

HCCA Atlanta Regional Conference Compliance Officer Roundtable

January 24, 2020

Panel Members

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Agenda

- Compliance Landscape
- Compliance Hot Topics
 - Opioids
 - Third-Party Vendors
 - 60-Day Overpayment Rule
 - Cybersecurity
- Questions

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Compliance Landscape

2019 False Claims Act Recoveries

- In Fiscal Year 2019, the Department of Justice (DOJ) recovered over \$3 billion in settlements and judgments in civil cases involving fraud and false claims against the government.
 - Compared to over \$2.8 billion in Fiscal Year 2018.
- Of the over \$3 billion in recoveries, \$2.6 billion related to healthcare industry matters.
 - Compared to \$2.5 billion in Fiscal Year 2018. ■

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Potential Consequences of Non-Compliance

Corporation	<i>Financial</i>	<ul style="list-style-type: none"> • Penalties • Settlements • Impact on Ability to Obtain Financing • Impact on Insurance Premiums
	<i>Other</i>	<ul style="list-style-type: none"> • Exclusion • Deferred Prosecution Agreement • Corporate Integrity Agreement • Mandatory Divestiture • Impact on Business Partnerships
Individuals	<i>Financial</i>	<ul style="list-style-type: none"> • Penalties • Settlements • Forfeiture
	<i>Other</i>	<ul style="list-style-type: none"> • Jail Time • Exclusion • Reputational Harm

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Continuing Focus on Compliance Effectiveness

Risk Spectrum

Highest Risk ← → Lower Risk

Exclusion Heightened Scrutiny CIAs No Further Action Self-Disclosure

U.S. Department of Justice

**U.S. Department of Justice
Criminal Division**

Evaluation of Corporate Compliance Programs

Guidance Document
Updated: April 2019

Measuring Compliance Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 27, 2017

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC

§8B2.1 - EFFECTIVE COMPLIANCE AND ETHICS PROGRAM

(a) To have an effective compliance and ethics program, the organization shall:

- (1) exercise due diligence to prevent and detect criminal conduct;
- (2) otherwise promote an organizational culture that encourages ethical conduct and compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that it will be generally effective in preventing and detecting criminal conduct. The fact that an organization has a compliance and ethics program does not necessarily mean that the program is not generally effective.

(b) Due diligence and the promotion of an organizational culture that encourages ethical conduct and compliance with the law within the meaning of subsection (a) shall include:

- (1) The organization shall establish standards and procedures for compliance with the law.
- (2) (A) The organization's governing authority shall be responsible for the establishment and maintenance of the compliance and ethics program and shall exercise reasonable oversight over the program.

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Updated DOJ Guidelines For Evaluating Compliance Programs

- In April 2019, DOJ issued updated compliance program effectiveness guidelines.
 - The revised guidelines updated a document initially released in February 2017.
 - Not limited to healthcare industry.
- Although primarily designed to provide guidance to federal prosecutors, the guidance offers valuable insights regarding government expectations and best practices.

"Today's guidance document is part of our broader efforts in training, hiring, and enforcement to help promote corporate behaviors that benefit the American public and ensure that prosecutors evaluate the effectiveness of compliance in a rigorous and transparent manner." – Brian Benczkowski, Assistant Attorney General, on the release of the April 2019 guidelines

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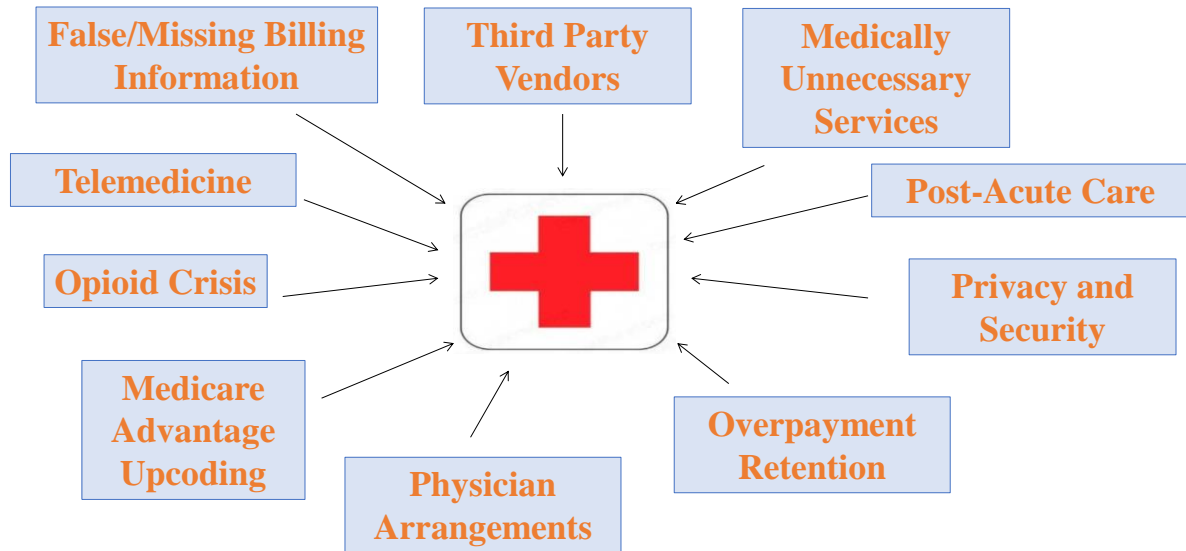
Updated DOJ Guidelines For Evaluating Compliance Programs

- The guidelines emphasize that compliance programs are not one-size-fits all and should be tailored to the organization's risk profile.
 - DOJ does not use a rigid formula to assess compliance program effectiveness but instead makes individualized determinations.
- The new guidelines are organized under the Justice Manual's three "fundamental questions" prosecutors should ask in evaluating compliance programs:
 - "Is the corporation's compliance program well designed?"
 - "Is the program being applied earnestly and in good faith?"
 - "Does the corporation's compliance program work?" (JM § 9-28.800).

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Compliance Hot Topics

Enforcement Priorities (Not Exhaustive)



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Compliance Hot Topic: Opioids

Significance of Opioid Crisis

Significance of Opioid Crisis
<ul style="list-style-type: none"> • Opioids killed more than 47,000 people in 2017, or 130 people per day. • 36% of all opioid overdose deaths involve a prescription opioid. • The CDC estimates that the total “economic burden” of prescription opioid misuse alone in the U.S. is \$78.5 billion a year.

Enforcement Focus
<ul style="list-style-type: none"> • In 2018, DOJ created the Prescription Interdiction & Litigation (PIL) Task Force to focus and coordinate its efforts to combat the opioid crisis. • In 2019, the government continued bringing enforcement actions to combat the crisis. • Significantly, the government has signaled a willingness to prosecute a variety of defendants, including compliance officers and pharmaceutical distributors.

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Opioid Crisis Enforcement

- **June 2019:** Insys Therapeutics agreed to pay **\$195 million** to resolve allegations that it violated the FCA for, among other violations, engaging in practices related to opioid prescription and marketing.
- **July 2019:** Reckitt Benckiser Group plc (RB Group) agreed to pay **\$1.4 billion** to resolve its potential criminal and civil liability related to a federal investigation of the marketing of the opioid addiction treatment drug Suboxone.
- **February 2019:** DOJ filed a **temporary restraining order (TRO)** to stop two Tennessee pharmacies, their owner, and three pharmacists from unlawfully dispensing opioids.
 - DOJ later unveiled a complaint alleging that the same parties violated the FCA and Controlled Substances Act.
- **August 2018:** DOJ filed a **TRO** against two Ohio doctors who were allegedly prescribing opioids illegally under the Controlled Substances Act (CSA).

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Compliance Officers in Crosshairs

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION		FILED RICHARD W. BAGEL CLERK OF COURT 2019 JUL 17 PM 2:54 U.S. DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION
UNITED STATES OF AMERICA, Plaintiff,	CASE NO. 1:19CR 081	
vs.	JUDGE DLOTT	
ANTHONY RATTINI (1), JAMES BARCLAY (2), DEVONNA MILLER-WEST (3), SAMUEL R. BALLENGEE (4), MIAMI-LUKEN, INC. (5),	INDICTMENT 21 U.S.C. § 846	
Defendants.	4. Beginning on or around January 1, 2008, to on or about April, 2015, JAMES BARCLAY was the Compliance Officer of MIAMI-LUKEN . As Compliance Officer, BARCLAY was responsible for supervising MIAMI-LUKEN's compliance with federal and state drug laws.	
THE GRAND JURY CHARGES		
At all times relevant to this Indictment:		

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Proactive Compliance Strategies

- Discuss potential compliance strategies, including:
 - Quality of care efforts;
 - Compliance with Prescription Drug Monitoring Programs;
 - Policies and procedures; and
 - Physical safeguards and controls against drug diversion.

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Compliance Hot Topic: Third-Party Vendors

Outsourced Providers and Joint Ventures

- Actions of business partners can have significant compliance consequences on providers.
- Important to understand and assess risks associated with key business partners.
 - Not every business partner requires the same amount of scrutiny – important to evaluate risk profile for each business relationship.

Third Party Relationships – DOJ Focus

U.S. Department of Justice
Criminal Division
Evaluation of Corporate Compliance Programs
(Updated April 2019)

Introduction

The “Principles of Federal Prosecution of Business Organizations” in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a

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E. Third Party Management

A well-designed compliance program should apply risk-based due diligence to its third-party relationships. Although the degree of appropriate due diligence may vary based on the size

compliance program for purposes of calculating the appropriate organizational criminal fine. See U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled “Selection of

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Investigations of Vendors and Contractors

- Rise in settlements related to third-party service providers:
 - RehabCare settlement – *therapy services vendor*
 - Healogics Settlement – *wound care services vendor*
 - eClinical Works – *EHR vendor*
 - Greenway Health – *EHR vendor*
- Consider potential impact on the contracting provider:
 - Credible information of potential overpayments?
 - Inclusion in government investigation?
 - Several Skilled Nursing Facilities (SNFs) who used RehabCare’s services also entered into settlements.

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Impact of Third-Party Service Provider Issues

- Potential that an Independent Review Organization (IRO) review in connection with a Corporate Integrity Agreement (CIA) of a third-party service provider could impact a contracting provider:
 - Rehabcare CIA:
 - The RehabCare CIA requires an IRO medical necessity review of rehabilitation therapy services under contracts between RehabCare and third-party owned and operated SNFs.
 - RehabCare must notify each service location of services for which the IRO has determined not to be medically necessary.

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Proactive Compliance Strategies

- Discuss potential compliance strategies, including:
 - Compliance Department's involvement in engagement and onboarding of outsourced providers;
 - Conflicts of Interest processes; and
 - Oversight and monitoring of business partners.

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Compliance Hot Topic: 60-Day Overpayment Rule

60-Day Overpayment Rule

- Statutory requirement that providers report and return overpayments within 60 days.
 - Regulatory Definition of Identification: *An overpayment is identified “when the person **has, or should have** through the **exercise of reasonable diligence**, determined that the person has received an overpayment and **quantified** the amount of the overpayment.” 42 C.F.R. § 401.305(a)(2).*
- Enforced through the False Claims Act.
- Six-year lookback period.
- Low-hanging fruit for whistleblowers.

60-Day Overpayment Rule Settlements

- *Caris Healthcare* - June 2018 settlement for \$8.5 million.
- *First Coast Cardiovascular* - October 2017 settlement for \$440,000.
- *Continuum Health Partners* - August 2016 settlement for \$2.95 million.
- *Pediatric Services of America* - August 2015 settlement for \$6.88 million.


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60-Day Overpayment Rule OIG Audits

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

**MEDICARE COMPLIANCE REVIEW
OF COMMUNITY HOSPITAL**

Inquiries about this report may be addressed to the Office of Public Affairs at
PublicAffairs@oig.hhs.gov



Gloria L. Jaramon
Deputy Inspector General
for Audit Services

February 2019
A-09-17-00026

What OIG Recommends

We recommend that the Hospital refund the Medicare contractor \$22 million (of which \$1,266,758 was net overpayments identified in our sample) in estimated overpayments for the audit period for claims that it incorrectly billed; exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule; and strengthen controls to ensure full compliance with Medicare requirements.

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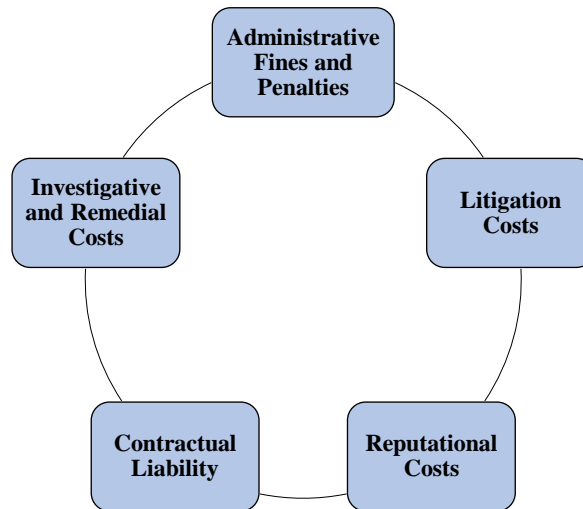
Proactive Compliance Strategies

- Discuss compliance considerations and strategies, including:
 - Approaches and considerations when evaluating voluntary disclosures and refunds;
 - Overpayment and internal investigations policies, including considerations relating to the 60-Day clock;
 - Involvement of appropriate stakeholders in Legal and Compliance Departments;
 - Training; and
 - Refund documentation.

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Compliance Hot Topic: Cybersecurity

Potential Cybersecurity Costs



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Cybersecurity Case Study

- Discuss mobilization and response strategies:
 - **Fact Scenario:** Potential data breach of your organization's data system.
 - **Fact Scenario:** Potential data breach of your Business Associate's data system.

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Questions