



# HCCA Regional Conference – Washington, DC

## OIG Update

March 8, 2019

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## Overview

- Enforcement activity
- OIG priorities
- Compliance and Corporate Integrity Agreements
- Innovative care
- Resources





## OIG's Multidisciplinary Approach

- Office of Audit Services (OAS)
- Office of Evaluation and Inspections (OEI)
- Office of Investigations (OI)
- Office of Counsel to the Inspector General (OCIG)
- Office of Management & Policy (OMP)



## OIG Statistics FY 2018

<b>Criminal Actions</b>	<b>764</b>
<b>Civil Actions</b>	<b>813</b>
<b>Exclusions</b>	<b>2,712</b>





## DOJ Statistics FY 2018

**Healthcare Fraud Recoveries:  
\$2.5 Billion**

**More than 645 Qui Tams Filed  
(~12 a week)**



## OIG's Current Priorities

- Work Plan
- Semi-Annual Reports to Congress
- HCFAC Reports
- Top Management Challenges





## OIG Work Plan Development

- Mandatory OIG reviews
- Requests from Congress and HHS management
- OIG Top Management Challenges and Strategic Plan
- Discussions with CMS and other HHS agencies
- Emerging issues
- Unimplemented OIG recommendations



## OIG Semi-Annual Report

- Identifying Improper Payments and Opportunities for Savings in HHS Programs
- Fighting Fraud in HHS Programs
- Preventing and Treating Opioid Misuse
- Protecting the Health and Safety of Children in HHS Programs
- Ensuring Quality and Integrity in Medicare's Hospice Program
- Improving Financial Management and Reducing Improper Payments in Medicare
- Protecting the Integrity of the Medicaid Program
- Protecting Health and Safety in Adult Day Care Facilities
- Ensuring Quality & Integrity in Programs Serving American Indian/Alaska Natives



## OIG Top Management Challenges

1. Opioid Misuse
2. Administration of Medicare
3. Administration of Medicaid
4. Managed Care and Other Innovative Models
5. Health and Safety of Vulnerable Populations
6. Financial and Administrative Management and Reducing Improper Payments
7. Integrity of HHS Grants
8. Safety of Food, Drugs, and Devices
9. Quality/Integrity in Programs for American Indian/Alaska Natives
10. Cybersecurity Threats
11. Management of HHS Prescription Drug Programs
12. Preparation and Response to Public Health Emergencies



## Drug Pricing- OIG Report Work

- Provision of Drug Rebates
  - Medicare Part D Drugs
  - Medicaid Drugs
  - 340B Pharmacies
- Calculating Coverage Gap Decisions
- Drug Price Reporting
- Specialty Drug Pricing





## Drug Pricing- Enforcement Actions

- Patient Assistance Programs
  - United Therapeutics
    - Rescission of OIG Advisory Opinion No. 06-04
    - Letter to PhRMA
    - First CIA with specific provisions overseeing PAPs
  - Pfizer
  - Actelion Pharmaceuticals
- Discount Drug Pricing
  - Walgreens, Kmart



## Opioids- OIG Report Work

- OIG Report- Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing
  - 1 in 3 Medicare Part D patients prescribed opioids
  - 400 prescribers found to have questionable practices
- OIG Toolkit
  - Using data analytics to identify patients at risk
  - Suggested practices for correcting overprescribing





## Opioids- Enforcement

- 2018 Takedown
- Criminal cases
  - Pill mills, invalid prescriptions, marketing, kickbacks
  - Examples: Dr. Rasan Mohammad Tarabein, Dr. Michael Alson Smith
- Civil Cases
  - invalid prescriptions, marketing, kickbacks
  - Companion and derivative cases
  - Examples: Matthew Anderson, and PMC Management Company, LLC
- Scope of OIG's CMP Exclusion Authorities in this Area
  - Exclusion of Dr. Vinod Sharma for 3 years



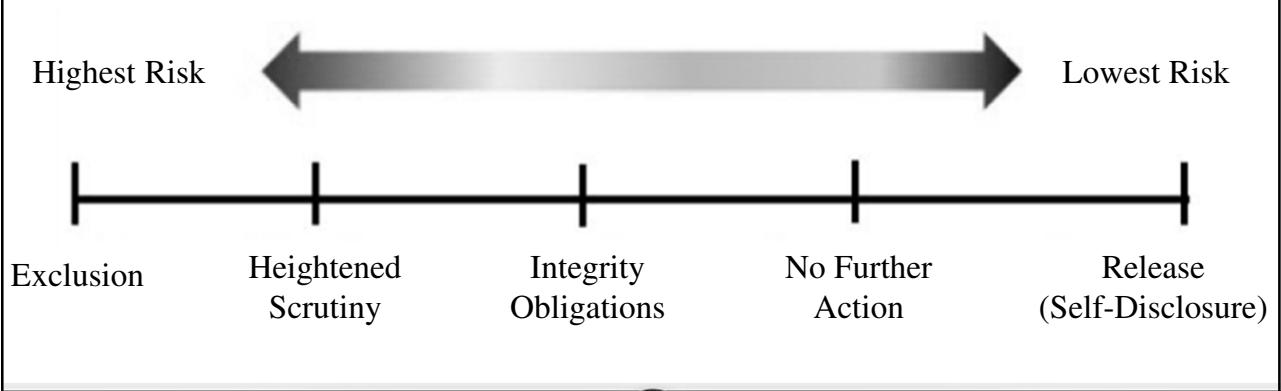
## Anticipated Priorities

- Continued fight on opioid crisis
- Focus on using data to detect fraud and improper payments
- Working with CMS on innovative care delivery redesign
- Regulatory sprint





# OIG Fraud Risk Indicator

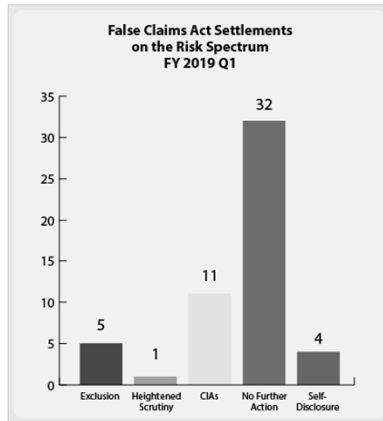


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## High Risk - Heightened Scrutiny

Parties are in the High Risk category, and subject to heightened scrutiny, because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter [Corporate Integrity Agreements](#) (CIAs) sufficient to protect Federal healthcare programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later will be listed below.

Provider	Date Settled	City/State	Press Release
ImmediaDent of Indiana, LLC & Samson Dental Partners, LLC	10-31-2018	various cities in Indiana and Leawood, Kansas	<a href="#">Link</a>



## OIG Revised Exclusion Criteria

- Issued April 18, 2016 (Criteria for Implementing Section 1128(b)(7) Exclusion Authority, available at – <http://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>)
- Replaced criteria issued in 1997
- Increases OIG's expectations for providers to implement robust compliance programs, promptly respond to government investigations, and self-disclose fraud
- Begins with presumption that exclusion should be imposed
- Provides a compliance "risk spectrum" from low to high risk based on: (1) nature and circumstances of conduct; (2) conduct during government investigation; (3) significant ameliorative efforts; and (4) history of compliance
- Highest risk will result in exclusion; below highest risk, OIG may choose to impose heightened scrutiny or no further action





## OIG Affirmative Litigation

- Use exclusion remedy to protect patients
- Complement the work of the components
- Support OIG guidance and level the playing field
- Change industry behavior
- Hold individuals accountable



## Care Delivery Innovation

- Types of models (e.g. Accountable Care Organizations, Bundled Payments)
- Fraud and Abuse waivers
- Opportunities to enter into new types of care delivery relationships





## Coming Down the Pike....

- Regulatory Sprint to Coordinated Care
- Regulations and/or other guidance in response to the CMS and OIG RFIs
- OIG Proposed Rule related to Rebates
- Continued Focus on Quality of Care



## Questions?

