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The Tricky Gets Trickier: Escalating Reliance on Provider Certification

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FCA False Certification Liability

- FCA imposes civil liability on “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”
- When are claims “false” or “fraudulent”?
- “Factual falsity” vs. “legal falsity”



FCA False Certification Liability

- Under what circumstances can a defendant be liable under the FCA for violating a statutory, regulatory, or contractual obligation?
- “Express false certification” vs. “implied false certification”



FCA False Certification Liability

- Circuit Split
 - Seventh: rejected implied false certification liability
 - Second and Sixth: limited scope to legal requirements expressly designated as conditions of payment
 - First, Fourth, Tenth, Eleventh, D.C.: endorsed broader view of implied certification liability
- Many courts distinguished between “conditions of participation” and “conditions of payment”

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U.S. ex rel. Escobar v. UHS

- History
 - Teenage Medicaid beneficiary died after receiving treatment from unlicensed and unsupervised professionals
 - Parents filed complaints with several state agencies and a *qui tam* action
 - *Qui tam* suit alleged that lack of compliance with state regulations governing staff qualifications and supervision rendered claims “false”

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U.S. ex rel. Escobar v. UHS

- District Court
 - Granted motion to dismiss
 - Parents’ complaint failed to allege that compliance with regulations at issue was a condition of payment of Massachusetts Medicaid
- 1st Circuit Court of Appeals
 - Reversed
 - Supervision standards at issue were “express and absolute” conditions of payment and provided “dispositive evidence of materiality”

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U.S. ex rel. Escobar v. UHS

- Supreme Court granted cert on two issues:
 - Whether implied certification theory of liability under the FCA is viable.
 - Whether liability under the implied certification theory requires the underlying statute, regulatory, or contractual provision expressly state that it is a condition of payment.

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U.S. ex rel. Escobar v. UHS

- Whether implied certification theory of liability under the FCA is viable.
- Yes, in “at least some circumstances”:
 - (1) if the claim submitted by the defendant, in addition to requesting payment, “makes specific representations about the goods and services provided,” and
 - (2) “the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.”

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U.S. ex rel. Escobar v. UHS

- Whether liability under the implied certification theory requires that the underlying statute, regulatory, or contractual provision expressly state that it is a condition of payment.
 - “What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.”
 - Scope of FCA liability can be policed through “strict enforcement” of materiality and scienter
 - Defendant’s “knowledge” can be actual knowledge, reckless disregard, or deliberate indifference

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U.S. ex rel. Escobar v. UHS

- “We now clarify how that materiality requirement should be enforced”:
 - Standard is “demanding” and “rigorous.”
 - Court “need not decide” whether (a)(1)(A) materiality governed by (b)(4) “natural tendency” definition or by common law.
 - Materiality “look[s] to the effect on the likely or actual behavior of the recipient of the misrepresentation.”
 - How the regulation is labeled is relevant but not dispositive.

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U.S. ex rel. Escobar v. UHS

- “We now clarify how that materiality requirement should be enforced” (cntd.):
 - Government’s right to refuse payment if aware of violation is insufficient, by itself, to demonstrate materiality.
 - Noncompliance cannot be minor or insubstantial.
 - Proof can include, but is not 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.”
 - Government’s payment of “particular claim,” or practice of paying “particular type of claim,” with “actual knowledge” of violation of certain requirements, is “strong evidence” that those requirements are not material.

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Escobar: Answers or More Questions?

- Does *Escobar* narrow or expand the scope of FCA liability for healthcare providers?
- Materiality “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”
 - Which is it?
 - Does *Escobar* change what is required to prove materiality?
 - Will *Escobar* change how discovery is conducted in implied certification cases?

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On Remand . . .

- *U.S. ex rel. Escobar v. Univ. Health Servs., Inc.*, 2016 WL 6872650 (1st Cir. Nov. 22, 2016).
 - Supreme Court adopted “holistic approach” to determining materiality
 - “whether a piece of information is sufficiently important to influence the behavior of the recipient”

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On Remand . . .

- Compliance with staffing regulations was material
 - Relator alleged compliance was a condition of payment
 - Centrality of licensing and supervision requirements go to “very essence of the bargain.”
 - Fact that Government might have paid with knowledge is not dispositive

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The Big Question:

- Post-*Escobar*, how does a provider evaluate whether a particularity regulatory or contractual requirement is material to payment?

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HYPOTHETICAL

Background Facts

- You are the Chief Compliance Officer ("CCO") at a public, not-for profit acute care hospital located in the Southeastern United States. You report to the hospital's Chief Executive Officer ("CEO") and Board. Your hospital also has a Chief Operating Officer ("COO") that is responsible for much of the day-to-day operations of the hospital.
- Your hospital is a "safety-net" hospital and is one of the largest hospital in the region, with over 500 beds. Its payor mix includes a significant amount of Medicare patients. It offers a variety of in-patient services, including a dedicated 16 bed inpatient rehabilitation facility (the "IRF") within the hospital. The IRF's 16 beds are physically separate and not comingled with the hospital's other beds.

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HYPOTHETICAL, Cont.

Background Facts, Cont.

- The 16 bed IRF has been certified for several years as a distinct part unit that is excluded for payment purposes from CMS' Inpatient Hospital Prospective Payment System ("IPPS"). This means, of course, that services provided in the IRF are paid by Medicare at a significantly higher rate than the IPPS.
- To maintain the IRF's exclusion from IPPS, in June of each year your hospital has to provide an attestation, signed by the hospital's CEO and the director of the IRF, to your state's survey agency certifying that the IRF continues to meet all of the applicable CMS regulations for exclusion from the IPPS.

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HYPOTHETICAL, Cont.

- Included in that attestation process is a CMS work sheet that goes through each CMS regulatory requirement and asks whether or not the hospital is in compliance with each regulatory requirement. The CMS work sheet has the following question:

TAG	REGULATION	GUIDANCE	THE HOSPITAL REPRESENTATIVE WHO COMPLETES THIS ENTIRE FORM	YES	NO	N/A
A506	(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds. NOTE: (412.204 (b) (7)) are verified by the IRF.	<ul style="list-style-type: none"> • Is the space containing the rehab beds physically separate from the beds in other units of the hospital? • There cannot be any beds that are located within the physical confines of the excluded rehab unit that are not excluded beds. • The IRF unit cannot use its beds for medical surgical patients or any other type of patient. Those beds are solely for the use of IRF patients. • If the unit doesn't have enough patients to fill those beds, the beds must be left empty or the unit can decrease the number of beds in the unit after the hospital has notified CMS of its intent. 	Representative will verify that the beds on the rehab unit do not belong to medical/surgical patients but are dedicated to rehab patients only.			

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Scenario A

- It is currently mid-January and your region is experiencing a particularly virulent flu season. As a result, inpatient admissions have surged and your hospital is regularly reaching full bedded capacity and is having to divert admissions due to a lack of bed space. At the same time, the IRF's daily census is regularly below 6, meaning that there are currently at least 10 empty beds in the IRF on a regular basis.
- Frustrated with having to turn away patients to competitors, your hospital's COO identifies the available bed space in the IRF as a potential solution. The COO asks the CEO for permission to begin putting overflow medical/surgical patients in the available IRF beds. The CEO asks you whether this intended course of action would raise any compliance concerns.
- **Question: How do you respond to this suggestion by the COO?**

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Scenario B

- It is currently mid-May and your region has just emerged from one of the worst flu seasons in recent history. This flu outbreak in your region made local and national news. After receiving a draft of the IRF attestation and work sheet that your hospital's CEO will be required to sign in June, the COO of your hospital asks to meet with you regarding the attestation. During that meeting, the COO discloses to you that during the flu season, IRF beds were regularly used for overflow medical surgical patients due to the surge in-patient admissions. However, the COO tells you that:
 - a. The medical/surgical patients who were placed in IRF unit beds were treated as such for billing purposes – these patients were not billed as if they were patients who had been admitted to the IRF unit. These patients were also treated by nurses and other staff who provided services to other medical/surgical patients; and

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Scenario B, Cont.

- b. The medical/surgical patients who were placed in IRF unit beds patients did not displace any patients who could have been admitted to the IRF unit.
- During the meeting, the COO stresses the importance to the hospital of maintaining the IRF's exclusion from the IPPS and wants to know how the CEO might be able to handle the upcoming attestation requirement.

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Scenario B, Cont.

- **Question: Is there any way that the CEO can attest to the ongoing compliance with applicable CMS regulations to continue exclusion from the IPPS?**
- **Question: If the COO insists that the CMS worksheet question regarding commingled beds has to be completed with an unqualified yes, what should you do to fulfill your duties as Chief Compliance Officer?**
- **Question: What other actions must you consider in attempting to fully mitigate this scenario?**

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