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**The 9th Annual
Pharmaceutical Regulatory and Compliance
Congress and Best Practices Forum
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Afternoon Track III

**Creating an Environment for Productive Post-
Settlement Interactions with the Government**

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I. Overview of the False Claims Act Settlement Documents

Possible Universe of FCA Settlement Documents

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– Criminal DOJ Settlement Documents

1. Criminal Information
2. Plea Agreement
3. Sentencing Memorandum
4. Deferred or Non-prosecution Agreement
5. Any side letters
6. Other?

– Civil DOJ Settlement Documents

1. Settlement Agreement
2. Relator's Complaint(s)
3. Stipulation of Dismissal
4. Order from District Court Granting Dismissal
5. Any side letters
6. Any Key Correspondence or presentations with DOJ to achieve settlement
7. Other?

– OIG Settlement Documents

1. Corporate Integrity or Corporate Compliance Agreement
2. Any side letters
3. Any Key Correspondence or presentations with DOJ to achieve settlement
4. Other?

– State Settlement Documents

1. State AG Settlement Agreement (MFCU)
2. State AG Settlement Agreement (Consumer Protection Assurance of Voluntary Compliance)

– Press Releases

II. Certain Settlement Integrity Provisions: Which Provisions are Likely to Require Post- Settlement Interactions with the Government?

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1. DPAs, NPA Integrity Obligations

- “Monitors” that are outside companies that report to DOJ
- Annual Needs Assessment
- Public disclosures on the Internet

2. State Integrity Obligations

- MFCU – price reporting
- Consumer Protection – promises of appropriate conduct and disclosures to consumers

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3. CIA - Reportable Events

– Overview

- Substantial Overpayment (applicable to direct providers).
- A matter that a reasonable person considers a probable* violation of law applicable to a Federal health care program and for which penalties or exclusion may be authorized.

II. Certain Settlement Integrity Provisions: Which Provisions are Likely to Require Post-Settlement Interactions with the Government?

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Reportable Events

- “Substantial” Overpayment (applicable to direct providers)
 - “Substantial” does not just refer to the dollar amount.
 - The term could be related to the scope of the issue that led to the overpayment.
 - There is no dollar threshold:
 - “The OIG believes, as does the SEC, that a percentage or numeric threshold is “only the beginning of an analysis of materiality; it cannot appropriately be used as a substitute for a full analysis of all relevant considerations.” See <http://oig.hhs.gov/fraud/cia/docs/ciafaq1.html>
 - Routine adjustments generally do not constitute a “Substantial Overpayment.”

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Reportable Events

- “Probable”
 - More likely than not.
 - A few CIAs require reporting of issues that are “potential” violations of law.
 - The OIG does allow an entity a reasonable opportunity to conduct an investigation before the entity makes a determination that a Reportable Event has occurred.
 - Maintain a government chronology file.

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Reportable Events

- **“Applicable to Federal health care programs”**
 - The relevant law for which there is a probable violation should have a close association with a Federal health care program.
 - What is a law applicable to a Federal health care program?

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Reportable Events

- **What does this all mean?**
 - A Reportable Event may be the result of an isolated event or series of occurrences.
 - The determination of whether a Reportable Event exists is based on the totality of the circumstances.
 - The OIG wants reports on issues that essentially could trigger a serious investigation.
 - Innocent errors and technical violations generally are not Reportable Events. (However, remember the CIA obligations regarding “Substantial Overpayments” for direct providers.)

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Reportable Events

- What must be reported to the OIG?
 - Notify the OIG within 30 days of determining that a Reportable Event exists.
 - Description of Reportable Event.
 - Description of Corrective Action.
 - Further Steps to Prevent Reportable Event from Recurring.
 - Overpayment Information, if any.

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The OIG “Monitor”

- Once a CIA is negotiated and effective, the OIG assigns the company with a “monitor” who is from DHHS-OIG.
- The relationship between the monitor and the company is not expected to “adversarial.”
- The role of the OIG monitor during the CIA negotiation process has been changing.
- The OIG monitor is a good resource for the company under a CIA to discuss issues such as the IRO and the CIA engagements.
- Establish a good relationship with the OIG monitor.