



Health Care Compliance Association
Healthcare Enforcement Compliance Conference
Washington, D.C.
False Claims Act: Negotiating and Mediating an FCA Case
Steve Altman, Sara Vann and Mike Theis

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1:30-3:00 p.m.

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Overview

- The FCA is DOJ's primary tool to hold companies and individuals accountable for defrauding the government and to recover taxpayer funds.
- Over 30 States have FCAs, many of which are geared specifically towards recovering Medicaid funds.
- Health care fraud accounts for most of cases and settlements under the FCA, with more than \$50 billion of the total recoveries over the last 37 years (when the Act was overhauled) coming in cases involving fraud on Federal Health Care Programs.
- The overwhelming majority of FCA cases pursued by DOJ resolve by settlement: settlement of FCA cases is a complicated and difficult process involving multiple parties and multiple issues.
- This panel is intended to cover the basics of the FCA settlement process, including the background, setting and issues arising in settlement negotiations.

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Legal Framework

- FCA settlement negotiation often requires consideration of three related enforcement regimes:
 1. **Civil** (the Federal False Claims Act (FCA) and state analogues)
 2. **Criminal** (*e.g.*, the Anti-Kickback Statute (AKS), Food Drug and Cosmetic Act (FDCA), mail fraud and wire fraud statutes)
 3. **Administrative** (OIG administrative remedies, including permissive exclusion and Corporate Integrity Agreements in lieu of exclusion)
- The Government pursues criminal, civil and administrative remedies simultaneously to the extent possible, and the Government and most putative defendants prefer simultaneous “global” resolution of all three remedies
- The health care provider’s goal in virtually every case is to resolve the investigation without a guilty plea or exclusion from Government programs, and with the broadest possible release and the lowest possible financial impact.

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False Claims Act causes of action

- **False claims based upon upcoding or billing for services not rendered** (including double-billing, and miscoding non-covered services)
- **Claims based on Violations of other statutes and regulations** (AKS, Stark, FDCA)
- **Overutilization and lack of medical necessity** (including “outlier” cases based on audits by Medicare data analytics and integrity contractors)
- **Opioid-related fraud** (labs, pharma manufacturers, pain management clinics, kickbacks to physicians and clinics)
- **Exploitation of senior citizens** (so-called “failure of care” cases)
- **Electronic health records** (misrepresentation of capabilities of software)
- **Telehealth/cybersecurity** (telemedicine, false time-based codes)
- **Managed care fraud** (misrepresentation of data supporting claims under Medicaid managed care or Medicare Advantage programs)

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The Players

- **United States Attorney**
 - Criminal charging and plea authority; recommendation on FCA settlement
- **Civil Division, U.S. Department of Justice**
 - FCA settlement authority
- **State Attorneys General and Medicaid Fraud Control Units (MFCUs), NAMFCU Settlement Team**
 - State FCA authority, and jurisdiction over settlement of state portion of Medicaid funds
- **Relator and Relator’s counsel**
 - Right to object to FCA settlement, to share in settlement proceeds, to recover attorneys’ fees, costs and expenses—may also have personal claim for retaliation damages
- **Office of Counsel to the Inspector General**
 - Signs FCA settlement on behalf of HHS, exercises exclusion authority, negotiates CIA
- **Investigating agencies**

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When to Initiate Settlement Negotiations

- Before the intervention decision is made?
- After filing of complaint and motions?
- Immediately before or immediately after resolution of important motions?
- After key depositions or discovery?
- Following denial of motion for summary judgment?

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Roles of the Parties

- Who participates and what is their role?
- What is the relationship between DOJ, its agencies and state Attorneys General?
- Does relator have a seat at the table? Can relator object to a settlement?
- What is the relationship between civil and criminal matters?
- How do roles change after intervention? After case is declined?
 - DOJ in the lead:
 - Usually experienced counsel with good understanding of litigation risk; higher likelihood of fair valuation of the case; institutional concerns may temper DOJ demands
 - Relator and Relator’s counsel in the lead:
 - Can involve personal vendettas that are difficult to resolve; Relators’ counsel may be less risk averse; valuation may not be tethered to realistic case assessment

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What is the Relator’s Role?

- Relator’s role varies from case to case based on DOJ position in the investigation or litigation, knowledge of Relator and his or her counsel, and willingness of DOJ and Defendant to involve Relator in the process.
- At the very least, parties should ensure that settlement offers and litigation risk analysis is being conveyed to Relator through counsel
 - Don’t want to get to the end of the negotiations and then have to start over.
 - Defendant should be made aware of specific rights and claims of the Relator.
 - Relator has a right to recover attorneys’ fees, but fees must be reasonable and tethered to the successful claims in the case.
 - Relator may have independent claim for retaliation under § 3730(h) of the FCA, which can complicate negotiations

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Considerations for the Government

- Litigation risk
- Defendant's inability to pay
- Institutional concerns (bad precedent)
 - Bad precedent, the Yates memo, statutory requirements
- *In terrorem* effect – deterrence in an industry
- Court deadlines, motions, discovery, especially *Touhy* requests and agency discovery
- Consistency with other similar cases
- Government approval process

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Considerations for the Defendant

- Collateral consequences
 - Criminal prosecution
 - Exclusion/debarment
 - Licensing risks
 - Disclosure and possible SEC or shareholder litigation
- Board/investor concern
- Reputational risk
- Scope of release/limitation of future exposure
- Tax consequences
- Insurance coverage
- Sale or acquisition considerations

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Preparing the Client for Negotiations

- It is critical to educate client early and often about the unique settlement dynamics and elements of an FCA settlement
 - Different leverage than in a typical commercial lawsuit
 - Specific approval process on the government side
 - Very little negotiation room or flexibility on terms of settlement and release
 - Lots of boilerplate that may have no application to client
 - Narrow release of specific statutes and carefully defined “Covered Conduct”
 - No ability to negotiate confidentiality, press release or publicity
 - Obligation to pay attorneys’ fees to relator

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Negotiation Considerations

- What is the settlement strategy, and how much should you educate your adversary?
- Do you use witnesses? Experts?
- How do you build trust?
- If you narrow the investigation (by time, location or subject matter) do you narrow the release?
- How and when to negotiate the relator’s attorney fees?
- How do you push through impasse?

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Corporate Integrity Agreements

- How and when do you engage the agency and discuss a Corporate Integrity Agreement?
- Agency remedies
- Criteria applied by the OIG?
- Basis for a CIA
- Typical elements of a CIA
- Relevance of the FCA settlement
- What if the defendant does not want a CIA?

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Internal Investigations

- Factual and legal analysis is critical to effective negotiations: settlement can't happen until there is some common set of facts, legal theories, and loss calculations that can form the basis for a settlement discussion.
 - Thorough litigation risk assessment
 - Careful damages modeling
 - Analysis of monetary and non-monetary considerations
 - Reputational risks and impact on business relationships (including long-term relationships with government programs and payers)
 - Legal strategy and planning, including possible legal defenses
 - Arguments in mitigation
 - Analysis of ability to pay

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Impediments to Settlement

- Partisan, combative mindset
- Lack of trust
- Taking it “personally”
- Parallel negotiations over fees and “all-in” offers
- Multiple and overlapping qui tam cases
- Parallel or related unresolved matters
- Claims personal to the Relator (share of settlement proceeds, attorneys’ fees)

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Ability to Pay Settlements

- DOJ only compromises cases on grounds of litigation risk and inability to pay: If the defendant is genuinely unable to meet financial demands of the government, it is possible to settle based on the defendant’s ability to pay.
- The process requires specific financial disclosures and certifications, followed by DOJ analysis.
- Defendant must be prepared to document inability to pay, and address the issue with acceptable payment terms.
- Litigation risk is disregarded when ability to pay is controlling.

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Mediation and Settlement Conferences with a Neutral

- When is mediation appropriate?
 - Help with case evaluation
 - Create opportunity to build trust and communicate
 - Educate difficult client
 - Help with process, discovery and parallel proceedings
- Expertise in FCA cases can help
 - Qui tam cases have unique dynamics
 - Government process, authority and concerns can be unfamiliar and frustrating
- Facilitative vs. evaluative mediator

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Unique Features of FCA Settlements

- Scope of release
 - Specific statutes
 - Specific common law and equitable claims
 - Specific definition of “Covered Conduct”
 - Specific carve outs
- Boilerplate provisions
- Claims by relator
 - Retaliation
 - Attorneys’ fees, costs and expenses

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Unique Features of FCA Settlements

- Usually there is no admission of liability (but, there are exceptions in some districts)
- Denial of liability may be possible
- “Cold comfort” may be provided in certain circumstances
- No release of individuals (unless they are participating in settlement)
- No negotiations on press release or media disclosure
- Specific characterization for purposes of tax code (to distinguish restitutionary and punitive components of settlement)

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Unique Features of FCA Settlements

- Multi-State Settlements:
 - Each State has separate Settlement Agreement, that are negotiated globally
 - Interest is expected
 - Reimbursement for State Team Expenses
 - Consumer Protection and Anti-Trust Carve Outs

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Role of Compliance in Settlement

- **Demonstrating commitment to compliance can be a critical factor in the settlement process:**
 - Implementation of written policies and procedures—including a comprehensive code of conduct—that describe a clear commitment to corporate integrity and compliance;
 - Implementation of effective compliance training programs throughout the organization;
 - Implementation of comprehensive and effective auditing plan;
 - Prompt corrective action plans for identified violations, including appropriate remediation of identified compliance issues, and continued monitoring and enforcement to prevent future violations;
 - Demonstrated commitment to review and take action on “hot line” or other compliance complaints; and
 - Internal investigation and enforcement using publicized disciplinary guidelines.