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How to Deal Effectively With Recent Legal Developments

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What We Will Cover

- Regulatory, legal and enforcement trends
 - How *Escobar* and progeny have helped us
 - The Brand Memo helps too
- Challenges for compliance professionals
 - The “Report and Return” morass
- Practical and effective approaches



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Favorite Quotes from a post-*Escobar* Case

“*Escobar* rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely – multiplied by three – because of some immaterial contractual or regulatory non-compliance.”

“... a scattering of claims in a smattering of facilities is a wholly insufficient basis from which to infer the existence of a massive, authorized, cohesive, concerted, enduring, top-down, corporate scheme to defraud the government.”

Ruckh v. Salus Rehab., LLC, No. 8:11-cv-1303, 2018 WL 375720, at *8 (M.D. Fla. 2018 Jan. 11, 2018)



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Escobar: Important Considerations

- The Court:
 - rejected many government positions.
 - held that the FCA “is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.”
 - held that the FCA “is not an all-purpose statute.”
 - held that FCA plaintiffs must comply with FRCP 8 and 9(b) by “pleading facts to support allegations of materiality.”

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Escobar: When Materiality Not Met

- “merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment;”
- “[when] the Government would have the option to decline to pay if it knew of the defendant’s noncompliance;” or
- “where noncompliance is minor or insubstantial.”

Escobar, 136 S. Ct. at 2003.

TERMS AND CONDITIONS

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Recent Trends – Materiality

Government’s knowledge of alleged non-compliance and continued payment demonstrates lack of materiality:

- Government’s allowance of costs after learning of allegations. *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1033-34 (D.C. Cir. 2017)
- Government’s continued payment was “very strong evidence” that the alleged falsehoods were not material. *United States ex rel. Harman v. Trinity Indus.*, 872 F.3d 645, 667-68 (5th Cir. 2017)
- Government’s acceptance of reports despite non-compliance was proof of lack of materiality. *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017)

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Recent Trends – Materiality

Regulatory requirements are not material if the government does not take action once it learns of the violation:

- When the government allows action to continue even after “substantial investigation” this is strong evidence of lack of materiality.
United States ex rel. Abbott v. BP Explorations & Prod., 851 F.3d 384, 388 (5th Cir. 2017)
- Government was aware of disputed practices, whistleblower action, allegations and evidence, but it did not cease or threaten to stop payments.
United States v. Salus Rehab., LLC, No. 8:11-cv-1303, 2018 WL 375720, at * 1 (M.D. Fla. 2018 Jan. 11, 2018)

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Recent Trends – Knowledge



A defendant with a reasonable interpretation of an ambiguous rule or regulation is not acting with deliberate ignorance or reckless disregard:

- Absent evidence that the government officially warned defendant away from its otherwise facially reasonable interpretation of undefined and ambiguous term, the FCA’s objective knowledge standard did not permit a jury finding that defendant knowingly made a false claim.
United States ex rel. Purcell v. MWI Corp. 807 F.3d 281, 284 (D.C. Cir. 2015)
- There is no duty to ask CMS or a contractor whether a reasonable interpretation is proper.
United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC, 833 F.3d 874, 880 (8th Cir. 2016)

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Post-Escobar Issues to Raise

- What weight is given to evidence that the government was aware of the facts and circumstances on which relator’s allegations were based, but:
 - did not impose administrative sanctions?
 - continued to make payments on claims?
 - concluded there was no violation of law?
- Option to deny vs. what government would really do
- Labels used re: conditions do not matter
- Essence of the bargain
- Reasonable person standard re: both knowledge and diligence

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Brand Memorandum



- Guidance documents are not binding
- Agencies cannot create binding rights or obligations through guidance documents
- Noncompliance with guidance documents is not a basis for proving violations of the law

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Brand Memorandum – Cont’d

DOJ should comply with the following principles. “Guidance documents **should...**”

- “identify themselves as guidance, disclaim any force or effect of law...”
- “clearly state that they are not final agency actions, have no legally binding effect ... and may be rescinded or modified in Department’s complete discretion.”

“**should not...**”

- “be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action...”
- “use mandatory language such as ‘shall,’ ‘must,’ ‘required,’ or ‘requirement’... [and] should clearly identify the underlying law that they are explaining.”

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Practical Approaches for Providers

- Move from FCA to overpayment
- More favorable resolutions possible
- Which reimbursement standard applies?
- Seek discovery from government and relator
- Use government’s lack of standards against it
- Communicate your position to payors
- Document your position



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The Report and Repay Morass

- FERA (2009) amends FCA reverse false claims provision:
 - “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.”
 - “obligation” is an established duty, whether or not fixed, arising “from the retention of any overpayment.”
- ACA (2010) 60-day report and return provisions:
 - Recipients of Medicare and Medicaid funds who have “received an overpayment” must “report and return overpayments.”

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The Report and Repay Morass

- FCA “reverse false claim” provision applies generally to all government-funded programs
- The 60-day “report and repay” obligation is in ACA and CMS regulations
- CMS guidance allows up to 6 months to investigate potential *Medicare Part A and B* overpayments
- How to address reimbursements from these payors, and how long do you have?
 - Medicaid
 - Managed Medicaid
 - Medicare Advantage
 - Part D
 - TriCare/CHAMPUS, VA
 - FEHBP



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Report and Repay Questions

- Which payors to include in statistical sampling?
- Which documentation, coding, reimbursement standards to apply?
- Lookback period? (Consider contracts, claim finality, etc.)
- When did you “identify?”
 - When you got notice
 - After reasonable inquiry, not to exceed 6 months, for *Medicare*
- Do you have 60 days or 8 months to investigate?
- Who receives report and repayment?
 - What if there is a State voluntary disclosure program?
- What to do if investigation becomes protracted?
- What about Stark violation and Medicaid?

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Resolution of Claim Denials

- Go directly to payors
- Appeal as much as reasonably possible
- Admission orders no longer required for Part A payment
– can we use that?
- Renewed arguments re: guidance vs. law or regulation
- Due process arguments should be included in appeal submission

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