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Negotiating False Claims	
Act Settlements	
Sponsored by	
<u>Health Care Compliance Association</u> October 29, 2017, 1:30 p.m. – 3:00 p.m. Eastern	
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Presented by	
Andrea Treese Berlin, Esq. Senior Counsel, Office of Inspector General	-
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Overview]
Overview	-
Give "Big Picture" view of How False Claims Act ("FCA") Cases are settled	
 Highlight Defense/Government Concerns and Approaches to Negotiating FCA Case Settlements 	
 Describe roles of DOJ, OIG and defense counsel in negotiation/settlement process 	
Provide Guidance as to How to Successfully Achieve a Resolution of a FCA	
Case	

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Settlement Considerations: The Defense Perspective	
Potential Criminal Exposure	
Potential Civil/Administrative Exposure • Damages	
CMPs Exclusion/Corporate Integrity Agreements	
Analysis of Potential Legal Defenses Statute of Limitations	
Materiality Extrapolation/Sampling Methods	
Analysis of Potential Factual Defenses	
Medical Necessity – Defense vs. Government Experts Valuation – FMV Experts Critine – Expert Analysis	
Coding – Expert Analysis Whistleblowers' Credibility	
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Settlement Considerations: The Defense Perspective	
Settlement Considerations. The Defense Perspective	
Potential Targets	
Parent vs. SubsidiaryManagement/Individuals	
Related Parties, e.g. Physician Groups	
Damages Exposure • Number of incidents/cases	
Temporal Limits Potential Multipliers	
Litigation Costs	
Legal Experts	
E-Discovery Client resources/personnel/distraction	
Potential Client Transaction(s)	
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Settlement Considerations: The Government Perspective	
How Does the Government Assess its Case?	
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Government Assessment of Case	
Potential FCA Damages	
Potential Bases for CMPs	-
The Anti-Kickback Statute	
The Prohibition on Certain Physician Referrals (Stark Law)	
False or Fraudulent Claims	
Billing while excluded	
Select Agents	-
Patient dumping (EMTALA)	
About 40 other OIG CMPs	
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Government Assessment of a Case	
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How does the OIG use	
Civil Monetary Penalty	
authorities?	
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Government Assessment of Case:	
Potential Exclusion	
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■ Mandatory vs. Permissive Exclusion	
■ Length of Exclusion	
Factors OIG Considers in Seeking Exclusion ¹	

 1 On April 18, 2016, OIG issued updated criteria for implementing permissive exclusion which can be found on OIG's website.

Government Assessment of Case: Evaluating Compliance Programs/Cooperation	
 March 2017 DOJ Guidance: Evaluation of Corporate Compliance Programs 	
 January 2017 Publication of HCCA/OIG: Measuring Compliance Program Effectiveness 	
■ Targets' Cooperation with Government FCA Investigation	
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Negotiating Settlements: The Government Perspective	
Who Negotiates?	
Role of U.S. Attorney's Office	
Role of Main DOJ	
Role of OIG/HHS	
Role of Relator's Counsel	
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Negotiating Settlements: The Government Perspective	
Who Negotiates: Special Circumstances:	
Joint State/Federal Matters	
Pending Federal Criminal Investigation	
Use of Tolling Agreements	
o Civil	
o Criminal	
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Negotiating Settlements: The Government Perspective	
Calculating Damages	
Multiples	
Interest	
Payment Methodologies	
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Negotiating Settlements: The Government Perspective	
Individual Liability	
■ The "Yates Memorandum"	
• Issued on September 9, 2015	
Signed by Sally Quillian Yates, Deputy Attorney General	
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Negotiating Settlements: The Government Perspective	
Persuading Defense Counsel	
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Negotiating Settlements: The Defense Perspective	
Persuading the Government: Strength of Case	
Attorney Proffers Witness Interviews	
 Waiver of Privilege to Internal Investigation (?) Disclosure of Expert Analyses/Reports (?) 	
Persuading the Government: Good Corporate Citizenship	
Policy/Procedure Reforms	
Compliance Programs/Resources Number of Employees/Economic Impact	
Service to Indigent Population Charitable/Educational Activities	
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Negotiating Settlements: The Defense Perspective	
Persuading the Government: Ability to Pay	
Available Funds/Credit	
 Trends for Revenues/Profits/Surplus/Deficit 	
Bond ObligationsUnion Contracts	
• Financial Disclosures (?)	
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Negotiating Settlements: The Defense Perspective	
Calculating Damages/Multipliers	-
Medical Necessity Value of Services Received	
CMS vs. Provider Data	
Sampling /Extrapolation	
Interest	
Payment Methodologies • Ability to Pay	
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Negotiating Settlements: Drafting the Agreement	
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Drafting Settlements Agreements: The Government Perspective	
Contents of the Settlement Agreement	
Defining "Covered Conduct"	
Carve Outs	
Defining the Settling Entity	-
• Signatories	
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Drafting Settlements Agreements: The Government Perspective	
Release Language	
Relator's Counsel Fee	
Relator's Share of Recovery	
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Drafting Settlements Agreements: The Defense Perspective	
Contents of the Settlement Agreement	
Defining "Covered Conduct"	
Carve Outs	
Defining the Settling Entity	
Signatories	
• HHS/OIG	
Main Justice	
US Attorney's Office	
Relators	
Relators' Counsel	
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Drafting Settlements Agreements: The Defense Perspective	
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Release Language	
Former Employee/Whistleblower vs. Professional Relators	
Allegations in Complaint	
Temporal Extensions	
Cross-Release	
Covered Conduct vs. Potential Claims	
Relators' Share of Recovery	-
Relators' Counsel Fee	
Disclaimer of Liability/Wrongdoing	
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Negatiating Cattlements, Comparate Integrity, Agreements	
Negotiating Settlements: Corporate Integrity Agreements	
 Contents of Corporate Integrity Agreements: 	
Can be claims, arrangements, or both.	
Typically last 5 years and include requirements to:	
Hire a compliance officer/appoint a compliance committee; Develop written standards and policies:	
 Develop written standards and policies; Implement a comprehensive employee training program; 	
Retain an independent review organization to conduct annual reviews;	
o Establish a confidential disclosure program;	
o Restrict employment of ineligible persons;	
o Report overpayments, reportable events, and ongoing investigations/legal proceedings; and	
o Provide an implementation report and annual reports to OIG on the status of the entity's compliance	
activities.	
Integrity Agreements are for smaller entities and have slightly different terms, like quarterly reviews and can be a short as three years.	
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Negotiating Settlements: Corporate Integrity Agreements	
 Factors Government Considers in Whether to Require a Corporate Integrity Agreement 	
■ Defense Perspective on Corporate Integrity Agreements	
 Cost/Challenges of Corporate Integrity Agreements 	
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Negotiating Settlements: Special Concerns for the Defense	
Special Circumstances: • Joint State/Federal Matters	
 Pending Criminal Investigations Government Intervention on Only a Portion of Relators' Case 	
Tolling AgreementsInsurance Coverage	
EXPERIMENTAL SAME AS S	
Secondary Concerns: The Defense Perspective	
Publicity:	
Government Press Release	
 Posting on Government Website Government Press Conference Unsealing of Complaint 	
• FOIA	
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Secondary Concerns: The Defense Perspective	
Cooperation Clauses	
Confidentiality of Documents	
Compliance Reform	
Follow-up Litigation:	
Class Action Lawsuits	
 Securities Litigation/Derivative Actions Employment Litigation 	
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The Effect of Universal Health Services v. United States ex rel.	
Escobar on Settlement Negotiations: The Government Perspective	
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Escobar on Settlement Negotiations: The Defense Perspective	
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Government Perspective on the Yates Memorandum	
■ Focus on Individuals Needed for Deterrence	
 Need to Affirm Public Trust in Justice System by Assuring that Those Responsible for Organization/Corporation Misconduct 	
Are Held Accountable	
 Reinforces Importance of Establishing Corporate/Organization Culture of Compliance 	
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The Defense Perspective on the Yates Memorandum	
Concern that Focus on Individuals Will Deter Qualified Executives from	
Serving in Health Care Management	
 May Make Settlement/Resolution More Difficult Policy expressly forbids releasing individuals based on corporate resolutions 	
 Focus on individual liability in civil cases, without regard to ability to pay-very troubling 	
■ Pits Executives Against Their Health Care Employees	
 Emphasis on Joint Civil/Criminal Investigations Raises Ethical Concerns, see, e.g. New Jersey RPC 3.4(g) 	
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QUESTIONS?	
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