How to Deal Effectively With Recent Legal Developments

Frank Sheeder

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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



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."

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.

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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)

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)

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

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



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



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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