misreads our opinion. As the defendants themselves note, Appellee Br. at 24, the timing requirement in 42 C.F.R. § 424.22(a)(2) is longstanding and was in effect during the alleged wrongdoing. Thus, when the defendants were put on notice that they may be violating regulations, including 42 C.F.R. § 424.22(a)(2), they had an obligation to investigate. It is this alleged failure to make a reasonable inquiry that supports Prather's allegations of scienter, *Wall*, 697 F.3d at 356, and not—as the dissent states—the defendants' ability to anticipate the development of the law in this area.

timing requirement in 42 C.F.R. § 424.22(a)(2), and that they acted with “reckless disregard” as to whether they had complied with this requirement and whether this requirement was material. For the foregoing reasons, we **REVERSE** the district court’s judgment and **REMAND** for proceedings consistent with this opinion.

DISSENT

DAVID W. McKEAGUE, Circuit Judge, dissenting. For the second time, this panel has reversed a well-reasoned decision by the district court to dismiss Prather’s complaint. *See United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 775 (6th Cir. 2016) (*Prather I*) (McKeague, J., concurring and dissenting). Two years ago, the majority invented a more stringent timing-and-explanation requirement out of whole cloth and grafted it onto the Medicare regulations. Today, the majority decides both that this requirement (created by the court in 2016) was somehow material to the government’s decision to pay claims in 2011 and 2012, and that the defendants knew, seven years ago, that it was material—even though Prather identifies no authority in support of that position. Since Prather’s complaint does not satisfy Rule 8 or Rule 9(b), I respectfully dissent from the majority’s opinion.

I

This case involves home-health services billed to Medicare by the defendants (collectively, “Brookdale”). *Id.* at 755. Brookdale is a Home-Health Agency

(“HHA”) that coordinates the provision of care and the billing of those services to Medicare.

A

Medicare covers the cost of certain home-health services for patients who are confined to the home and need in-house medical care. 42 U.S.C. § 1395f(a)(2)(C); 42 C.F.R. § 424.22. Before Medicare will pay for these services, a physician must (among other things) certify that the patient is eligible for the home-health benefit, must establish a plan of care, and must complete a face-to-face encounter with the patient. 42 C.F.R. § 424.22(a). The signatures on these certifications “must be obtained at the time the plan of care is established or as soon thereafter as possible.” *Id.* § 424(a)(2); *Prather I*, 838 F.3d at 762–63.

Billing for home-health services occurs in sixty-day cycles. In other words, Medicare pays the HHA a fixed amount, designed to reimburse it for all costs associated with sixty days of covered services. *Prather I*, 838 F.3d at 756. The sixty-day period is known as the “episode of care.” Reimbursement under this prospective payment system is done in two steps. First, the HHA submits a Request for Anticipated Payment (“RAP”), which prompts Medicare to transmit a percentage of the total payment to the HHA. *Id.* Once care is completed, the provider submits a final bill to Medicare. Medicare then settles the account and submits the balance of the payment. *Id.* Medicare itself is not directly involved in these transactions—the agency contracts with Medicare Administrative Coordinators (“MACs”), companies who handle the process on Medicare’s behalf. For the purposes of this

case, a false statement to a MAC is a false statement to Medicare.

A HHA can submit a RAP even if the certifications have not been signed. *See* Medicare Claims Processing Manual, Ch. 10, § 10.1.10.3 (stating that a RAP may be billed once “the OASIS assessment is complete,” “verbal orders for home care have been received and documented,” “[a] plan of care has been established and sent to the physician,” and “[t]he first service visit under that plan has been delivered”). Thus, while the provider must have the plan of care in place to bill a RAP, it need not have all the signatures squared away before billing the RAP. *See id.* However, the same guidance prohibits HHAs from submitting a final bill “until after all services are provided for the episode and the physician has signed the plan of care and any subsequent verbal order.” *Id.* § 10.1.10.4. The signed certifications must be kept on file with the provider and must be produced if the MAC or Medicare requests them. 42 C.F.R. § 424.22(c).

In *Prather I*, the court held that late signatures, if unexplained, could be “impliedly false” under the False Claims Act (“FCA”). 31 U.S.C. § 3729(a)(1)(A); *Prather I*, 838 F.3d at 765–66. Specifically, the court held that “delay [is] acceptable only if the length of the delay is justified by the reasons the home-health agency provides for it.” *Prather I*, 838 F.3d at 765. If those reasons are inadequate, then the claim is false, and a relator or the United States can recover damages under the FCA. *Id.* at 765–66. Between the briefing and the decision in *Prather I*, however, the Supreme Court held that implied-false-certification claims that rely on a misleading omission are only actionable if the omission

is material. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999–2001 (2016). We declined to address materiality in *Prather I*, opting to leave that issue for the parties on remand. *Prather I*, 838 F.3d at 761 n.2.

B

After Prather amended her complaint on remand to better comply with *Escobar*, Brookdale moved to dismiss. The district judge granted the motion, reasoning that Prather failed to plead materiality. Prather appeals that order.

I will not belabor the facts, which are addressed in detail elsewhere. However, it is important to understand what Prather has *not* claimed. Her complaint does not allege that Brookdale backdated the certifications so that they only appeared to be signed in a timely manner (which would be fraud). She does not allege that the certifications were not signed before final bills were submitted to Brookdale’s MAC (which would also be fraud). Neither does she allege that Brookdale withheld information from the MAC or from Medicare, nor does it appear any request was ever issued (if that were true, this would be a fraudulent-concealment case, rather than a fraud-by-omission case). *Compare* Restatement (Second) of Torts § 550 (Liability for Fraudulent Concealment) *with* § 551 (Liability for Nondisclosure). Finally, it does not appear that the certification forms were part of the billing package sent to the MAC. Stated differently, the mechanics of the billing process would not inherently

disclose to the MAC that the certification signatures were late.¹

Instead, Prather alleges that the defendants submitted over 1,000 claims where the certifications or other crucial documents were not signed until long after the episode of care had ended. She offers up four patients as exemplars:

¹ This is an important concern raised by the United States as an *amicus* in this case. If the MAC reviewed the physician certifications alongside the bills, then it would be nearly impossible for Prather to show materiality. If the government was able to compare the date of the signature on the certification to the episode of care on the bill itself, then it had all the information it needed to deny the claim as not properly payable due to a late signature. *See Escobar*, 136 S. Ct. at 2003–04. If the government paid those hypothetical claims anyway, Prather would struggle to show materiality. *See id.* However, since the government had no reason to know about the potential defect in the signatures, I agree with the United States that Medicare’s decision to pay in this context cannot be held against them (in a FCA prosecution) or against a relator (in a declined FCA case).

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	Episode	RAP	F2F encounter signed	Certific ation signed	Final bill
Patient A	12/14/11 – 2/11/12	12/14/ 11	2/24/12 (+14 days)*	6/29/12 (+4.5 months)	7/10/12
Patient B	9/9/11 – 11/7/11	9/9/11	6/4/12 (+7 months)	7/10/12 (+8 months)	7/12/12
Patient C	7/25/11 – 9/22/11	7/25/ 11	12/11/11 (+2.5 months)	12/11/11 (+2.5 months)	7/5/12
Patient D	1/10/12 – 3/9/12	1/10/ 12	6/12/12 (+3 months)	6/12/12 (+3 months)	6/22/12

**Dates in parentheses are dates from the last day of the episode of care. To calculate from the beginning of the episode, add two months to the time listed.*

Prather alleges that these delays would be material to the MAC's payment decisions, and therefore that Brookdale committed fraud by failing to disclose them and explain the delay.

To state a claim for fraud, Prather must make two related showings in her complaint. First, she must plead, with particularity, that these omissions were material to the government. Second, she must allege facts plausibly suggesting that Brookdale acted with fraudulent intent. In my opinion, her complaint accomplishes neither of these things.

II

I address the materiality issue first. To survive a motion to dismiss, the plaintiff must show that the *Prather I* requirement was material to the government's decision to pay Brookdale's claims. In other words, even if the length of the delay was unacceptable or if the explanation for such delay was insufficient, Prather must show that these errors were significant enough to influence the government's actual payment decisions, not merely its abstract legal rights.

A

Fraud is typically premised on affirmative misrepresentations. This is because a party to a business transaction ordinarily has no duty to disclose facts to his adversary. *See* Restatement (Second) of Torts § 551(1). However, in *Escobar* the Court clarified that the False Claims Act imposes, at least, a duty to avoid certain misleading omissions in claims for monetary reimbursement from the government. *Escobar*, 136 S. Ct. at 1999–2000. Because this kind of “silent fraud” is an exception to the rule, the Court limited its application to cases where a person “state[s] the truth so far as it goes” but knows the statement to be “materially misleading because of his failure to state additional or qualifying matter.” *Escobar*, 136 S. Ct. at 1999–2000 (quoting Restatement, § 529). Under this rule, a “half-truth may be as misleading as a statement wholly false” and is equally tortious. Restatement, § 529; *Escobar*, 136 S. Ct. at 2000.

The Court was also painfully clear that not all regulatory violations are material. The government frequently requires contractors to “aver their

compliance” with all relevant regulations, and the Court was unwilling to embrace the “extraordinarily expansive” liability that would exist if “failing to mention noncompliance with any of those requirements” would be fraudulent. *Escobar*, 136 S. Ct. at 2004. This statement was not mere dicta—it was in direct response to the United States’ argument that every undisclosed regulatory violation would trigger FCA liability. *See id.*

Instead, the fundamental question here is whether the government agents on the ground would have acted differently if they knew of the omitted fact. Stated differently, Prather must show that the government justifiably relied on the nondisclosure, assuming that if something had been out of place, Brookdale would have said so. *See* Restatement (Second) of Torts §§ 537–38 (observing that materiality is inextricably rooted in the concept of justifiable reliance); 31 U.S.C. § 3729(b)(4) (stating that a fact is material if it has “a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property”). Although this broad standard is clear, applying it to the particulars of this case has proven difficult for everyone involved. When pressed at oral argument, Prather was unable to provide an answer to this question, and the United States was unwilling to do so. In my mind, the majority opinion is equally unenlightening on this issue. Before explaining why Prather has failed to plead materiality, then, I attempt to put more flesh on the skeleton provided by *Escobar*.

B

All agree that Prather bears the burden of showing that these omissions were material. *Escobar*, 136 S. Ct.

at 2004. But exactly how is she supposed to accomplish that, in this context? It's a fair question, and it has not been answered by us or any of the other Circuits. Since I would affirm the dismissal of her complaint, it is only fair that I explain, in detail, why she has fallen short of the goal.

1

Whenever a plaintiff alleges fraud, he or she must “state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). The Sixth Circuit has never asked whether the materiality of an omission is one of those circumstances and, if so, what it means to plead the material nature of an omission with particularity. I would hold that the particularity requirement applies here, and that it requires Prather to explain how and why these omissions deceived the government.

Rule 9(b) imposes the particularity requirement for several reasons. Requiring the plaintiff to plead the “circumstances constituting fraud” provides notice, alerting the defendants “as to the particulars of their alleged misconduct” so that they can respond. *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 503 (6th Cir. 2007). It also “protect[s] defendants against spurious charges of immoral and fraudulent behavior,” *Prather I*, 838 F.3d at 771 (internal citations and quotation marks omitted), and discourages “fishing expeditions,” *Bledsoe*, 501 F.3d at 503 n.11. We have stated that the particulars of fraud include, “at a minimum . . . the time, place, and content of the alleged misrepresentation on which [the plaintiff] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.” *United States ex rel. Marlar v. BWXT Y-12*,

LLC, 525 F.3d 439, 444 (6th Cir. 2008) (internal citations and quotation marks omitted).

The Court has strongly suggested that materiality should be added to this list. In *Escobar*, the Court recognized that “the common law could not have conceived of fraud without proof of materiality.” *Escobar*, 136 S. Ct. at 2002 (quoting *Neder v. United States*, 527 U.S. 1, 22 (1999)). Indeed, the purpose of the *Escobar* opinion was to emphasize that materiality is essential to a successful silent-fraud claim; it is the lodestar by which the courts separate the careless from the nefarious. Add to this the Court’s decision to characterize the materiality standard as “demanding,” a label that fits more comfortably with the “special pleading” framework of Rule 9 than the notice-pleading regime established by Rule 8.

Furthermore, every Circuit to address this question agrees that Rule 9(b) governs materiality allegations. See *Minzer v. Keegan*, 218 F.3d 144, 151 (2d Cir. 2000); *Grabcheski v. Am. Int’l Grp., Inc.*, 687 F. App’x 84, 87 (2d Cir. 2017) (“Materiality must be pleaded with particularity under Rule 9(b).”) (interpreting the False Claims Act); *In re Donald J. Trump Casino Securities Litig.*, 7 F.3d 357, 374–75 (3d Cir. 1993); *Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter*, 607 F.3d 1029, 1033 (5th Cir. 2010); *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 798–80 (8th Cir. 2011); *Hemmer Grp. v. SouthWest Water Co.*, 527 F. App’x 623, 626 (9th Cir. 2013); *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1329–30 (11th Cir. 2009); *Sampson v. Wash. Mut. Bank* 453 F. App’x 863, 866 (11th Cir. 2011).

In *Prather I*, we relaxed the Rule 9(b) standard slightly. We did so because Prather was close enough to the billing department to say with near certainty that the claims were submitted to the government. *Prather I*, 838 F.3d at 769–73. But Prather has no similar proximity to the government’s payment decisions, and so she cannot avail herself of the relaxed standard in this context. Thus, she must overcome the full force of the particularity requirement if her complaint is to survive.

2

What does it mean to plead a material omission with particularity? Although our precedent is sparse on the issue, other Circuits have offered a near-uniform test for answering this question. Put simply, a plaintiff must explain *why* the omissions were material to the government and *how* the government was misled by those omissions. *See Vigil*, 639 F.3d at 798–800 (“[T]he Complaint fails to allege with particularity . . . why these alleged regulatory violations were material to the government’s decision to pay. . . .”); *Hopper*, 588 F.3d at 1330 (holding a complaint deficient when it “d[id] not link the alleged false statements to the government’s decision to pay false claims.”); *Hemmer Grp.*, 527 F. App’x at 626 (“A plaintiff must ‘show with particularity how the [accounting irregularities] affected the company’s financial statements and whether they were material in light of the company’s overall financial position.’” (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1018 (9th Cir. 2005)); *Sampson*, 453 F. App’x at 866 (“[A] plaintiff must state with particularity . . . the content and manner in which the[] statements misled the Plaintiffs.”) (internal quotation marks omitted).

The Eighth Circuit provides a particularly enlightening analysis of this issue. In *Vigil*, the court addressed a False Claims Act complaint alleging that a student-loan contractor was using false certifications to defraud the U.S. Department of Education of interest subsidies. Although the plaintiff set out, in detail, how the certifications were false, the panel held that this was not enough to plead materiality. *Vigil*, 639 F.3d at 798–800. “Merely alleging *why* the Certifications were false is insufficient” to satisfy Rule 9(b); instead, the court required the complaint to allege “why these alleged regulatory violations were material to the government” and to connect “the alleged false statements to the government’s decision to pay false claims.” *Id.* at 799–800; *see also Grabcheski*, 687 F. App’x at 87 (holding that the plaintiff “failed to allege with particularity facts that demonstrate how th[e] difference in value . . . was likely to have had any effect on the Agreements” with the government).

A product-safety case from California also provides excellent guidance into what the particularity rule requires in this context. *Arroyo v. Chattem, Inc.*, 926 F. Supp. 2d 1070, 1078–80 (N.D. Cal. 2012). In *Arroyo*, the plaintiff alleged that a pharmaceutical company committed fraud by promoting a weight-loss supplement as “safe,” while failing to disclose the existence of a chemical (hexavalent chromium) in the product. *Id.* at 1073. The court noted that the labels did not affirmatively state that the product was hexavalent-chromium free, and therefore that “Plaintiff must specifically allege that hexavalent chromium at the level present in [the product] makes statements about the product’s safety false or misleading.” *Id.* at 1079. The plaintiff relied on general statements that

“hexavalent chromium is unsafe” to plead materiality. *Id.*

The district court dismissed the claim, holding that the materiality allegations in the complaint did not satisfy Rule 9(b). *Id.* at 1078–79. In doing so, the district court reasoned:

Many foods and drugs on the market are not one hundred percent safe, and general allegations that a product’s safety is less than one hundred percent do not give rise to a lawsuit for fraud . . . Under this theory of materiality . . . Plaintiff’s FAC is insufficient because it does not allege a level of hexavalent chromium [in the product] that materially changes its safety profile from safe to unsafe.

Id. at 1079. This theory provides a helpful framework for evaluating materiality. In a silent-fraud case where violations occur by degree, the plaintiff must allege, with particularity, the point at which the defendants crossed from innocuous mistakes to fraudulent omissions. In a product-safety case like *Arroyo*, that means the plaintiff must plead the scientific threshold for safe levels of the offending chemical. Here, Prather has a similar task.

3

In *Prather I*, we held that a late certification is false if “the length of the delay is [not] justified by the reasons the home-health agency provides for it.” *Prather I*, 838 F.3d at 765. This general standard leaves crucial issues unresolved. At what point does a late signature require an explanation? It depends. When an explanation is required, how detailed must

the explanation be? It depends. What kind of justifications suffice? Again, it depends: In *Prather I*, the majority refused to answer these questions, suggesting instead that each case must rise and fall on its own facts, and even noting that “the rare excuse . . . could justify a delay” beyond the 60-day episode of care, despite the fact that the government has said such delays are “not acceptable.” *Id.* at 765 n.6.

It follows that Prather (or any other relator) must plead facts connecting the defendant’s insufficient justifications to Medicare’s decision to pay. She must explain to us (and to Brookdale) why and how the government would have been deceived by the failure to include the explanations omitted here. Put another way, she must pinpoint the limits of the government’s patience, as applied to her allegations. Even assuming that the delay was “due only to the fact that Brookdale had accumulated a large backlog of Medicare claims,” *id.* at 765, Prather must allege facts showing that this excuse is either unacceptable to the government in all cases, or that the government would not have accepted it under the circumstances of this case. Otherwise, we have no basis for finding (a) that the government wanted Brookdale to disclose this delay and explain it at the billing stage, and (b) that if had Brookdale done so, then the government probably would have denied reimbursement.

This might seem like an unduly harsh requirement. But it is essential if Rule 9 is to serve the notice-providing function Congress ascribed to it. Particularly when the regulation offers a vague threshold (“as soon thereafter as possible”) and where we have made it even more vague by interpretation, a silent-fraud

plaintiff *must* be able to explain, with particularity, if and how the specific violation would have influenced the government’s payment decision. Otherwise, Brookdale is left to guess about how it has allegedly defrauded the government.

C

How can Prather—or any other relator—meet this threshold? *Escobar* made it clear that the world is Prather’s oyster: No “single fact or occurrence [i]s always determinative” in deciding whether something is material. *Escobar*, 136 S. Ct. at 2001. Instead, the Court subscribes to an approach that treats everything as relevant, so long as it sheds light on the government’s behavior, rather than its abstract legal rights. *Id.* at 2001–03 (observing that the relevant barometer of influence is “the effect on the likely or actual behavior of the recipient,” not merely whether “the Government would have the option to decline to pay”). Relevant facts include the government’s payment history, the way the government characterizes the requirement, and whether the omission goes to the essence of the bargain. *Id.* at 2001–04. Prather may use any combination of these facts (and others) to demonstrate that Brookdale’s excuses are unacceptable to the government in all cases, or that the government would not have accepted the excuses due to the larger delays present in this case. She has not accomplished this.

1

The government’s payment habits are, by far, the best evidence of materiality. If the government “refuses to pay claims in the mine run of cases based on

noncompliance” with a particular rule, then the requirement is almost certainly material. *Id.* at 2003. In contrast, if the government “regularly pays a particular type of claim in full despite actual knowledge” of the violations, then Prather would be hard-pressed to demonstrate materiality. *Id.* at 2003–04.

Unfortunately, neither Prather nor Brookdale offer this information. Instead, each argues that the other’s silence on the subject is evidence that the government cares (or doesn’t care) about the information. This does not hurt Brookdale, who bears no legal burden in this context. Neither does it (technically) hurt Prather, except to say that it moves her no closer to the goal. *See id.* at 2000–02 (suggesting that a plaintiff need not present payment statistics to survive a motion to dismiss). Although we granted the United States’ motion to appear as an amicus at oral argument, counsel refused to say whether or not she knew of the government’s payment habits. Perhaps discovery will dredge up helpful information about the payment policies of Brookdale’s MAC; perhaps it won’t. The answer to that question will weigh heavily on Prather’s case at the summary-judgment stage. The Court has, however, indicated that we cannot deny a motion to dismiss simply because discovery might help flesh out a plaintiff’s claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 684–86 (2009).

So we are no closer to answering the materiality question than we were before. An inquiry into the government’s payment habits has placed no facts on the scale. Again, this does not technically hurt Prather; it has just removed one of her weapons. In other words,

Prather need not present us with this information now, but she still needs to present *something* to satisfy Rule 9(b).

2

I agree that we have made the timing-and-explanation requirement a condition of payment. However, this only means that the government would have the option to decline payment if it knew that the requirement had been violated. *Escobar* requires that we look beyond this bare fact and ask about the importance of the requirement under the circumstances of this case. *Escobar*, 136 S. Ct. at 2003. To do so, we must naturally examine what the government has said about it, and the way a provider might disclose a violation to the government. Prather can draw little solace from this information—indeed, a thorough examination shows that it hurts her case.

Medicare prescribes the method by which providers submit claims for reimbursement. *See* 42 U.S.C. §§ 1302, 1395hh; 42 C.F.R. § 424.32. Providers must use the forms indicated by the regulations. 42 C.F.R. § 424.32(a)–(b). Home health service providers primarily use Form CMS-1450 (Uniform Institutional Provider Bill) and sometimes use CMS-1500 (Health Insurance Claim Form). *Id.* § 424.32(b); Medicare Claims Processing Manual, Ch. 10, §§ 10.A, 40. This data usually must be submitted electronically, but both the paper and electronic claims forms contain substantially the same information. *See id.*; 42 C.F.R. § 424.32(d)(2).

The CMS-1450 has 81 fields. Most are for boilerplate information about the patient, the provider,

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and the services provided. *See* Medicare Claims Processing Manual, Ch. 25, § 75. The form also contains fields for the date of admission, start of care, and statement period. *See id.*, Ch. 10, § 40.1; *id.*, Ch. 25, § 75.1; CMS-1450, FL 6, 12–15. For HHA claims, the “statement period” field is the sixty-day episode of care mandated by the Prospective Payment System. Medicare Claims Processing Manual, Ch. 10, §§ 40.1–40.2.

The form also contains a blank, lined field titled “Remarks.” *See* CMS-1450, FL 80. The general instructions for completing the form indicate that this field should be used to enter “any remarks needed to provide information that is not shown elsewhere on the bill but which is necessary for proper payment.” Medicare Claims Processing Manual, Ch. 25, §75.6, FL 80. The specific guidance for HHA claims state that this field is “[c]onditional,” *id.*, Ch. 10, § 40.1–40.2, meaning that it is a field “that must be completed if other conditions exist,” *id.*, Ch. 1, § 70.2.3.1. For a final bill, remarks are “required only in cases where the claim is cancelled or adjusted.” *Id.*, Ch. 10, § 40.2.

The rear of the form lists multiple typewritten warranties, all of which are adopted (if applicable) by the provider when it submits the form. The general warranty affirms that “the billing information as shown on the face hereof is true, accurate and complete,” and that “the submitter did not knowingly or recklessly disregard or conceal material facts.” *See* CMS-1450, Gen. Warranty. Among the specific warranties is a verification that “[p]hysician’s certifications and re-certifications, if required by contract or Federal regulations, are on file” with the

provider. *See id.*, Spec. Warranty No. 3. Two observations can be drawn from this data.

First, nothing in the forms, regulations, or guidance suggests that the government cares to review the certifications during the billing process. The general warranty only refers to the accuracy and completeness of the data “shown on the face hereof.” *See id.*, Gen. Warranty. It does not require a provider to aver that it has fastidious recordkeeping policies. At most, the regulations require HHAs to keep the forms “on file” and provide the certifications and other medical records “upon request.” *Id.*, Spec. Warranty No. 3; 42 C.F.R. § 424.22(c). It appears that production is only necessary if the MAC initiates a medical review because it suspects improper payment. *See Medicare Program Integrity Manual*, Ch. 3, §§ 3.2.1, 3.2.3.A, 3.3.1.1; *id.*, Ch. 6, §§ 6.1–6.3. Indeed, the physicians need not actually use the CMS-485 (certification template) to certify patient need, “as long as a physician certifies that the five certification requirements” are satisfied. *Id.*, Ch. 6, § 6.2.1.

Second, the form does not contemplate that a provider would disclose a late certification at the billing stage. Neither does it request the date of the physician certification so that billing officials can compare it to the episode of care and evaluate lateness issues. The only place where they might do so on the face of the form would be in the remarks section. But the form instructions identify only two limited circumstances where a provider should complete this field before submitting a bill: “only in cases where the claim is cancelled or adjusted.” *Medicare Claims Processing Manual*, Ch. 10, §40.2. Thus, by Medicare’s own

definitions, a bill submitted without a late-signature disclosure would still be “complete,” because it would not omit any required information. *Id.*, Ch. 1, § 70.2.3.1. Although this is not dispositive, it fails to provide any support for Prather’s assertion that the omissions are material.

Prather’s theory fares no better in light of the Medicare Guidance. Medicare’s *Program Integrity Manual* devotes nearly 100 pages to instructing Medicare Administrative Coordinators (“MACs”) on how to identify “potential errors” and take “corrective actions.” *See generally* Medicare Program Integrity Manual, Ch. 3. The mine run of claims submitted to Medicare only include the bill, not the underlying medical records. *See id.*, § 3.3.1.1. Thus, records are only submitted to the MAC if it initiates a medical review to ensure that the services provided were medically necessary. *See id.*, §§ 3.2.1, 3.3.1.1; *id.*, Ch. 7, § 7.2. Although a MAC has the authority to demand records and “review any claim at any time,” the sheer size of Medicare “doesn’t allow for review of every claim.” *See id.*, Ch. 3, §§ 3.2.1, 3.2.3.A; *see also* 42 C.F.R. § 424.22(c).

Consequently, this guidance commands the MACs to prioritize their review efforts. In doing so, they must focus on “areas with the greatest potential for improper payment,” or “where the services billed have significant potential to be non-covered or incorrectly coded.” Medicare Program Integrity Manual, Ch. 3, § 3.2.1. The guidance lists five red flags that the MACs may use to

set priorities.² *Id.* Nowhere in this guidance or any of the regulations does the government even hint that any late signatures are so important to a MAC's auditing or payment decisions that a provider would be expected to disclose them every time.

Prather directs us to two pieces of information suggesting that *some* late signatures might be material. Reports from the HHS Inspector General addressing home-health service compliance indicate that a special area of concern to the agency was “[u]ntimely and/or forged physician certifications on plans of care.” *Compliance Program Guidance for Home Health Agencies*, HHS Office of Inspector General, 63 Fed. Reg. No. 152, 42410, 42414 (Aug. 7, 1998). Such statements count as one of the red flags that a MAC may use to set its auditing priorities. Medicare Program Integrity Manual, Ch. 3, § 3.2.1. Related guidance, addressed to the HHAs (rather than the MACs) states that “[i]t is not acceptable for HHAs to wait until the end of a 60-day episode of care to obtain a completed certification/recertification.” Medicare Benefit Policy Manual, Ch. 7, § 30.5.1 (2015).³

² These flags include (1) a high volume of services, (2) high cost of services, (3) a dramatic change in frequency, (4) high risk and problem-prone areas, and (5) data from OIG and other agencies indicating vulnerability. MEDICARE PROGRAM INTEGRITY MANUAL, Ch. 3, § 3.2.1.

³ Prather identifies two other pieces of guidance that are only minimally persuasive. First, she points to a policy factsheet from another MAC, which states that no payment will be made if the certification is not obtained prior to the care being given. R. 98, Third Amended Compl., ¶ 50, PID 1472. Although this somewhat relevant, it has little bearing on what *Brookdale*'s MAC requires,

Taken as a whole, the guidance and the forms undercut Prather's case. In the first place, they provide no support for Prather's (conclusory) allegation that the government would not have paid Brookdale's claims had they known about the late certifications. In other words, Prather has not pointed us to *any* governmental statements disapproving of Brookdale's alleged excuses, either as a per se matter or in the context of these particular delays. Neither has she used any of this information to explain how and why the government was misled by Brookdale's alleged omissions. Indeed, the forms and the guidance are completely silent about what excuses suffice to justify delays of this magnitude.

Second, the regulatory framework suggests that the government is not interested in the timing-and-explanation issue during the billing stage. The sheer size of the Medicare program requires a streamlined approach to billing review. To serve this purpose, CMS

which is the real question here. Prather does not provide similar information from Palmetto GBA, which processes claims for Brookdale. *Id.*, ¶ 57, PID 1474. Second, Prather identifies a CMS outreach pamphlet, stating that a HHA “may not add late signatures to medical records (beyond the short delay that occurs during the transcription process).” *Id.*, ¶ 52, PID 1473. However, she neglects to mention that the same guidance, in the very next sentence, states: “If the practitioner’s signature is missing from the medical record, submit an attestation statement from the author of the medical record.” *Complying with Medicare Signature Requirements*, CENTERS FOR MEDICARE AND MEDICAID SERVS., at 2 (March 2016). Elsewhere in her complaint, Prather appears to acknowledge that this “attestation method” was exactly how Brookdale obtained the late signatures. *See* R. 98, Third Amended Compl., ¶ 86, PID 1481.

created a uniform billing form that applies to most claims—a single page containing all the information necessary to process and pay the claim. 42 C.F.R. § 424.32(b); Medicare Claims Processing Manual, Ch. 10, §§ 10.A, 40. The form is not designed to accommodate the explanations contemplated by *Prather I*. The “remarks” field—the only conceivable place to offer such a justification—is tiny and ill-suited to accommodate the complete explanations necessary to avoid more accusations of silent fraud.

Instead, the timing-and-explanation requirement is probably enforced by auditing. No one disputes that the government might initiate an audit of Brookdale’s files and decide that it had not satisfied the certification requirements. In this context, Brookdale could offer the kind of detailed, patient-specific explanations for lateness that we required in *Prather I*. Under *Prather I*, a MAC might well be dissatisfied with those reasons and demand reimbursement. At the billing stage, however, it seems that the billing agents only look at the face of the form to ask whether “the services billed have significant potential to be non-covered or incorrectly coded.” Medicare Program Integrity Manual, Ch. 3, § 3.2.1. At a higher level, the MACs also use sophisticated algorithms and pattern-matching (e.g., unnatural spikes in volume, high-cost services) to identify potential areas for audits. *See id.* Although this is not dispositive, it does give us some insight into what the government is looking for at the billing stage—and if the government is not looking for the information that Brookdale omitted, then such information is probably not material.

Ultimately, this is another dead end for Prather. If the timing of the signatures was truly a fulcrum of the government's payment decisions, one would expect to find some reference to it in the instructions that CMS gives to the companies who make those judgments. Again, this is not fatal to Prather's case—it simply removes another arrow from her quiver. Without concrete evidence of the government's payment history or any helpful regulatory guidance, Prather must present some other particular information showing how and why these omissions deceived the government. *See Escobar*, 136 S. Ct. at 2001–03.

3

The government need not specify every single detail of a transaction in order to protect itself from silent fraud. *Id.* at 2001–02. Some things go without saying. The government is entitled to presume that the guns it orders “must actually shoot,” even if it does not expressly require that function. *Id.* Such omissions go to the very essence of the bargain and are usually material. *Id.* at 2001–03 & n.5. Prather and the majority conclude that Brookdale's failure to disclose an adequate justification goes to the very essence of the bargain; therefore, Prather can proceed even though she has not otherwise satisfied the particularity requirement.

The case law refutes this position. Start with *Escobar*. The defendants in *Escobar* provided mental health services to children and billed Medicaid for those services. *Id.* at 2000. However, they failed to disclose that their social workers did not have the training or credentials expressly required by the regulations. *Id.* This omission went to the essence of

the bargain—the defendants did not (and could not) perform the mental-health services for which they were paid. Another leading case cited by the majority involved similar facts—a mortgage lending executive who certified that he was eligible for a FHA-sponsored loan program without revealing that he had been indicted for wire fraud and obstruction of justice. *United States v. Luce*, 873 F.3d 999, 1001–03 (7th Cir. 2017). One might compare these cases to a person who bills the government for public-defender services without mentioning that he has never been licensed to practice law (*Escobar*) or that he is in imminent danger of disbarment (*Luce*).

History also provides colorful examples. The FCA was enacted during the Civil War to combat fraud (including silent fraud) in defense contracts. *See United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 753 (3d Cir. 2017). Among the culprits in those cases were contractors who sold “artillery shells filled with sawdust instead of explosives,” and uniforms “made of shredded, often decaying rags, pressed . . . into a semblance of cloth that would fall apart in the first rain.” *Id.* (internal citations and quotation marks).

Prather’s claims, as currently pled, are not in the same universe. Medicare was established to “provide[] basic protection against the costs of . . . home health services” for the elderly. 42 U.S.C. §§ 1395c, 1395j. The enforcing regulations for home-health services require physician certifications to ensure that Medicare does not pay for those services when they are not necessary, in order to preserve the financial integrity of the program for those who truly need it. *See* 42 C.F.R. § 424.22. The regulations accordingly require the

certifications to be done by a person with one of five specific levels of training. *See id.* § 424.22(a)(1)(v)(A). Had Prather alleged that the forms were signed by individuals not covered by the regulation, her case would be squarely covered by *Escobar*, and Brookdale would have deprived the government of the essence of its bargain. That is not the case here—Prather’s only theory of relief is that the forms were signed too late and that the lateness was unjustified, not that the caretakers were inherently unqualified or that the care was fundamentally defective.

The majority claims that these omissions are crucial because the timing-and-explanation requirement is an antifraud measure. This argument is a non-starter. Of course the regulations are designed to prevent fraud. Most (if not all) Medicare regulations exist to make sure the government gets what it paid for. But *Escobar* made it clear that only *significant* regulatory violations can be the basis for silent-fraud liability. *Escobar*, 136 S. Ct. at 2003–04. Thus, anti-fraud rhetoric set aside, all Prather can derive from this theory is the bare assertion that Brookdale violated § 424.22. This does not satisfy *Escobar*. Prather still has not offered an explanation for how and why Brookdale’s omissions actually deceived the government.

Perhaps the closest she comes to this goal is by pointing to the sixty-day period mentioned in the 2015 guidance revisions. That guidance states that “[i]t is not acceptable for HHAs to wait until the end of a 60-day episode of care to obtain a completed certification/recertification.” Medicare Benefit Policy Manual, Ch. 7, § 30.5.1 (2015). Although this language was added after the conduct at issue here, Prather

claims that this is longstanding policy that goes to the essence of the government's bargain. *See Prather I*, 838 F.3d at 765 n.6. This argument fails on two fronts. First, *Prather I* expressly refused to say that such lateness was categorically inexcusable, even while concluding that it was unjustified here. *Id.* at 765 n.6. If this is true, then it is hard to see how this kind of a violation is so egregious that it always goes to the very essence of the bargain.

Second, and in a related vein, the argument does nothing to explain why *this* delay is material. If a lengthy delay can be justified in some circumstances, Prather must show us why this is not one of those cases. The only excuse she identifies is a massive paperwork backlog. But she makes no compelling argument that disclosure of this excuse would have caused some adverse reaction from the government. Of all the problems faced by Medicare's antifraud contractors, "Paperwork backlog" is not Public Enemy No. 1, or anywhere close to it. Perhaps there is no excuse for Brookdale's conduct here. But my point is that Prather has utterly failed to explain *why* this is the case. Rule 9(b) expects more from someone making accusations of fraud under a statute that is inherently punitive. *See Vigil*, 639 F.3d at 798–80 ("The Complaint fails to allege with particularity . . . why these alleged regulatory violations were material to the government's decision to pay. . . ."); *Hopper*, 588 F.3d at 1330 (holding a complaint deficient when it "d[id] not link the alleged false statements to the government's decision to pay false claims.").

At the end of the day, Prather is left with an empty quiver. Though none of the factors discussed above are dispositive, Prather can only claim victory in half of one analysis (she correctly identifies the requirement as a condition of payment). This is not enough to demonstrate materiality. Accordingly, I would affirm the district court.

To some extent, the deficiency in Prather's complaint is not her fault. To show materiality, the plaintiff must make some showing that the omission would influence the government. Since past behavior and administrative guidance is the best predictor of future conduct, a plaintiff can typically mine the agency's publications and industry experience for guidance on what is material. But the timing-and-explanation requirement does not appear in any regulation. It does not come from any agency guidance, adjudication, or notice-and-comment process. It has no history in the Medicare billing system. It sprung, fully formed, from the minds of two federal judges. Consequently, Prather has no history, commentary, or guidance she can use to demonstrate materiality.

Judicial legislation always has pernicious consequences, and this case is no different. By inventing a rule out of whole cloth to preserve this case at the falsity stage, the *Prather I* majority failed to realize it was also crippling the plaintiff's case on materiality grounds. Today, rather than confessing its first error, the majority compounds it by twisting the law of materiality to cover up the mistakes it made two years ago. It would not surprise me if this case returns to us in a few years, presenting us again with a third

opportunity to correct ourselves or warp the law even further. The lesson, then, is clear: Leave rulemaking to the legislators and administrators, even when the present outcome appears unjust. The orderly development of the law is not without rough patches, but it is better than living under the law of unintended consequences.

III

The majority also addresses the scienter requirement of the statute, although the district judge did not. And again, the majority gets it wrong.

Like with all fraud claims, the FCA imposes a “rigorous” scienter requirement. *Escobar*, 136 S. Ct. at 2002. Even if a defendant’s claim suffers from a material omission, fraud liability does not attach unless the defendant *knows* that the requirement is material to the government’s payment decision. *Id.* at 1996. The majority admits as much. Maj. Op. at 18. A defendant acts knowingly if it “has actual knowledge of the information,” “acts in deliberate indifference of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. §3729(b)(1)(A). Finally, although Rule 9 does not apply to alleging a person’s state of mind, this “does not give [the plaintiff] license to evade the less rigid—though still operative—strictures of Rule 8.” *Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009).

Thus, Prather still faces a tough standard. She must allege facts plausibly showing that Brookdale knew omitting the explanations would influence the government’s payment decisions or that it recklessly

disregarded that possibility. The majority claims she has pled recklessness. She has not.

The first problem with the majority's argument is that the allegedly wrongful conduct occurred between 2011 and 2012. The timing-and-explanation requirement did not exist until we decided *Prather I* in 2016. True, the regulation states that the certifications must be obtained "at the time the plan of care is established or as soon thereafter as possible." 42 C.F.R. § 424.22(a)(2). But before *Prather I*, no one had any reason to think that this regulation required HHAs to submit explanations for all late signatures, or that a delay is "acceptable only if the length of the delay is justified by the reasons the home-health agency provides for it." *Prather I*, 838 F.3d at 765. I struggle to see how Brookdale can be held responsible for recklessly disregarding such a specific requirement when nothing—absolutely nothing—in the existing law required it to provide affirmative justifications for late signatures during the billing process.

The second problem is that most of Prather's scienter allegations have no relationship to the signatures. Though the nurses were instructed to review claims "only cursorily," Maj. Op. at 19, Prather concedes that they *were* told to "make sure the orders are signed, the face to face documentation is complete, and the therapy reassessments are present in the charts," R. 98, Third Amended Compl., ¶¶ 87, 91, PID 1481–82. So even while they were allegedly instructed to ignore other compliance issues, they were expressly told not to ignore the signature requirements. *Id.* I fail to see how this is evidence of reckless disregard as to

the timing-and-explanation theory on which Prather relies.

The same symptoms infect Prather's other scienter allegations. Prather alleges that management ignored her complaints about noncompliance in the forms. Maj. Op. at 19 (citing R. 98, Third Amended Compl., ¶¶ 91–92, PID 1482). But these paragraphs reveal that Brookdale only ignored her complaints about general flaws in the underlying medical records, not missing signatures—indeed, she was told specifically, and on several occasions, to scour the documents for missing signatures so the errors could be corrected. R. 98, Third Amended Compl., ¶¶ 91–93, PID 1482–83. The majority also cites an email where management said “not all physicians would be ‘comfortable’ with signing” the late certifications. Maj. Op. at 19. But again, this is not the whole picture: In the same breath, the emails acknowledge that “we can not force this process,” suggesting that Brookdale was trying to speed up the process as much as they could without resorting to the kind of unsavory methods indicative of fraud. R. 98, Third Amended Compl., ¶¶ 98, PID 1483–84.

The closest Prather comes to alleging scienter is in paragraphs 99 and 100. There, she alleges that Medicare would frequently cancel Brookdale's RAPs because the final bill was not submitted in time, but then Brookdale would immediately re-bill the RAP without having the physician signatures on file. *Id.*, ¶¶ 99–100, PID 1484–85. Prather's supervisors admitted in an email that this practice might “trigger a probe or review by Medicare.” *Id.*, ¶ 100, PID 1485. Thus, at least superficially, this suggests that

Brookdale knew some of its billing practices might draw the ire of Medicare auditors.

But again, these allegations fail because they are not connected to Prather's theory of relief: That Brookdale acted with reckless disregard for the materiality of the late signatures and omitted explanations. As explained earlier, a provider may bill a RAP—but not a final claim—without the physician signatures on file. *See supra*, at 23. Although this could be done with a nefarious or reckless motive, it is equally plausible that Brookdale was simply keeping the window open while it collected the signatures and explanations that the regulation requires. Nothing in this behavior inherently suggests that Brookdale was rebilling these claims with the intent to submit final bills that omitted material information. Since Prather has alleged facts that are, at best, only consistent with recklessness, she has not satisfied the requirements of Rule 8. *Iqbal*, 556 U.S. at 678.

IV

My dissent today should not be understood as endorsing Brookdale's conduct. Medicare providers can and should be much more careful and meticulous with their recordkeeping. But accusing someone of fraud is a serious thing, and I simply am not convinced that Prather has alleged anything more than sloppy management and negligence. Medicare has a myriad of tools to prevent and remedy the problems associated with these lesser forms of culpability, but no one contends that this power has also been delegated to relators. If Congress wants to permit relators to pursue negligence claims on behalf of the government, so be it.

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But we lack the authority to make that policy judgment by equating negligence with fraud.

For the reasons stated above, I respectfully dissent from the opinion of the court.

APPENDIX B

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**Case No. 3:12-cv-0764
Judge Aleta A. Trauger**

[Filed June 22, 2017]

UNITED STATES OF AMERICA,)
ex rel. MARJORIE PRATHER,)
)
Plaintiff,)
)
v.)
)
BROOKDALE SENIOR LIVING)
COMMUNITIES, INC., et al.,)
)
Defendants)
)

MEMORANDUM

Marjorie Prather, as relator, brings this action against defendants Brookdale Senior Living, Inc. (“BSLI”), Brookdale Senior Living Communities, Inc. and Brookdale Living Communities, Inc. (together, “Brookdale Communities”), and Innovative Senior Home Health of Nashville, LLC d/b/a Innovative Senior Care Home Health (“ISC Home”) (collectively, “Brookdale” or “defendants”) under the *qui tam*

provisions of the False Claims Act (“FCA”), 31 U.S.C. §§ 3729–3733. Prather alleges that the defendants submitted false claims to Medicare for reimbursement of the cost of providing home health care services. Now before the court is the defendants’ Motion to Dismiss Third Amended Complaint (Doc. No. 102). For the reasons explained herein, the motion will be granted.

In order to provide a basic vocabulary for understanding the plaintiff’s claims, the court will first give a summary of the relevant legal framework, before laying out the procedural history, factual analysis, and then a discussion of the claims.

I. LEGAL FRAMEWORK

A. The FCA

“The False Claims Act, 31 U.S.C. § 3729 et seq., imposes significant penalties on those who defraud the Government.” *Universal Health Servs., Inc. v. U.S. ex rel. Escobar* (“*Escobar*”), 136 S. Ct. 1989, 1995 (2016). The FCA focuses primarily “on those who present or directly induce the submission of false or fraudulent claims.” *Id.* at 1996; see 31 U.S.C. § 3729(a)(1)(A) (imposing civil liability on “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval”). It also imposes liability for knowingly or improperly avoiding or decreasing an obligation to pay or transmit money to the United States. 31 U.S.C. § 3729(a)(1)(G). Liability under § 3729(a)(1)(G) occurs when a party owes funds to the government but acts to avoid meeting its obligation to return those funds.

A “claim” includes direct requests to the government for payment and claims for reimbursement

under federal benefits programs. *Id.* § 3729(b)(2)(A). The FCA defines “knowing” and “knowingly” to mean that a person has “actual knowledge of the information,” “acts in deliberate ignorance of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information.” *Id.* § 3729(b)(1)(A). And the Act defines “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* § 3729(b)(4).

Liability under the FCA is “essentially punitive in nature.” *Escobar*, 136 S. Ct. at 196 (quoting *Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000)). Defendants who are found liable are subjected to treble damages plus civil penalties of up to \$10,000 per false claim. 31 U.S.C. § 3729(a); 28 CFR § 85.3(a)(9) (2015) (adjusting penalties for inflation).

An FCA action may be commenced either by the government itself, 31 U.S.C. § 3730(a), or, alternatively, by a private person, referred to as a “relator.” In the latter case, a relator brings a *qui tam* civil action “for the person and for the United States Government” against the alleged false claimant, “in the name of the Government.” *Id.* § 3730(b)(1).

B. Home Health Care Services Under Medicare

The FCA applies to claims submitted by healthcare providers to Medicare. *U.S. ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 714 (6th Cir. 2013).

Medicare Part A “provides basic protection against the costs of . . . home health services” for qualified individuals aged 65 and over. 42 U.S.C. § 1395c.

Medicare Part B is “a voluntary insurance program to provide medical insurance benefits,” 42 U.S.C. § 1395j, and it, too, provides coverage for certain home health services. 42 U.S.C. § 1395k(a)(2)(A). *See United States ex rel. Prather v. Brookdale Senior Living Cmities., Inc.*, 838 F.3d 750, 755, 775 (6th Cir. 2016).

Medicare pays for home health services only if a physician certifies the patient’s eligibility for and entitlement to those services. 42 U.S.C. § 1395n(a)(2); 42 C.F.R. § 424.22. Under the statute, payment for home health care “may be made . . . only if” a physician certifies that: (1) home health services “are or were required because the individual is or was confined to his home . . . and needs or needed” covered home-health services; (2) “a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician”; (3) “such services are or were furnished while the individual is or was under the care of a physician”; and (4) “prior to making such certification the physician must document that the physician . . . has had a face-to-face encounter . . . with the individual during the 6-month period preceding such certification.” 42 U.S.C. § 1395n(a)(2)(A); *see also* 42 U.S.C. § 1395f(a)(2)(C) (listing nearly identical requirements under Medicare Part A).

Under the Medicare regulations, “the certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.” 42 C.F.R. § 424.22(a)(2). The regulations state that the physician’s certification of the necessity of services is “a

condition for Medicare payment.” See 42 C.F.R. § 424.10(a). Generally, “[d]elayed certification . . . statements are acceptable when there is a legitimate reason for delay [but] must include an explanation of the reasons for the delay.” 42 C.F.R. § 424.11(d)(3).¹

As the Sixth Circuit explained, “Medicare payments for home-health services are made pursuant to ‘a prospective payment system,’ 42 U.S.C. § 1395fff(a), which uses a 60-day ‘episode of care’ as its standard measurement.” *Prather*, 838 F.3d at 756 (quoting 42 U.S.C. § 1395fff(a)). To be reimbursed for the costs of providing care, a home health agency submits an initial “request for anticipated payment,” or “RAP,” at the beginning of each 60-day episode of care, pursuant to which Medicare pays a percentage of the total anticipated payment. The home health agency later submits a request for a “final residual payment.” *Id.* (citing 42 C.F.R. § 484.205(b); 2011 Medicare Claims Processing Manual § 10.1.12). “Payment . . . is not based on a fee-for-service model that would consider the precise treatments that were provided during the 60-day episode; rather, the entire episode payment ‘represents payment in full for all costs associated with

¹ This regulatory subpart does not define the term “as soon thereafter as possible,” but it appears to apply generally to the provision of home health care, among other services for which physician certifications are required. See *Prather*, 838 F.3d at 763 & n.4 (holding that “[c]ertifications of need may be completed after the plan of care is established, but only if an analysis of the length of the delay, the reasons for it, and the home-health agency’s efforts to overcome whatever obstacles arose suggests that the home-health agency obtained the certification ‘as soon thereafter as possible,’” and noting that this requirement is “consistent with” § 424.11(d)(3)).

furnishing home health services previously paid on a reasonable cost basis.” *Id.* (quoting 42 C.F.R. § 484.205(b)).

The Centers for Medicare and Medicaid Services (“CMS”), a subsidiary of the Department of Health and Human Services, is the federal agency responsible for overseeing state compliance with federal Medicaid requirements. CMS is the government agency that makes the decision whether to pay a reimbursement claim under Medicare Part A. (Third Am. Compl. ¶¶ 16, 20, Doc. No. 98.)

II. PROCEDURAL HISTORY

Prather filed this lawsuit as a relator on July 24, 2012, asserting claims under the FCA as well as state law. (Compl., Doc. No. 1.) Generally, she alleged that the defendants knowingly submitted fraudulent statements and claims to Medicare seeking reimbursement for the provision of home health services beginning in 2011. After the United States declined to intervene (*see* Notice of Election to Decline Intervention, Doc. No. 23), the Complaint was unsealed and served on the defendants. (April 10, 2014 Order, Doc. No. 24.) Before the defendants responded to the initial Complaint, Prather filed an Amended Complaint. (First Am. Compl., Doc. No. 52.) The court granted the defendants’ Motion to Dismiss the First Amended Complaint, but without prejudice to Prather’s ability to amend her pleading to address the deficiencies identified by the defendants and the court at that time. (Doc. No. 71.)

Prather filed her Second Amended Complaint on June 1, 2015 (Doc. No. 73), narrowing the case to three

legal claims: (1) the presentation of false claims to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A) (Count I); (2) the making or using of false records or statements that were material to the submission of those false claims, in violation of 31 U.S.C. § 3729(a)(1)(B) (Count II); and (3) the failure to return overpayments, in violation of 31 U.S.C. § 3729(a)(1)(G) (Count III). (*Id.* ¶¶ 106–22.)

In a ruling issued on November 5, 2015 (Doc. Nos. 89, 90), the court granted the defendants’ Motion to Dismiss the Second Amended Complaint. (Doc. No. 78.) Prather appealed, and the Sixth Circuit Court of Appeals reversed the dismissal of Counts I and III but affirmed the dismissal of Count II. *United States ex rel. Prather v. Brookdale Senior Living Cmties., Inc.*, 838 F.3d 750, 755, 775 (6th Cir. 2016). In reversing the dismissal of Counts I and III, the appellate court recognized that the Supreme Court’s recent decision in *Escobar* might be relevant to the ultimate resolution of the case, but the court declined to analyze its effects, since the opinion had been issued after the briefs were filed in *Prather*.

Following remand, this court conducted a case management conference at which the defendants stated their intent to file a motion to dismiss the Second Amended Complaint for failure to meet the standards set forth in *Escobar*. Because the Second Amended Complaint was filed before *Escobar* was issued, the court afforded the relator an opportunity to amend her complaint again, specifically to attempt to satisfy the pleading obligations identified in that case.

Prather filed her Third Amended Complaint (“TAC”) on March 1, 2017. (Doc. No. 98.) Consistent with the

dismissal of Count II, the TAC contains only two claims for relief: Count I, asserting liability under 31 U.S.C. § 3729(a)(1)(A) for the knowing presentment of false or fraudulent claims for approval; and Count II, asserting liability under 31 U.S.C. § 3729(a)(1)(G) for the failure to return overpayments made by the government as a result of the defendants' alleged violations of § 3729(a)(1)(A).

Now before the court is the defendants' Motion to Dismiss the Third Amended Complaint on the basis that it fails to satisfy *Escobar*'s standards for pleading materiality and scienter as they pertain to FCA claims.

III. FACTUAL ALLEGATIONS

The basic facts underlying this matter have now been recited by this court in its rulings on two prior motions to dismiss as well as by the Sixth Circuit. The court presumes familiarity with the facts and will summarize them here only insofar as necessary for resolution of the issues now before the court.

Prather, who resides in Tennessee, is a registered nurse who was employed by defendant BSLI as a Utilization Review ("UR") Nurse from September of 2011 until November 23, 2012. BSLI and the other defendants "are interconnected corporate siblings who operate senior communities, assisted living facilities and home health care providers" within the Middle Tennessee area and throughout the United States. (TAC ¶¶ 3, 66.) The defendants provide home health care services that are subject to reimbursement under Medicare Part A.

Prather alleges generally that Brookdale engaged in "aggressive marketing and solicitation policies" to

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generate demand for home health services. (TAC ¶ 74.) Brookdale sought to enroll “as many of [its] assisted living facility residents as possible in home health care services that were billed to Medicare.” (TAC ¶ 3.) As a result of the scheme to increase the number of Brookdale residents receiving home health care services, Brookdale was left with “a backlog of thousands of claims for home health care services that did not comply with Medicare regulations.” (TAC ¶ 74.) As of September 2011, Brookdale had a backlog of “about 7000 unbilled Medicare claims”—referred to as “held claims”—“worth approximately \$35 million.” (¶¶ 76, 77.) Brookdale represented to Prather that this backlog constituted a “looming financial crisis.” (TAC ¶¶ 3, 97.)

To deal with this backlog of claims, Brookdale implemented the “Held Claims Project” in September 2011. (*Id.*) Prather was hired as a UR Nurse by Brookdale in September 2011 to work on the Held Claims Project, and she was terminated when the project ended. (TAC ¶ 75.) Prather’s responsibilities in working on the Held Claims Project included, among other things, (1) conducting pre-billing chart reviews to ensure compliance with Brookdale’s requirements and established policies, as well as state, federal, and insurance guidelines; (2) working to resolve documentation, coverage, and compliance issues; and (3) keeping Brookdale supervisory personnel apprised of problem areas requiring intervention. (TAC ¶ 80.) These responsibilities “directly related to Defendants’ efforts to bill the held claims to Medicare.” (*Id.*)

Prather worked with employees in Brookdale’s central billing office. (TAC ¶ 81.) She and her

colleagues followed a “billing release checklist” of “items that needed to be completed before the claim could be released for final billing to Medicare.” (TAC ¶ 82.) “Once the checklist was finished,” it would be combined with other relevant materials, “taken to the employees in the billing office,” and “immediately submitted . . . to Medicare.” (*Id.*)

Initially, Prather and the other UR Nurses “sent attestation forms to doctors for them to sign to correct the problem of missing signatures,” but they received few responses, and Brookdale’s management felt the process was too slow. (TAC ¶ 86.) In order to expedite the process, Prather and other UR Nurses were told that they needed to “just make sure the orders are signed, the face to face documentation is complete, and the therapy reassessments are present in the charts, and to ignore any compliance issues regarding the information in the records.” (TAC ¶ 87.) In addition, Brookdale announced that all claims older than 120 days would be sent back to the agencies that generated them. The agencies were “instructed to get the doctors to sign the old documents [and] complete the face to face documentation.” (TAC ¶ 88.) The same announcement noted that there was “a high sense of urgency to get these released ASAP.” (*Id.*)

Once the individual agencies got all the necessary documentation together, they would forward them to the UR Nurses to complete final reviews and checklists in order to release the claims for billing to Medicare. The nurses were instructed to do “quick reviews” for missing signatures and dates; they were told not to look for—and in fact to ignore—any other problems related to Medicare billing. (TAC ¶ 91.) Prather tried to

raise concerns with her supervisor about compliance problems, but she was told that it was the agencies' responsibility to correct the charts, not hers, and that there was just "such a push to get the claims through." (TAC ¶¶ 92, 96.) She was specifically instructed not to read the underlying documentation for billing (such as plans of care and face-to-face documentation) "but to make sure only that orders affecting billing were signed and dated (despite requirements that all orders be signed and dated), that the plans of care were signed and dated by a physician, and that face to face documentation contained an encounter date in the right time period, clinical findings, and a reason why the patient was homebound." (TAC ¶ 93.) The UR Nurses were instructed not to read the underlying chart for content other than to confirm that the documentation did not indicate that the patient was "not homebound" (TAC ¶ 94); they were also told not to consider whether the reason for home care documented by the physician's office matched the start-of-care or plan-of-care orders. (TAC ¶ 95.)

In May 2012, apparently still concerned about a "looming financial crisis" related to old unbilled claims, Brookdale announced a new initiative to help expedite the process of releasing the oldest claims for billing to Medicare: it would start compensating physicians "for the time they will spend with us to release these claims." (TAC ¶ 97.) Under this new policy, Brookdale "paid physicians to review outstanding held claims and sign orders for previously provided care." (TAC ¶ 98.) Brookdale also provided guidance for employees who encountered physicians who "did not want to sign a document," implicitly anticipating that some doctors would not be "comfortable" with the policy of "paying

doctors to certify stale claims for home health care services.” (TAC ¶ 98.) The same guidance acknowledged that Brookdale could not force doctors to sign the documentation. (*Id.*)

The TAC, compared with the Second Amended Complaint, contains only four new paragraphs in the “Facts and Allegations” section—as distinct from sections devoted to describing Medicare’s legal framework and articulating the claims for relief. In the first of these, Prather alleges that Miaona Osborne, the supervisor of the employees in the billing offices submitting claims to Medicare, was directly involved in billing RAPs and in rebilling RAPs that were canceled if the final bill was not submitted within the time prescribed by 42 C.F.R. § 409.32(c)(2) (“the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment”). (TAC ¶ 99.) Prather alleges that Brookdale repeatedly, with respect to the held claims, “billed RAPs without having physician certifications, and then re-billed them immediately after the RAPs were canceled in order to keep the funds received through the RAPs, while still lacking the physician certifications.” (TAC ¶ 99.)

Second, Prather points to an email issued by Osborne in June 2012, notifying the UR Nurses that there was a “trend” at one of the Brookdale facilities

of no orders for nursing in the recert episode and there are a lot of 1st billable charges in the recert episode that we have had to delete. When we are doing this we are having to cancel the Rap with Medicare, wait until the cancellation is complete, then bill the correct rap and then either re-bill the final or correct the final that

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was rejected. I just wanted everyone aware that this may trigger a probe or review by Medicare.

(TAC ¶ 100.)

Third, Prather alleges that Sonja Nolan sent an email in June 2012, notifying “others working on the Held Claims Project” that she had “sent over 100 pages of Physicians orders to be signed. We have a follow up plan in place to get these expedited. We are working the oldest claims and while waiting on signed documents plan to grab the low hanging fruit, this way we will stop the newer claims from aging.” (TAC 102.) And finally, Prather alleges that Nolan, a few weeks later, sent a follow-up email, reflecting that “21 physician certification orders were obtained that day, including one for an episode of care dated May 25, 2011, through July 23, 2011, and another for an episode dated June 29, 2011, through August 27, 2011. Out of the 21 patients identified in this email, 14 involved episodes of care that ended in 2011.” (TAC ¶ 104.)

As she did in the Second Amended Complaint, Prather references as examples of Brookdale’s fraudulent billing practices the billing history of four specific patients, referred to in the TAC as Patients A, B, C, and D (collectively, the “Exemplar Patients”). Patient A, for example, received home health care services from December 14, 2011 through February 11, 2012, but her face-to-face encounter documentation was not signed by the physician until February 24, 2012 (TAC ¶ 109), and no doctor signed the certification for home health care services until June 29, 2012 (TAC ¶ 105).

Brookdale submitted the RAP for Patient A in December 2011 and billed Medicare at that time for 60 percent of the episode rate. According to Prather, this RAP violated Medicare conditions of payment because

(1) no physician certified Patient A's need for home health care services until June 29, 2012; and (2) there was no properly attested verbal order from the physician to start care, or a signed plan of care. Additionally, on or about July 10, 2012, Defendants billed Medicare \$800 for the final episode payment. Sally Horvath, ISC's Regional Director, released the claim for final billing. Defendants' claim for the final episode payment violated Medicare conditions of payment for the same reasons that the RAP did.

(TAC ¶ 106.)²

Similarly, Prather alleges that other Exemplar Patients received home health care services, but, in each case, no physician certified that the patient needed such services until long after the services had been provided. In addition, in some cases, the start-of-care and face-to-face encounter documentation was not signed by the doctor until a few weeks or even several months after the services had been provided. For each of these patients too, Prather asserts that the RAP was

² Prather also alleges that the treatment provided pursuant to the plan of care was inconsistent with the primary diagnosis indicated on the plan of care, or even medically inappropriate. (TAC ¶ 105.) As the Sixth Circuit noted, however, Prather makes it clear that she is not attempting to "state a claim of medically unnecessary care as an independent ground of recovery." *Prather*, 838 F.3d at 758 n.1.

submitted around the date of the start of care, at which time Medicare was billed fifty or sixty percent of the episode rate, and the final bill was submitted months later. She alleges that the RAPs violated Medicare conditions of payment, because no physician had certified a need for home health care services prior to the submission of the RAP. She alleges that the requests for final payment violated Medicare conditions of payment because the physician certifications were not signed until several months after the episode of payment ended, and in most cases the certifications were obtained just prior to the submission of the claim for final payment. (TAC ¶¶ 108–13.)

In addition to the Exemplar Patients identified in the body of the TAC, the plaintiff attached to her pleading two exhibits listing additional patients whose billing, she alleges, violated Medicare's conditions of payment. Exhibit A consists of a list of 489 claims that, she asserts, were submitted in violation of the Medicare requirement that the physician certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible. (*See* Doc. No. 38-1.)

Exhibit A reflects only patient names (redacted), episode beginning date, episode end date, the particular home health network involved, and the Brookdale Community of which the patient was a resident. However, Prather alleges that, “[f]or every patient reflected in Exhibit A, at the beginning of the episode, [Brookdale] submitted a RAP to Medicare that violated the condition of payment requiring that a doctor certify that the patient needed home health services.” (TAC ¶ 116 (citing 42 C.F.R. §§ 424.22(a) and

409.41(b)).) She asserts that each RAP is a claim for purposes of the FCA and that each RAP violated a Medicare condition of payment because, in each case, Brookdale “did not obtain the required certification until several months after the patient had been discharged and/or the episode was complete.” (TAC ¶ 117.) She alleges that, even though Brookdale “knew that this condition of payment was not satisfied,” it nonetheless submitted the RAPs for payment and actually received Medicare reimbursement. (*Id.*)

In Exhibit B, Prather identifies an additional 771 Brookdale patients who received home health care with respect to which Medicare reimbursement claims were processed through the Held Claims Project. She alleges that these claims were fraudulent because they were submitted “in violation of the condition of payment that an appropriate physician document a face-to-face encounter with the patient.” (TAC ¶ 118.) To be clear, she does not allege that there was no timely face-to-face encounter or that there was no documentation of the face-to-face encounter. Rather, she states that, for each patient listed in Exhibit B, Brookdale submitted a RAP that violated the Medicare timing requirement for the documentation of the face-to-face encounter, which is supposed to take place before the physician’s certification of need for home health services. (TAC ¶ 119 (citing 42 C.F.R. §§ 424.22(a) 409.41(b), 42 U.S.C. § 1395f(a)(2)(C)).) She alleges that, for each patient/claim reflected in Exhibit B, Brookdale submitted a RAP to Medicare at the beginning of the episode but “did not obtain the required documentation [of the face-to-face encounter] until several months after the patient had been discharged and/or the episode was complete.” (TAC ¶ 120.) She further

alleges that the timing requirement that pertained to documenting the face-to-face encounter was a condition of payment and that Brookdale knew that this condition was not satisfied at the time it submitted the RAPs and received payment from Medicare. (*Id.*)

IV. STANDARD OF REVIEW

The factual allegations supporting FCA claims must be pleaded with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure, “because ‘defendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts.’” *Prather*, 838 F.3d at 760 (quoting *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)). Dismissal of a complaint for failure to comply with Rule 9(b) is reviewed as a dismissal for failure to state a claim. *See United States ex rel Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 502 (6th Cir. 2007).

In the *qui tam* context, “the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains ‘enough facts to state a claim to relief that is plausible on its face.’” *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Under the special pleading rules contained in Rule 9(b), a complaint alleges sufficient facts to survive a motion to dismiss when the plaintiff states “with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b).

V. DISCUSSION

Boiled down to its essence, the TAC alleges that Brookdale violated the False Claims Act (“FCA”) by

(1) billing Medicare for home health services, despite knowing that it had not obtained face-to-face documentation or physician signatures on certifications at the time that the physician established the patient’s plan of care “or as soon thereafter as possible,” as required by 42 C.F.R. § 424.22(a)(2); and (2) retaining such payments after reimbursement by Medicare, despite knowing that Medicare would not have paid the claims if it had known about the regulatory violations, that is, Brookdale’s failure to comply with the “as soon as possible” requirement in § 424.22(a)(2). The relator proceeds under an implied-false-certification theory, based upon which a claimant may be liable for “knowingly falsely certify[ing] that it has complied with a statute or regulation the compliance with which is a condition for Government payment.” *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)). This court initially dismissed Prather’s claims on the grounds that obtaining late signatures on certifications and face-to-face documentation—as opposed to not obtaining the signatures at all—did not constitute a violation of Medicare regulations or laws. (Doc. No. 89, at 41.) On appeal, the Sixth Circuit reversed and remanded, holding that late physician signatures could violate 42 C.F.R. § 424.22(a)(2), depending on “the length of the delay, the reasons for it, and the home-health agency’s efforts to overcome whatever obstacles arose.” *Prather*, 838 F.3d at 763.

In a footnote, the Sixth Circuit recognized the Supreme Court’s recent holding that “an implied-false-certification claim may be brought only in relation to a misrepresentation regarding a legal or contractual

violation that was ‘material to the other party’s course of action.’” *Prather*, 838 F.3d at 761 n.2 (quoting *Escobar*, 136 S. Ct. at 2001). However, because *Escobar* was decided after the parties briefed their positions in the Sixth Circuit, that court expressly declined to consider what effect *Escobar* might have on Prather’s theories of recovery.

Following remand to this court, Brookdale immediately signaled its intent to file a renewed motion to dismiss based on *Escobar*. Because Prather could not have taken *Escobar* into account in drafting the Second Amended Complaint, the court permitted her to amend her pleading again to satisfy *Escobar*’s requirements. She has now done so, but Brookdale maintains in its present motion that, even as amended for the third time, the relator’s allegations are insufficient to state a claim under the standards imposed by *Escobar* for pleading materiality and scienter.

More specifically, Brookdale argues under *Escobar* that the alleged failure to comply with an applicable statute or regulation can give rise to liability under the FCA only if “rigorous” materiality and scienter requirements are satisfied. *Escobar*, 136 S. Ct. at 2002. Brookdale asserts that Prather has failed to adequately allege facts showing that the timing requirements in 42 C.F.R. 424.22(a)(2) are material to Medicare’s decision to pay claims or that Brookdale had actual or constructive knowledge that the timing requirements are material, for purposes of the FCA’s scienter requirement. Prather insists, to the contrary, that she has adequately alleged facts supporting both materiality and scienter.

A. *Escobar*

In *Escobar*, the Supreme Court confirmed that the implied-false-certification theory can be a basis for liability under the FCA under certain circumstances. 136 S. Ct. at 1995. Specifically, the Court held that, “[w]hen . . . a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.” *Id.* at 1999. The Court made clear that courts should continue to police expansive implied certification theories “through strict enforcement of the [FCA’s] materiality and scienter requirements.” *Id.* at 2002 (citation omitted). In particular, “a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government’s payment decision in order to be actionable under the False Claims Act.” *Id.*

The FCA defines the term “material” to mean “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). The Supreme Court provided some guidance for determining whether a particular statutory or regulatory provision is material under that definition:

A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. 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. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if 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.

Id. at 2003–04 (internal citations and footnote omitted).

In sum, in considering the question of materiality, courts should consider, but are not bound by, the questions of (1) whether the statute or regulation at issue has been expressly designated by the government as a condition of payment; (2) whether the government has consistently refused to pay claims based on noncompliance with the particular statute or regulation;

and (3) conversely, whether the government has regularly paid claims despite knowledge of technical violations, without signaling a change in position. *Id.*

Courts are to apply a holistic approach in determining materiality; no one factor is necessarily determinative. *Id.* at 2001. Materiality “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.” *Id.* at 2002–03 (citing Williston on Contracts § 69:12 (4th ed. 2003) and the Restatement (Second) of Torts, § 538). Materiality is more likely to be found where the information at issue goes “to the very essence of the bargain,” *id.* at 2003 n.5 (quoting *Junius Constr. Co. v. Cohen*, 178 N.E. 672, 673 (N.Y. 1931)). Materiality “cannot be found where noncompliance is minor or insubstantial.” *Id.* “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.” *Id.* Moreover, the Court expressly affirmed that the question of materiality is not “too fact intensive” to be addressed in the context of a motion to dismiss. *Id.* at 2004 n.6 (“The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality.”).

The *Escobar* Court also touched upon the FCA’s scienter requirement, noting that the Act imposes liability on any person who “knowingly” presents a false claim for payment to the government, 31 U.S.C. § 3729(a), and defines “knowing” and “knowingly” to mean that a person has “actual knowledge of the

information,” “acts in deliberate ignorance of the truth or falsity of the information,” or “acts in reckless disregard of the truth or falsity of the information.” *Id.* § 3729(b)(1)(A). The Court appeared to construe the scienter requirement together with the materiality requirement to mean that a claimant must not only “know,” as the term is defined by the FCA, about a violation of a particular statutory or regulatory provision, but also must “know” that compliance with that provision is “material” to the government’s payment decision. *See* 136 S. Ct. at 2001–02 (“A defendant can have ‘actual knowledge’ that a condition is material without the Government expressly calling it a condition of payment. . . . Likewise, [where] a reasonable person would realize the imperative of a [particular condition], a defendant’s failure to appreciate the materiality of that condition would amount to ‘deliberate ignorance’ or ‘reckless disregard’ of the ‘truth or falsity of the information’ even if the Government did not spell this out.” (quoting 31 U.S.C. § 3729(b)(1)(A))).

Finally, the Court emphasized that the Act’s materiality and scienter requirements are “rigorous,” and “demanding,” largely because the FCA is not intended to be “‘an all-purpose antifraud statute’ or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Id.* at 2002–03 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

B. Materiality

In support of its Motion to Dismiss the Third Amended Complaint, Brookdale argues that the TAC fails to plead materiality as required by *Escobar*,

because (1) the text of 42 C.F.R. § 424.22 makes it clear that its timing and signature provisions are not conditions of payment; (2) the TAC does not allege that the government has ever denied claims based on violations of the timing requirements of § 424.22(a)(2); (3) the allegations in the TAC and the authority cited therein fail to establish materiality; and (4) a violation of the signature timing requirement does not go to the “essence of the bargain” between CMS and Brookdale.

Prather disputes all of those contentions in her response, arguing that (1) the regulations indicate that the timing requirement is an express condition of payment; (2) *Escobar* does not mandate a showing that the government has refused to pay claims based on the violation alleged; (3) she has adequately alleged that the United States was “unaware of the falsity of the claims that Defendants submitted” and that it paid Brookdale on “claims that would otherwise not have been allowed” (Doc. No. 106, at 14 (quoting TAC ¶ 125)); and (4) the authorities she identified in the TAC demonstrate materiality.

After consideration of each of these arguments, the court concludes that the allegations in the TAC fail to establish that the certification-timing requirement is material to CMS’s payment decision.

(1) 42 C.F.R. § 424.22

The parties argue heatedly about whether the regulatory provision containing the certification timing requirement is or is not expressly designated as a condition of payment. The primary provision in question, 42 C.F.R. § 424.22, is labeled “Requirements

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for home health services,” and it states, in pertinent part, as follows:

Medicare . . . pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) Certification—

(1) Content of certification. As a condition for payment of home health services . . . , a physician must certify the patient’s eligibility for the home health benefit . . . as follows in paragraphs (a)(1)(i) through (v) of this section. The patient’s medical record, as specified in paragraph (c) of this section, must support the certification of eligibility as outlined in paragraph (a)(1)(i) through (v) of this section.

(i) The individual needs or needed intermittent skilled nursing care, or physical therapy or speech-language pathology services as defined in § 409.42(c) of this chapter. . . .

(ii) Home health services are or were required because the individual is or was confined to the home

(iii) A plan for furnishing the services has been established and will be or was periodically reviewed by a physician

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(iv) The services will be or were furnished while the individual was under the care of a physician

(v) A face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by a physician or allowed non-physician practitioner The certifying physician must also document the date of the encounter as part of the certification. . . .

(2) Timing and signature. The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(b) Recertification—

(1) Timing and signature of recertification. Recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed, and must be signed and dated by the physician who reviews the plan of care. Recertification is required at least every 60 days

(2) Content and basis of recertification. The recertification statement must indicate the

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continuing need for services and estimate how much longer the services will be required.

42 C.F.R. § 424.22(a)–(b).

In addition, 42 C.F.R. § 409.41, titled “Requirement for payment,” states: “In order for home health services to qualify for payment under the Medicare program . . . [t]he physician certification and recertification requirements for home health services described in § 424.22” “must be met.” *Id.* § 409.41(b). And, as also noted above, another provision specifies that “[d]elayed certification and recertification statements are acceptable when there is a legitimate reason for delay.” 42 C.F.R. § 424.11(d)(3).

Brookdale argues that the plain language of § 424.22 makes it clear that only the *contents* requirements contained in § 424.22(a)(1) and (b)(2) are conditions of payment, but the *timing* requirements in § 424.22(a)(2) and (b)(1) are not expressly identified as conditions of payment. It argues that this conclusion is further supported by 42 U.S.C. § 1395n(a)(2)(A) and other Medicare statutes that cover the contents of the regulations but do not incorporate a timing requirement for the physician certification. It also points out that the Medicare statute expressly conditions reimbursement on the making of a request for payment “no later than the close of the period ending 1 calendar year after the date of service,” 42 U.S.C. § 1395n(a)(1), thus demonstrating that, “[w]hen Congress or CMS wants to make timing a condition of payment, it knows how to do so.” (Doc. No. 103, at 18.) Brookdale further argues that the language of 42 C.F.R. § 409.401(b), generally requiring compliance

with the “certification and recertification requirements . . . described in § 424.22,” does not create new conditions of payment simply by cross-referencing § 424.22(a) and that the more specific language in § 424.22 trumps the more general language of § 409.41(b). In short, Brookdale argues that the government did not expressly condition payment on compliance with § 424.22(a)(2), thus strongly suggesting that the signature-timing requirement is not material.

The relator insists, to the contrary, that the signature-timing requirement is an express condition of payment. She argues that “the unmistakable language employed by CMS in 42 C.F.R. § 409.41 (labeled ‘Requirement for Payment’)” shows that CMS intended the timing requirement to be a condition of payment. She also points out that the Sixth Circuit noted that “the same certification requirement—and the same timing requirement for that certification—is applied by’ 42 C.F.R. § 409.41.” (Doc. No. 106, at 12 (quoting *Prather*, 838 F.3d at 766).)

The court agrees with the relator that the regulations, read together, make compliance with the timing requirement an express condition of payment. Part 424 of Title 42 of the Code of Federal Regulations is titled “Conditions for Medicare Payment,” and Section 424.22 is titled “Requirements for home health services.” Section 409.41, titled “Requirement for payment,” unambiguously makes payment conditional upon compliance with “[t]he physician certification and recertification requirements for home health services described in § 424.22,” 42 C.F.R. § 409.41(b), without distinguishing among those requirements. *Accord*

Prather, 838 F.3d at 766 (“The certifications are made a condition of Medicare payment, in a provision that does not distinguish between requests for final payment and requests for anticipated payment.”).

However, under *Escobar*, the fact that the requirement is expressly designated a condition of payment is not dispositive to liability under the FCA. *See Escobar*, 136 S. Ct. at 2001 (“[W]e . . . conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.”). While this factor weighs somewhat in favor of a finding in favor of the relator, the ultimate question remains whether the alleged misrepresentation was “material to the other party’s course of action.” *Id.*

(2) *Government Action*

Brookdale also argues that *Prather* fails to allege that the government has ever denied a claim based on a violation of the timing requirements of § 424.22. *Prather* does not dispute that assertion. She simply argues that *Escobar* does not mandate a showing that the government has refused to pay claims based on the alleged regulatory violation. She also argues that Brookdale’s reference to *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017), is inapposite, because that case was decided at the summary judgment stage after discovery had been conducted.³ For its part, the United States contends

³ In *McBride*, the government agency charged with auditing defense contracts investigated the relator’s allegations of fraud

that there are no allegations in the TAC suggesting that CMS knew of the violations alleged here at the time it paid the home health care claims and that CMS's failure to act is relevant only where it is shown that CMS approved payment with actual knowledge of the alleged misrepresentations in the payment demands.⁴ (See Doc. No. 107, at 7 (“[*Escobar*] is clear that the government’s decision to pay claims despite violations of a regulatory requirement is only evidence of a lack of materiality where the government has ‘actual knowledge’ of the violation.” (citing *Escobar*, 136 S. Ct. at 2003–04)).) The United States further argues that the relator should not be charged with having access to this type of information at this stage of the litigation and that discovery is required to permit the relator to obtain information “concerning the government’s ‘actual knowledge’ and the resulting pattern of action (or inaction) with respect to the types of violations alleged.” (*Id.*)

after the relator filed the complaint but before it was unsealed. The agency did not issue formal findings but neither did it disallow any of the amounts billed under the defendant’s contract. The D.C. Circuit, in considering the question of materiality, noted that it had the “benefit of hindsight and should not ignore what actually occurred” and considered it “very strong evidence” that the government did not disallow charges and in fact awarded the defendant an award fee for exceptional performance even after learning of the allegations. 848 F.3d at 1034.

⁴The government filed a Statement of Interest in which it declines to take a position as to the overall merits of the case or the sufficiency of the TAC but nonetheless raises several arguments in opposition to dismissal. (Doc. No. 107.)

This latter argument ignores the *Escobar* Court's determination that the materiality inquiry is not "too fact intensive" to be addressed in the context of a motion to dismiss. *136 S. Ct.* at 2004 n.6 ("We reject [the defendant's] assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality.").

Moreover, as Brookdale points out, the timing requirement in § 424.22 has been part of the Medicare regulations for fifty years, and home health care is a huge industry making up a significant portion of the millions of Medicare claims submitted every year. In light of the sheer volume of claims, the relator's inability to point to a single instance where Medicare denied payment based on violation of § 424.22(a)(2), or to a single other case considering this precise issue, weighs strongly in favor of a conclusion that the timing requirement is not material.

(3) *Authorities Cited in the Complaint*

Brookdale argues that the allegations in the TAC and the authority cited therein fail to establish materiality. Prather insists that the TAC adequately alleges facts and law supporting a finding of materiality.

She points, for instance, to the allegation that Medicare paid Brookdale's claims "that would

otherwise not have been allowed” if Medicare had been aware of the false representations (TAC ¶ 125)—that is, if it had known that the physicians’ signatures on certifications were not obtained within the time-frame required by § 424.22. Because this statement is nothing more than a conclusory assertion unsupported by actual facts, however, the court cannot presume its truth for purposes of the Motion to Dismiss. *See Iqbal*, 556 U.S. at 678 (“Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” (quoting *Twombly*, 550 U.S. at 557)). Likewise, the relator’s argument that “there is nothing in the record to indicate otherwise” (Doc. No. 106, at 14) is a red herring. Brookdale has no obligation to prove a negative; rather, it is the relator’s obligation to allege facts establishing materiality.

The relator also refers the court to allegations in the TAC that, to bill Medicare for home health care services, Brookdale must submit a claim form, Form 1450, to its Medicare Administrative Contractor and/or fiscal intermediary. (TAC ¶ 34.) By submitting Form 1450, Brookdale “certified that the contents of the claim were true, correct and complete, and that the form was prepared in compliance with all Medicare laws and regulations,” and further certified that it did not “knowingly or recklessly disregard or misrepresent or conceal material facts.” (TAC ¶¶ 35–36.) In addition, with Form 1450, Brookdale certified that the physician certifications and recertifications “are on file.” (TAC ¶ 37.) Finally, Prather asserts, in wholly conclusory fashion, that the information in Form 1450 “is material to Medicare’s payment of the claim.” (TAC ¶ 38.)

While submission of the Form 1450 is clearly relevant to an implied-false-certification theory of recovery under the FCA, insofar as it may constitute the necessary certification, it does not establish materiality. To find otherwise would make every technical misstatement or misrepresentation in a particular claim “material,” a result that *Escobar* clearly did not countenance. *See Escobar*, 136 S. Ct. at 2004 (“Likewise, if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability.”).

The TAC also incorporates reference to CMS Form 855A, the Medicare Enrollment Application, in which the applicant provider acknowledges being legally bound by Medicare laws and regulations, and CMS Form 1500, which individual health care practitioners providing home health care services use to submit claims and on which they certify that the services rendered were medically necessary, that the information on the claim form is true, and “that the provider ‘understand[s] that . . . any false claims, statements or documents, or concealment of a material fact, may be prosecuted under applicable Federal . . . laws.’” (TAC ¶ 40.) Submission of these forms, like submission of Form 1450, is insufficient to establish the materiality of any particular provision of the Medicare laws and regulations. *Accord U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 676–77 (S.D. Tex. 2013) (citing *U.S. ex rel. Wall v. Vista*

Hospice Care, Inc., 775 F. Supp. 2d 709, 720–21 (N.D. Tex. 2011)).

The relator also points to the “Compliance Program Guidance for Home Health Agencies” issued by the Office of the Inspector General (“OIG”) for the Department of Health and Human Services in August 1998. (TAC ¶ 47 (citing 63 Fed. Reg. 42410 (Aug. 7, 1998) (“OIG Guidance”)).) According to the TAC, the OIG Guidance identifies as a “Risk Area” “[u]ntimely and forged physician certifications on plans of care.” (TAC ¶ 47.) The OIG Guidance further confirmed that home health agencies should only submit claims for services the agency believes are medically necessary and that were ordered by a physician or other appropriately licensed medical provider. (*Id.*) Further, at a minimum, home health agencies should ensure that services are only billed “if the home health agency is acting upon a physician’s certification . . . that the services . . . are medically necessary and meet the requirements for home health services to be covered by Medicare.” (*Id.* (quoting OIG Guidance at 42416–17).

This OIG Guidance was intended to assist home health care agencies in the adoption of a voluntary compliance program in an effort to combat fraud and abuse, specifically through “[i]mplementing written policies, procedures and standards of conduct; [d]esignating a compliance officer and compliance committee; [c]onducting effective training and education; [d]eveloping effective lines of communication; [e]nforcing standards through well-publicized disciplinary guidelines; [c]onducting internal monitoring and auditing; and [r]esponding promptly to detected offenses and developing corrective action.” 63

Fed. Red. 42410-01, at 42410, 1998 WL 453988 (Aug. 7, 1998). While its fleeting reference to the timeliness of physician certifications as an area of concern is relevant and noteworthy, it is not sufficient on its own to establish that timeliness *per se* is a material condition of payment, particularly in light of the OIG Guidance's overall emphasis on certification of the necessity of care for patients that are actually homebound and on accurate billing.

The relator alleges that an OIG publication titled "The Physician's Role in Medicare Home Health 2001," emphasized "the significance of [the physician's] responsibility as the party who certifies the medical necessity for home health care, signs off on the level of services needed, and certifies that the patient is homebound." (TAC ¶ 49 (citing <https://oig.hhs.gov/oei/reports/oei-02-00-00620.pdf>)). According to the relator's allegations, however, this publication, too, highlights the importance of the *contents* of the physician certification, rather than its *timing*.

The relator also refers to several CMS publications issued well after the events giving rise to her claims, including a Medicare Benefit Policy Manual (CMS Pub 100-02), Ch. 7, § 30.5.1 (May 2015) (available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html>); and a publication dated March 2016 titled "Complying with Medicare Signature Requirements," http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Signature_Requirements_Fact_Sheet_ICN905364.pdf. This court already held, regarding the relator's citation to the

same publications, that new guidance from CMS does not apply retroactively to conduct that predates it. (Doc. No. 89, at 39.)⁵ Consequently, these publications are not relevant to the question of materiality during the relevant time frame or Brookdale's knowledge of such materiality.

In sum, none of the references cited by Prather in the TAC supports a finding that the certification-timing requirement is material.

(4) *The Regulatory Scheme and the Essence of the Bargain*

To be clear, the relator does not allege that physicians lied when they completed certifications stating that patients were under their care, home-bound, and under a plan of care established or to be established by the physician, that the patients required medically necessary services, or that the physicians had seen the patients in timely face-to-face encounters. The relator only alleges that the signatures on those documents were sometimes obtained late.

The relator asserts generally that compliance with the certification-timing requirement is necessary to prevent Medicare fraud and that the language in the regulation, requiring that the certification of need be obtained at the time the plan of care is established or *as soon thereafter as possible*," 42 C.F.R. § 424.22(a)(2)

⁵ Although not addressed in the majority opinion, Judge McKeague likewise noted in his partial dissent that a guidance issued in 2015 "could not establish that defendants were required *in 2010 and 2011* to obtain certifications before care had ended." *Prather*, 838 F.3d at 777.

(emphasis added), “suggests urgency.” (Doc. No. 106, at 15 (quoting *Prather*, 838 F.3d at 764).) The United States further argues that “the timing requirements are fundamental to the certification requirement, which in turn is a fundamental part of the bargain between a home health care provider and the Medicare program.” (Doc. No. 107, at 5.) The Sixth Circuit, in *Prather*, likewise seemed to suggest that the timing requirement went to the essence of the bargain and was key to the prevention of fraud:

The deadline also makes it more difficult to defraud Medicare. Absent a deadline, a home-health agency might be able to provide unnecessary treatment absent a doctor’s supervision and take the time to find doctors who are willing to validate that care retroactively. A deadline allowing only a short—and justified—delay between the beginning of care and the completion of the physician certification could make such a scheme difficult to pull off.

838 F.3d at 764.

On the other hand, as this court noted in the vacated opinion dismissing the Second Amended Complaint, numerous CMS publications from the relevant time period suggest that, while the certification of need is, indeed, a critical part of the bargain between home health care providers and Medicare, the timing of such certification is not. Instead, CMS appeared to require only that the certification be obtained prior to the submission of the claim for reimbursement at the end of the episode:

CMS permits claims to be filed up to one year after the date of service. *See* 42 C.F.R. § 424.44(a). In 2011 (the relevant time period . . .), CMS provided specific guidance that, for purposes of billing Medicare, the physician signature only needed to be obtained prior to the submission of the final claim. *See* Medicare General Information, Entitlement, and Eligibility Manual (“MGIEEM”) (CMS Pub. 100-01, Ch. 4, § 30.1 (April 2011) (stating that “the attending physician signs and dates the POC/certification *prior to the claim being submitted for payment*”) (emphasis added). Moreover, in 2013, in connection with CMS and the Medicare Learning Network, the American Medical Association published advisory guidance to the same extent. *See* Medicare Learning Network, MLN Matters Article SE1436 at p. 4, available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1436.pdf> (“The certification must be complete *prior to when an HHA bills Medicare for reimbursement.*”) (emphases added). FIs – the contractors working under CMS supervision who must comply with Medicare billing rules – have also issued similar guidance. *See, e.g.*, Ask-the-Contractor (ACT) Questions and Answers, June 21, 2015 at No. 5 (citing MLN Matters Article SE1436 and CMS Pub. 100-01, Ch. 4, § 30.1) (“The physician certification must be signed prior to billing. . . . *The physician certification must be signed before the final claim is submitted.*”) (available at <https://www>.

cgsmedicare.com/hhh/education/faqs/act/act_qa062415.html (emphasis added).

(Doc. No. 89, at 38–39.)

In short, the physician certification itself is clearly an essential and material component of the bargain between home health providers and Medicare. The relator however, has not pointed to facts in the record, including conduct on the part of CMS, legal precedent, or relevant Medicare guidance supporting a conclusion that the timing requirement is likewise material. Based on weighing all of the factors identified in *Escobar* as relevant to the question of materiality, the court concludes that Brookdale’s alleged implied misrepresentations about compliance with the certification-timing requirement are not material to CMS’s payment decision and therefore are not actionable under the FCA.

Having found that the misrepresentations in question were not material, the court has no need to reach the scienter component of the relator’s claims.

C. Count Two

The FCA’s reverse false claims provision extends liability to persons who “knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the United States.” 31 U.S.C. § 3729(a)(1)(G). An “obligation” under the FCA includes, inter alia, “the retention of any overpayment.” 31 U.S.C. § 3729(b)(3).

For purposes of its motion, Brookdale does not distinguish between the RAPs and final billed claims. It argues that Prather’s failure to adequately plead

materiality requires dismissal of all of her claims under § 3729(a)(1)(A) and (a)(1)(G). It argues that, because Prather failed to plead the materiality of the signature-timing requirement, she likewise cannot allege that Brookdale improperly retained any payments that it might have received from RAP billing.

In response, Prather effectively concedes that her cause of action under 31 U.S.C. § 3729(a)(1)(G) is valid only to the same extent as her claim under 31 U.S.C. § 3729(a)(1)(A). (Doc. No. 106, at 19.) As the court has already determined that the alleged conduct did not amount to a materially false claim and therefore did not give rise to an overpayment, Count Two also fails as a matter of law.

V. CONCLUSION

For the reasons set forth herein, the TAC will be dismissed. Because the relator has had the opportunity to amend the Complaint to bring it into compliance with the pleading requirements established by *Escobar*, the dismissal will be with prejudice.

An appropriate Order is filed herewith.

/s/ Aleta A. Trauger
ALETA A. TRAUGER
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**Case No. 3:12-cv-0764
Judge Aleta A. Trauger**

[Filed June 22, 2017]

UNITED STATES OF AMERICA,)
ex rel. MARJORIE PRATHER,)
)
Plaintiff,)
)
v.)
)
BROOKDALE SENIOR LIVING)
COMMUNITIES, INC., et al.,)
)
Defendants)
)

ORDER

For the reasons set forth in the accompanying Memorandum, the defendants' Motion to Dismiss Third Amended Complaint (Doc. No. 102) is **GRANTED**. Because the relator has had four opportunities to plead her claims, this action is **DISMISSED WITH PREJUDICE**.

It is so **ORDERED**.

This is the final Order in this case for purposes of Fed. R. Civ. P. 58.

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/s/ Aleta A. Trauger
ALETA A. TRAUGER
United States District Judge

**UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE**

Case No.: 3:12-cv-00764

[Filed June 22, 2017]

United States of America, et al.)
 Plaintiff,)
)
v.)
)
Brookdale Senior Living Inc., et al.)
 Defendant,)

)

ENTRY OF JUDGMENT

Judgment is hereby entered for purposes of Rule 58(a) and/or Rule 79(a) of the Federal Rules of Civil Procedure on 6/22/2017 re [113].

Keith Throckmorton, Clerk
s/ Dalaina Thompson, Deputy Clerk

APPENDIX C

**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

No. 17-5826

[Filed August 22, 2018]

UNITED STATES OF AMERICA)
EX REL. MARJORIE PRATHER,)
)
Relator-Appellant,)
)
v.)
)
BROOKDALE SENIOR LIVING)
COMMUNITIES, INC. ET AL.,)
)
Defendants-Appellees.)

O R D E R

BEFORE: MOORE, McKEAGUE, and DONALD,
Circuit Judges.

The court received a petition for rehearing en banc. The original panel has reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision. The petition then was circulated to the full court. Less than a majority of the judges voted in favor of rehearing en banc.

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Therefore, the petition is denied. Judge McKeague would grant rehearing for the reasons stated in his dissent.

ENTERED BY ORDER OF THE COURT

/s/ Deborah S. Hunt

Deborah S. Hunt, Clerk

APPENDIX D

31 U.S.C. § 3729 - False Claims

(a) Liability for Certain Acts.—

(1) In general.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a

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member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this

title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions.—

A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.—For purposes of this section—

(1) the terms “knowing” and “knowingly”—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term “claim”—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

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(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) Exemption From Disclosure.—

Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.—

This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

42 U.S.C. § 1395f(a)(2)(C)

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if—

...

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner, a clinical nurse specialist, or a physician assistant (as those terms are defined in section 1395x(aa)(5) of this title) who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,¹ or, in the case of services described in subparagraph (C), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such

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recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that—

...

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; such services are or were furnished while the individual was under the care of a physician, and, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter

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(including through use of telehealth, subject to the requirements in section 1395m(m) of this title, and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary; or

42 U.S.C. § 1395n(a)(2)(A)

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e) of this section, payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if—

...

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that--

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or,

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in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary;

42 C.F.R. § 424.22 (eff. Feb. 18, 2011)

Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) Certification—

(1) Content of certification. As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify as follows:

(i) The individual needs or needed intermittent skilled nursing care, or physical or speech therapy, or (for the period from July through November 30, 1981) occupational therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(ii) Home health services were required because the individual was confined to the home except when receiving outpatient services.

(iii) A plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine,

osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

(iv) The services were furnished while the individual was under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(v) The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) respectively. Under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, the face-to-face encounter must be performed by the certifying physician himself or herself or by a nurse practitioner, a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, a certified nurse midwife (as defined in section

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1861(gg)of the Act) as authorized by State law, or a physician assistant (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician. The documentation of the face-to-face patient encounter must be a separate and distinct section of, or an addendum to, the certification, and must be clearly titled, dated and signed by the certifying physician.

(A) The nonphysician practitioner performing the face-to-face encounter must document the clinical findings of that face-to-face patient encounter and communicate those findings to the certifying physician.

(B) If a face-to-face patient encounter occurred within 90 days of the start of care but is not related to the primary reason the patient requires home health services, or the patient has not seen the certifying physician or allowed nonphysician practitioner within the 90 days prior to the start of the home health episode, the certifying physician or nonphysician practitioner must have a face to face encounter with the patient within 30 days of the start of the home health care.

(C) The face-to-face patient encounter may occur through telehealth, in compliance with Section 1834(m) of the Act and subject to the list of payable Medicare telehealth services established by the applicable physician fee schedule regulation.

(D) The physician responsible for certifying the patient for home care must document the

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face-to-face encounter on the certification itself, or as an addendum to the certification (as described in paragraph (a)(1)(v) of this section), that the condition for which the patient was being treated in the face-to-face patient encounter is related to the primary reason the patient requires home health services, and why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services as defined in § 409.42(a) and (c) respectively. The documentation must be clearly titled, dated and signed by the certifying physician.

(2) Timing and signature. The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

(b) Recertification—

(1) Timing and signature of recertification. Recertification is required at least every 60 days, preferably at the time the plan is reviewed, and must be signed and dated by the physician who reviews the plan of care. The recertification is required at least every 60 days when there is a—

(i) Beneficiary elected transfer; or

(ii) Discharge and return to the same HHA during the 60-day episode.

(2) Content and basis of recertification. The recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy. If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician will include a brief narrative describing the clinical justification of this need. If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature. If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must sign immediately following the narrative in the addendum.

(c) [Reserved]

(d) Limitation of the performance of physician certification and plan of care functions. The need for home health services to be provided by an HHA may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician who has a financial relationship as defined in § 411.354 of this chapter, with that HHA, unless the physician's relationship meets one of the exceptions in section 1877

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of the Act, which sets forth general exceptions to the referral prohibition related to both ownership/investment and compensation; exceptions to the referral prohibition related to ownership or investment interests; and exceptions to the referral prohibition related to compensation arrangements.

(1) If a physician has a financial relationship as defined in § 411.354 of this chapter, with an HHA, the physician may not certify or recertify need for home health services provided by that HHA, establish or review a plan of treatment for such services, or conduct the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act unless the financial relationship meets one of the exceptions set forth in § 411.355 through § 411.357 of this chapter.

(2) A Nonphysician practitioner may not perform the face-to-face encounter required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act if such encounter would be prohibited under paragraph (d)(i) if the nonphysician practitioner were a physician.