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PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

UNITED STATES OF AMERICA, ex rel. STACEY L. JANSSEN, as Special Administrator of the Estate of Megen Corin Duffy,

Plaintiff Counter Defendant - Appellant,

v.

LAWRENCE MEMORIAL HOSPITAL,

Defendant - Appellee.

No. 19-3011

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF KANSAS (D.C. NO. 2:14-CV-02256-SAC)

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Andrew W. Lester (Mark A. Cole, Andrew R. Ramirez, and Kathryn G. Lee, with him on the brief), Spencer Fane LLP, Overland Park, Kansas, for Appellee.

Before **TYMKOVICH**, Chief Judge, **MURPHY**, and **CARSON**, Circuit Judges.

TYMKOVICH, Chief Judge.

In this False Claims Act case, Stacey Janssen alleges Lawrence Memorial Hospital engaged in two healthcare schemes to fraudulently receive money from the United States. Janssen first contends LMH falsified patients' arrival times in order to increase its Medicare reimbursement under certain pay-for-reporting and pay-for-performance programs the Government uses to study and improve hospitals' quality of care. Next, Janssen contends LMH falsely certified compliance with the Deficit Reduction Act in order to receive Medicare reimbursements to which it was otherwise not entitled.

LMH moved for summary judgment below, arguing Janssen failed to show her allegations satisfied the Act's materiality requirement—that the alleged falsehoods influenced the Government's payment decision as required under the FCA. The district court granted LMH summary judgment on all of Janssen's claims on this basis, and we AFFIRM.

I. Background

We first explain the fraud schemes alleged in the complaint and then discuss the procedural background relevant to the legal issues on appeal.

A. LMH's Alleged Fraud Schemes

Janssen claims LMH engaged in two fraudulent schemes. The first concerns LMH's alleged falsification of patients' arrival times. The second centers on LMH's false certification of compliance with the Deficit Reduction Act.

1. Falsification of Patients' Arrival Times

LMH contracts with the Centers for Medicare and Medicaid Services (CMS) to provide services to Medicare patients. CMS pays LMH for services based on pre-determined rates. These rates are affected by certain programs, including the Inpatient Quality Reporting (IQR) program, the Outpatient Quality Reporting (OQR) program, and the Hospital Value Based Purchasing (HVBP) program. To varying degrees, each of these programs rely on measures that incorporate patients' arrival times. The arrival time data is considered because it helps the Government analyze the timeliness of the care patients receive.

a. The IQR, OQR, and HVBP Programs

The IQR program is a pay-for-reporting program. Under this program, hospitals report certain designated quality measures regarding inpatient care. In exchange for timely and accurately reporting, hospitals receive an annual increase—what is termed a "market basket index increase"—in the rate at which they are reimbursed under Medicare. *See* 42 C.F.R. § 412.64. Those hospitals

that fail to submit accurate data on a timely basis have their market basket index increase reduced.[1] *Id.* at (d)(2).

The OQR program operates similarly to the IQR program, except it relates to outpatient, as opposed to inpatient, care. Hospitals must report certain quality measures regarding outpatient care under the program. In exchange for accurate and timely data, hospitals protect their annual market basket index increase from reduction.

For both the IQR and OQR programs, LMH understands that submitting accurate and complete data was a condition of receiving its full market basket index increase. For the IQR program, LMH also submits Data Accuracy and Completeness Acknowledgments on an annual basis certifying that the data submitted is "accurate and complete." App. at 2608.

The HVBP program is a pay-for-performance program. It operates as an incentive program based on hospitals' relative performance on a subset of IQR measures. Unlike the IQR and OQR programs—which reward the mere submission of data to CMS without regard for the substantive content of that data—the HVBP program considers how well or poorly hospitals performed

[1] For fiscal years 2007 through 2014, noncompliant hospitals' increases were reduced by 2 percent. 42 C.F.R. § 412.64(d)(2)(i)(B). For fiscal years 2015 and later, noncompliant hospitals' increases were reduced by one-fourth. 42 C.F.R. § 412.64(d)(2)(i)(C).

compared to their peers. Under this program, CMS withholds a percentage from the total annual Medicare payments due to all participating hospitals and redistributes these funds according to each hospital's performance score. A hospital's performance score is calculated based on four different domains. Each domain has a number of different measures within it. Accordingly, during the relevant time period, LMH's performance on certain IQR measures affected its overall HVBP performance score, which in turn impacted its Medicare reimbursement rate.

The healthcare measures used in the IQR, OQR, and HVBP programs change from year to year. During the relevant period some, but not all, of these measures incorporated patients' arrival times. For example, the only measures in the HVBP program that incorporated arrival times were AMI-7a (fibrinolytic therapy received within 30 minutes of hospital arrival) and AMI-8a (primary surgical intervention received within 90 minutes of hospital arrival). In fiscal year 2015, these constituted two out of twelve measures contributing to LMH's Clinical Process of Care Domain score—one of four domain scores that contributed to LMH's overall HVBP performance score. Similarly, of the measures utilized by the IQR and OQR programs, only a subset include arrival

times.[2] Moreover, for certain periods, LMH did not report any data for even those measures that incorporate arrival times.[3]

LMH reports data for the IQR and OQR programs to CMS either through automatically generated reports or by "abstracting" the data from patient charts. Abstraction is performed using Specifications Manuals promulgated by CMS. Abstractors do not, and cannot, alter data or patient records, nor do they investigate the accuracy of the data. Thus, for both forms of reporting, any inaccuracies in patients' records are simply carried over to the data reported to CMS.

b. Reporting False Patient Arrival Times

Under the IQR and OQR programs, LMH must report a patient's arrival time as the earliest time shown among a variety of documentation, including the

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[2] At oral argument, counsel for Janssen responded to a question regarding the extent each program utilized arrival times:

> Q: How many other of the metrics employ the arrival time?
> A: I don't have a dispositive number for you there, your honor. . . .
> Q: Is it like two of three employed arrival time or is it two of twenty?
> A: I think it's probably, on the inpatient side, it may be two or three of eighteen . . . and on the outpatient side there are a few more.

Oral Argument Recording, 32:02–33:00, Nov. 11, 2019.

[3] For example, for fiscal year 2015, LMH did not report any data with respect to AMI-7a because it had no relevant cases. App. at 3435.

patient's triage record or emergency department fact sheets.[4] As the district court notes in its order granting summary judgment, numerous pieces of evidence in the record support the contention that "LMH knowingly falsified patient records with the intent of causing abstracted 'arrival times' to be later than they would have been absent the falsification." App. at 3641.

For example, the former director of LMH's Emergency Department testified that LMH used "interim forms" and "triage sheets" to record patient arrival times but later discarded these forms so that the recorded arrival times did not enter the patient's hospital record. App. at 814–16. A former registration clerk in LMH's Emergency Department also declared that she was trained and instructed to delay registration of patients until after the administration of electrocardiograms (EKGs) so that the arrival time on the patient's record was synonymous with their EKG time. She also declared that LMH altered patients' arrival times to match EKG times in order to obtain Medicare compensation. *Id.* at 1369.

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[4] According to CMS Specifications Manuals, arrival time is "the earliest documented time the patient arrived" at the hospital emergency department or as an outpatient. App. at 255. This may be gleaned from a number of acceptable sources, including (1) any emergency department documentation; (2) nursing admission assessment/admitting note; (3) observation record; (4) procedure notes; and (5) vital sign graphics record. *Id.* at 265. As of July 1, 2012, CMS defined emergency department documentation to include "any documentation from the time period that the patient was an ED patient e.g., ED fact sheet, ED consent/Authorization for treatment forms, ED/Outpatient Registration/sign-in forms, ED vital sign record, triage record, ED physician orders, ECG reports, telemetry rhythm strips, laboratory reports, x-ray reports." *Id.* at 313.

Certain statistics are consistent with these assertions. Between 2010 and 2017, LMH reported a total of 17,714 records that incorporated "arrival time" as part of the IQR program. App. at 2606. For 15.89% of these records, the patient's arrival time was either the same as or later than a recorded EKG time. *Id.* During the same period, LMH reported 8,672 records to CMS that incorporated arrival time as part of the OQR program. *Id.* Of these, 4.09% contained an arrival time that was either the same as or later than a recorded EKG time. *Id.* Moreover, from the second quarter of 2008 through the last quarter of 2010, LMH frequently reported a median arrival-to-EKG time of more than eight minutes and never reported a time below three minutes. *Id.* at 948. But beginning in the first quarter of 2011, LMH began frequently reporting a median arrival-to-EKG time of zero or one minute. *Id.*

A reasonable inference from this testimonial and statistical evidence is that LMH falsified certain patient arrival times and reported some inaccuracies to CMS through the IQR and OQR programs. But the record is silent as to the extent LMH's alleged falsification of arrival times affected the accuracy of its IQR and OQR reporting or its HVBP performance score.[5]

[5] As Janssen concedes, "there is little evidence of the precise degree to which each measure is off is solely a function of LMH's scheme." Aplt. Br. at 59.

2. False Certification of Compliance with the Deficit Reduction Act

As a condition of receiving more than $5 million each year from Medicare, LMH must comply with Section 6032 of the Deficit Reduction Act. Section 6032 requires LMH to educate its employees with detailed information regarding the False Claims Act. *See* 42 U.S.C. § 1396a(a)(68). Among other things, Section 6032 requires that "any employee handbook" include "specific discussion" of "detailed information about the False Claims Act . . . administrative remedies for false claims and statements . . . any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs . . . ." *Id.*

From 2007 to 2016, LMH's New Associate Resource Handbooks lacked detailed discussion of the FCA, although these sources were supplemented with additional training and informational materials.

LMH also signed Attestations of Compliance for at least fiscal years ending September 30, 2014 through 2017. Each attestation states that "as a condition for receiving payments exceeding $5 million per federal fiscal year" the executor has "examined" LMH's policies and procedures and read Section 6032 of the Deficit Reduction Act. App. at 1707, 1714. Each further certifies that LMH is in compliance with the requirements of Section 6032.

For the fiscal years ending September 30, 2016 and 2017, the executors of LMH's attestations testified that they signed the forms without engaging in the activities to which they attested. Specifically, LMH's Chief Financial Officer executed the attestation for the fiscal year ending September 30, 2016, and testified that he did so without reviewing any educational materials distributed to employees. *Id.* at 1704. LMH's Chief Operating Officer executed the attestation for the year ending September 30, 2017, and testified that she did so without reviewing any policies or procedures. *Id.* at 1722.

B. Procedural and Investigatory History

In November 2013, the original Relator in this action, Megen Duffy,[6] called a CMS hotline to report LMH for alleged Medicare fraud. NCI AdvanceMed (NCI), a third-party investigative service for CMS, subsequently began investigating the allegations, including the claim that LMH committed fraud by "manipulating their door-to-EKG times" so as to "avoid losing money as a result of a reduced Medicare reimbursement." App. at 2534.

On May 30, 2014, Duffy filed her initial complaint. On June 16, 2015, she filed her second amended complaint. The Department of Justice received each, and sought additional time to consider intervention, stating it "assembled an investigative team and commenced an investigation." Supp. App. at 1. The DOJ

[6] On October 26, 2018, the district court ordered Stacey L. Janssen, the Special Administrator of Duffy's estate, substituted as the *qui tam* Relator.

notified the Health and Human Services Office of Inspector General, interviewed Duffy, and expressed interest in "thoroughly review[ing] and analyz[ing]" the allegations. *Id*. at 2. Ultimately, the DOJ opted not to intervene.

Around August 2014, NCI closed the investigation, noting "CMS is aware of quality issue." *Id.* at 2542. To date, CMS has not taken any action with respect to LMH. It has not ceased paying the Medicare claims that LMH continues to submit or asked LMH to adjust its reporting practices under the IQR, OQR, or HVBP programs.

After several years of litigation, LMH moved twice for summary judgment. The district court denied the first motion, which was filed before the close of discovery. The district court granted the second motion. With respect to both alleged fraud schemes, the district court held Janssen failed to raise a genuine issue of material fact with respect to the materiality of the alleged falsehoods. This appeal followed.

II. Analysis

Janssen brings the present claims under 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G).[7] To show a false claim, Janssen must establish (1) a false statement or

[7] Subsection (A) creates liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Subsection (B) creates liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* at § 3729(a)(1)(B). Subsection (G), (continued...)

fraudulent course of conduct; (2) made with the requisite scienter; (3) *that is material*; and (4) that results in a claim to the Government or conceals, decreases, or avoids an obligation to pay the Government. *See U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 734 (10th Cir. 2018). Here, the focus is on materiality, a required element under each of the provisions Janssen relies on. *See* 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G); *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).[8] Materiality is a mixed question of law and fact that can be decided as a matter of law if reasonable minds could not differ on the question. *See Long v. Ins. Co. of N. Am.*, 670 F.2d 930, 934 (10th Cir. 1982). We review the district court's grant of summary judgment de novo,

[7](...continued)
sometimes referred to as the reverse false claims section, creates liability for anyone who "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." *Id.* at § 3729(a)(1)(G).

[8] With respect to 31 U.S.C. §§ 3279(a)(1)(B) and (G), this requirement is explicitly included in the text of the statute. With respect to 31 U.S.C. § 3729(a)(1)(A), the Supreme Court has unequivocally stated a materiality requirement exists. *See Escobar*, 136 S. Ct. at 2001–02. The parties do not advance, and we do not take, any position with respect to whether any distinctions exist between the materiality requirements applicable to each subsection. For purposes of this appeal, any such distinctions are irrelevant as Janssen fails to meet any conception of materiality. *See Escobar*, 136 S. Ct. at 2002 (declining to decide whether "§ 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law" because "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'").

applying the same standard as the district court. *Smothers v. Solvay Chems.*, 740 F.3d 530, 538 (10th Cir. 2014).

A. Legal Framework

When originally enacted in 1863, the FCA aimed to stop "massive frauds perpetrated by large contractors during the Civil War." *United States v. Bornstein*, 423 U.S. 303, 309 (1976). Today, the FCA's focus "remains on those who present or directly induce the submission of false or fraudulent claims" to the Government. *Escobar*, 136 S. Ct. at 1996. But the FCA does not impose liability for any and all falsehoods. *Id.*; *see also* 31 U.S.C § 3729(a)(1)(A) *et seq*. Simply put, the FCA is not an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003 (citations omitted); *U.S. ex rel Bulbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("The FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." (quoting *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999))). Instead, FCA liability attaches only where the alleged misrepresentations are material to the Government's payment decision. *See Escobar*, 136 S. Ct. at 2001–02.

In the FCA context, materiality is a "rigorous" and "demanding" requirement. *Id.* at 2002–03; *see also U.S. ex rel. Coffman v. City of Leavenworth*, 770 F. App'x 417, 419 (10th Cir. 2019) (holding "[a]n FCA claim

must satisfy materiality . . . which [is] 'rigorous' and strictly enforced"). Assessing materiality requires analysis of the "effect on the likely or actual behavior of the recipient of the alleged misrepresentation."[9] *See Escobar*, 136 S. Ct. at 2002; *see also* 31 U.S.C. § 3729(b)(4) (defining materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"). Thus, the sine qua non of materiality is some quotient of potential influence on the decisionmaker—in this case, CMS.

Janssen dedicates much of her briefing to arguing for a "broad" interpretation of materiality. Aplt. Br. at 31. She contends the Supreme Court in *Escobar* adopted the concept of materiality familiar to contract and tort law and, under such a view, materiality may be shown through either an objective or subjective showing.[10] *Id.* at 27, 33. According to Janssen, under either an

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[9] Although the focus is on the Government's likely conduct, Janssen need not demonstrate actual reliance to survive summary judgment. *Cf. United States v. Williams*, 934 F.3d 1122, 1128–30 (10th Cir. 2019). That is, a false statement can be material even if the government's decision to pay or not pay the claim does not hinge on that statement alone. To erect such a bar—one requiring a showing of actual reliance—would impermissibly go beyond the text of the statute. *See, e.g.*, 31 U.S.C. § 3729(a)(1)(A) (attaching liability to the presentment of a false or fraudulent claim for payment rather than the actual payment of the claim); *see also U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009) ("The False Claims Act . . . lacks the elements of reliance and damages.").

[10] Janssen also cites numerous cases in support of her argument in favor of a purely objective or subjective understanding of materiality. We find these unpersuasive. *Long v. Insurance Co. of North America* involved allegations of insurance fraud between two private parties. 670 F.2d at 934. *Gilbert v. Nixon*

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objective or subjective showing, the focus need not be on the recipient of the misrepresentation. *See* Aplt. Br. at 34 (stating that "absent from both the objective and subjective tests is any requirement of proof of what the recipient of a misrepresentation actually thought or did in response to it").

But contrary to Janssen's argument, the Supreme Court in *Escobar* did not adopt the formulation of materiality contained in the Restatement (Second) of Torts § 538 and the Restatement (Second) of Contracts § 162(2). Instead, the Court cited these formulations in support of the statement that "under any understanding of the concept, materiality 'look[s] to the *effect on the likely or actual behavior of the recipient* of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (emphasis added). Thus, rather than directing courts to focus exclusively on a reasonable person—as they would under a purely objective

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involved allegations of fraud connected to investments in certain oil and gas leases executed between two private parties. 429 F.2d 348, 351–54 (10th Cir. 1970). Neither case offers an analogy to the present FCA allegations, much less a persuasive reason to distinguish and attempt to depart from the controlling directive of *Escobar*. *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), and *United States v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017), involve FCA allegations, but neither control nor support Janssen's conceptualization of materiality. First, both cases concerned the sufficiency of pleadings to withstand a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *See Brookdale*, 892 F.3d at 825–26; *Triple Canopy*, 857 F.3d at 175. Second, each explicitly considered the likely or actual effect of the alleged misrepresentations on the Government in its analysis, consistent with the approach adopted here. *Brookdale*, 892 F.3d at 832–38. *Triple Canopy*, 857 F.3d at 178–79.

analysis—or exclusively on the mindset of the misrepresenter—as they would under a purely subjective analysis—*Escobar* focuses the materiality inquiry on the likely reaction of the recipient.[11]

This inquiry is holistic. In cases such as this one, where the allegations base FCA liability on noncompliance with regulatory or contractual provisions, relevant factors include, but are not limited to (1) whether the Government consistently refuses to pay similar claims based on noncompliance with the provision at issue, or whether the Government continues to pay claims despite knowledge of the noncompliance; (2) whether the noncompliance goes to the "very essence of the bargain" or is only "minor or insubstantial;" and (3) whether the Government has expressly identified a provision as a condition of payment. *Escobar*, 136 S. Ct. at 2003 & n.5. None of these factors alone are dispositive. *See United States v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

Applying this standard of materiality, we turn first to LMH's alleged falsification of arrival times before addressing LMH's alleged false certifications of compliance with the Deficit Reduction Act.

[11] Evidence of objective or subjective materiality are not irrelevant. Such evidence may be probative in the materiality analysis. *U.S. ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). But it is relevant primarily because it casts light on the likely reaction of the recipient, not because it holds any isolated independent importance.

B. Patient Arrival Times

Assessing the factors discussed above, we conclude Janssen has failed to present sufficient evidence to raise a fact issue with respect to whether the alleged falsification of arrival times was material to the Government's payment decision.

1. Government's Prior Conduct

The Government's prior conduct weighs in favor of immateriality. Where the "Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," this demonstrates materiality. *Escobar*, 136 S. Ct. at 2003–04. 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." *Id.*

Neither party presents other cases concerning CMS reimbursement under the IQR, OQR, or HVBP programs, and we are aware of none. But the Government's actual behavior in *this* case suggests Janssen's allegations are immaterial.[12] *See U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("[W]e have the benefit of hindsight and should not ignore what

[12] We focus here on CMS's inaction despite knowledge of the allegations. Although stressed in LMH's briefing, we put little weight on the fact that the DOJ was aware of the allegations and declined intervention. To infer much, if anything, from such a declination would undermine the purposes of the FCA, which is explicitly designed to permit private persons to litigate suits in lieu of the Government. *Brookdale*, 892 F.3d at 836; *see also* 31 U.S.C. § 3730(d)(2).

actually occurred."). The record shows that in 2014 NCI conducted an investigation over several months into the central allegations presently at issue and made CMS aware of the quality issues complained of. To this day, CMS has done nothing in response and continues to pay LMH's Medicare claims. Although CMS may not have independently verified LMH's noncompliance—and thus may not have obtained "actual knowledge" of the alleged infractions—its inaction in the face of detailed allegations from a former employee suggests immateriality. *See U.S. ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 538 (9th Cir. 2018) (upholding summary judgment where the Government continued to pay claims "up to at least 2008, despite being aware of Relators' fraud allegations since 2002 [and] the results of its own audit since 2003"); *see also D'Agostino v. Ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations.").

Janssen claims that NCI did not engage in an "actual investigation." Aplt. Br. at 61. But NCI's report undermines this claim, and an affidavit from the NCI custodian of record avers that "NCI AdvanceMed investigated Megen Duffy's claim against Lawrence Memorial Hospital that is the subject of this lawsuit." App. at 2530. Janssen also contends the scope of the investigation was confined to whether or not "door-to-EKG" was, at the time, an HVBP measure. Aplt. Br.

at 61. This too is belied by the record. Although the NCI documents fail to precisely detail the scope of the investigation, they indicate that NCI was focused on the central complaint at issue here. For example, the cover sheet for the CMS hotline states that "Ms. Duffy claims that the employees of LMH are falsifying patients' charts . . . in order to get higher reimbursements." App. at 2532. The NCI closing investigative summary further describes the allegations under review as involving LMH "manipulating their door-to-EKG times . . . so that Lawrence Memorial Hospital can receive the highest reimbursement possible." App. at 2537. Although the evidence with respect to NCI's investigation is not overwhelming, the NCI summary details identification of a "quality issue" with respect to the precise allegations at issue and notes that CMS was made aware of the matter. This constitutes some evidence in favor of immateriality.[13]

[13] Janssen cites to the First Circuit's decision on remand in *Escobar*, arguing that nothing should be drawn from the CMS's continued payment of claims where it had only knowledge of allegations, as opposed to actual violations. *U.S. ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[A]wareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance.") While the distinction between allegations and actual knowledge is relevant, we find the First Circuit's decision distinguishable. In *Escobar* the court assessed the sufficiency of a complaint at the motion to dismiss stage, finding that potential knowledge of allegations was insufficient to warrant dismissal where the alleged noncompliance went to the essence of the bargain. The procedural posture here is quite different. It is not inconsistent to state that knowledge of allegations is insufficient, alone, to warrant dismissal under Rule 12(b)(6) and yet constitutes some evidence of immateriality under Rule 56(a). Moreover, in *Escobar* the allegations only noted that the Government continued to pay claims up to the filing of litigation. Here

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2. Essence of the Bargain

The minimal aspects of LMH's alleged misconduct similarly suggest immateriality. Where noncompliance with a regulatory requirement is "minor or insubstantial," it indicates immateriality. *Escobar*, 136 S. Ct. at 2003. Conversely, where noncompliance goes to the "essence of the bargain," it suggests materiality. *Id.* at 2003 n.5.

Janssen emphasizes the importance of accurate reporting to the effective operation of the IQR, OQR, and HVBP programs as justification for the importance and centrality of LMH's misconduct. Aplt. Br. at 45. The need for accurate reporting is at least arguably enshrined in the statutory and regulatory requirements for the programs, and was understood, at least at a general level, by LMH staff. But in the complex matrix of Medicare reporting and reimbursement, such broad appeals to the importance of accurate reporting cannot clear the rigorous materiality hurdle. *See U.S. ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1221 (10th Cir. 2008) (holding a hospital's failure to comply perfectly with Medicare regulations does not automatically generate FCA liability). As we noted in *Conner*, the Government has an "administrative scheme for ensuring that hospitals remain in compliance and for bringing them back into

[13](...continued)
CMS has continued to pay claims—and has requested no changes in LMH's data reporting or Emergency Room practices—for years despite ongoing litigation.

compliance when they fall short of what the Medicare regulations and statutes require." *Id.* at 1220.

Here, that scheme envisions administrative procedures designed to address noncompliance with requirements of the IQR and OQR programs, including inaccurate reporting. *See* 42 C.F.R. §§ 412.140, 419.46. Substituting FCA liability for every failure to achieve perfect compliance with Medicare regulations would not only undermine the Government's administrative program, but would render the FCA a general antifraud statute and tool for policing minor regulatory compliance issues, contrary to the Court's directive in *Escobar*. *See Conner*, 543 F.3d at 1221; *see also Escobar*, 136 S. Ct. at 2003.

Accordingly, we must look not to simply whether Janssen has shown some inaccuracies in LMH's reporting, but to whether Janssen has demonstrated sufficiently widespread deficiencies that they would likely affect the Government's payment decision. We conclude she has failed to do so.

As Janssen concedes, there is "little evidence" demonstrating the extent to which inaccurate arrival times affected the accuracy of LMH's reporting. Aplt. Br. at 59. In the IQR and OQR programs, arrival time is only incorporated into a subset of measures for which LMH reports data. Moreover, not all the patient records relating to each affected measure were falsified. Even taking all reasonable inferences in Janssen's favor, we can at most conclude that relatively

few records reported false arrival times. *See* App. at 2606 (averring that only 15.99% of inpatient records and 4.09% of outpatient records incorporating arrival time had an EKG time identical to or earlier than the patient's arrival time). Thus, at most, LMH's alleged misconduct affected only a subset of a subset of the data reported under the IQR and OQR programs.

The effect of LMH's alleged misconduct is similarly limited with respect to the HVBP program. Only two measures in one of the four domains that affect LMH's performance score under the program incorporated arrival times. Within these measures, the degree to which LMH's alleged misconduct affected its performance is not ascertainable. At most, Janssen has shown uncertain effects on a factor of a factor of LMH's performance score. This evidence is insufficient to raise a fact issue with respect to materiality. *See Conner*, 543 F.3d at 1220–21; *Escobar*, 136 S. Ct. at 2003–04.

Nor has Jassen put forward evidence of a cover-up, which might signal materiality despite the minor effects of the alleged misconduct. *See United States v. Triple Canopy, Inc.*, 775 F.3d 628, 638 (4th Cir. 2015) *judgment vacated by Triple Canopy, Inc. v. U.S. ex rel. Badr*, 136 S. Ct. 2504 (2016), *but reaffirmed in Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017). In *Triple Canopy*, the Fourth Circuit inferred materiality, in part, from a "scheme" the defendant orchestrated to cover up the deficiencies of guards contracted to provide security services on

U.S. military bases overseas. There, after learning of the guards' deficient training, defendant's supervisors falsified scorecards so that its guards would meet the marksmanship requirements in its contract with the Government. Supervisors signed and post-dated the guards' false marksmanship scorecards despite knowing the guards could not zero their rifles or shoot straight.

Here, no analogous cover-up is evident. Janssen points to Medicare claim forms and Data Accuracy and Completeness Acknowledgments, arguing both constitute false certifications of accuracy regarding LMH's reported arrival times. But these boilerplate compliance documents are part of the complex Medicare regulatory system and fail to elevate potentially less-than-perfect compliance to FCA liability. *See Conner*, 543 F.3d at 1221 (rejecting the "sweeping" argument that Medicare certifications give rise to FCA liability with respect to minor or insubstantial regulatory noncompliance). Moreover, none of the deposition testimony Janssen cites supports the assertion that LMH's certifications were signed despite knowledge of inaccuracies similar to the guards' scorecards in *Triple Canopy*.

In light of the, at most, minimal nature of the inaccuracies in LMH's reporting under the IQR, OQR, and HVBP programs, we find Janssen's allegations do not go to the essence of the bargain between LMH and CMS and are therefore immaterial.

3. Express Condition of Payment

Finally, Janssen contends that the Government has expressly required accurate reporting as a condition of payment under the IQR, OQR, and HVBP programs. Aplt. Br. at 41, 52 (citing 42 U.S.C. §§ 1395ww(b), 1395l(t)(17), 1395ww(o); 42 U.S.C. §§ 1395ww(b)(3)(B)(viii)(I), 1395l(t), 1395ww(o)(1); and 42 C.F.R. § 482.24). Such requirements, while relevant, are not dispositive. *Escobar*, 136 S. Ct. at 2003.

Certain conditions for participating in Medicare are provided by 42 C.F.R. § 482.24. Among other things, participating hospitals such as LMH must maintain accurate medical records. While this requirement casts some light on the general importance of accurate reporting to the Government, it does not directly address the IQR, OQR, and HVBP programs. More importantly, such generic regulatory requirements fall short of establishing the materiality of perfect compliance therewith, especially when encased in a complex regulatory system with separate administrative remedies. *Conner*, 543 F.3d at 1218–22.

The remaining provisions of 42 U.S.C. §§ 1395ww(b), 1395l(t), and 1395ww(o) similarly fail to establish materiality. Even assuming these statutes require accurate reporting as an express condition under the relevant programs, that alone is insufficient to establish materiality. *Escobar*, 136 S. Ct. at 2003.

Accordingly, we find that the statutes and regulations related to the IQR, OQR, and HVBP programs do not overcome Janssen's failure to establish materiality with respect to LMH's alleged falsification of arrival times.

C. Deficit Reduction Act

Janssen's claims with respect to the Deficit Reduction Act similarly fail for lack of materiality. Although the record reveals a fact issue with respect to whether all of LMH's employee handbooks comply with Section 6032, not all potential compliance failures warrant FCA liability. *Escobar*, 136 S. Ct. at 2003 (noting the FCA is not a "vehicle for punishing garden-variety breaches of . . . regulatory violations").

Numerous New Associate Resource Handbooks distributed by LMH between 2007 and 2016 lack detailed, if any, discussion of the False Claims Act or the specific topics required to be communicated to employees under Section 6032. This may raise a jury issue with respect to whether LMH violated Section 6032. *See* 42 U.S.C. § 1396a(a)(68). Further, it is reasonable to infer from the testimony of LMH's Chief Financial Officer and Chief Operating Officer that LMH management submitted inadequate or false attestations of compliance with the DRA.

But while LMH's potential failure to educate its employees in the manner and detail required by Section 6032 and its management's certification of

compliance without sufficient knowledge, investigation, or review raise concerns with respect to LMH's regulatory compliance, these points do not translate into FCA liability. As we have previously explained, the FCA is not a tool to police everyday regulatory noncompliance. *U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("The FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."); *see also Escobar*, 136 S. Ct. at 2002. This rings especially true where complex regulatory schemes are managed by specific agencies with extensive technical experience. *See Conner*, 543 F.3d at 1221 ("It is therefore with good reason that the agencies of the federal government, rather than the courts, manage Medicare participation in the first instance . . . ."). In such scenarios, not every regulatory foot-fault will enable Relators to avail themselves of the FCA's potentially costly damages awards.

LMH's potential DRA compliance failures are precisely the type of garden-variety compliance issues that the demanding materiality standards of the FCA are meant to forestall. First, Janssen has at most demonstrated limited compliance issues, not a wholesale failure of LMH's compliance function. Outside of the new employee resource handbooks and attestations mentioned, Janssen does not dispute that LMH provides employees information regarding FCA compliance in line with the requirements of Section 6032. For example, LMH provides specific compliance training to new employees, which include discussion of the FCA,

state-based equivalents, and other fraud-related issues. Even the new employee resource handbooks assailed by Janssen include cross-references to other resources containing FCA information.

Second, Janssen fails to show any likely effect the DRA compliance issues would have on the Government's payment decision. Janssen argues DRA compliance was an "absolute prerequisite" to LMH receiving Medicare compensation. Aplt. Br. at 69. But as the Supreme Court made clear in *Escobar*, making a certain contractual or regulatory requirement an explicit condition of payment is insufficient to establish materiality. *Escobar*, 136 S. Ct. at 2003 ("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.").

Recognizing this, Janssen also cites the Kansas Medical Assistance Program Fee-for-Service Provider (KMAP) manual. This manual, generated by the Kansas state government, reiterates the requirements of Section 6032 of the DRA and notes that hospitals receiving over $5 million annually in Medicare must comply therewith. Such inclusion fails to demonstrate any peculiar importance Section 6032 may have to the Government's payment decision. To the contrary, as a compliance aid, it is unsurprising the KMAP manual reiterates compliance requirements.

Accordingly, Janssen fails to raise a fact issue with respect to the materiality of LMH's alleged noncompliance with Section 6032 of the DRA.

III. Conclusion

For the foregoing reasons, we **AFFIRM** the decision of the district court.