OIG UPDATE

4TH ANNUAL HCCA HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE

NOVEMBER 6, 2018

Gregory E. Demske

Chief Counsel

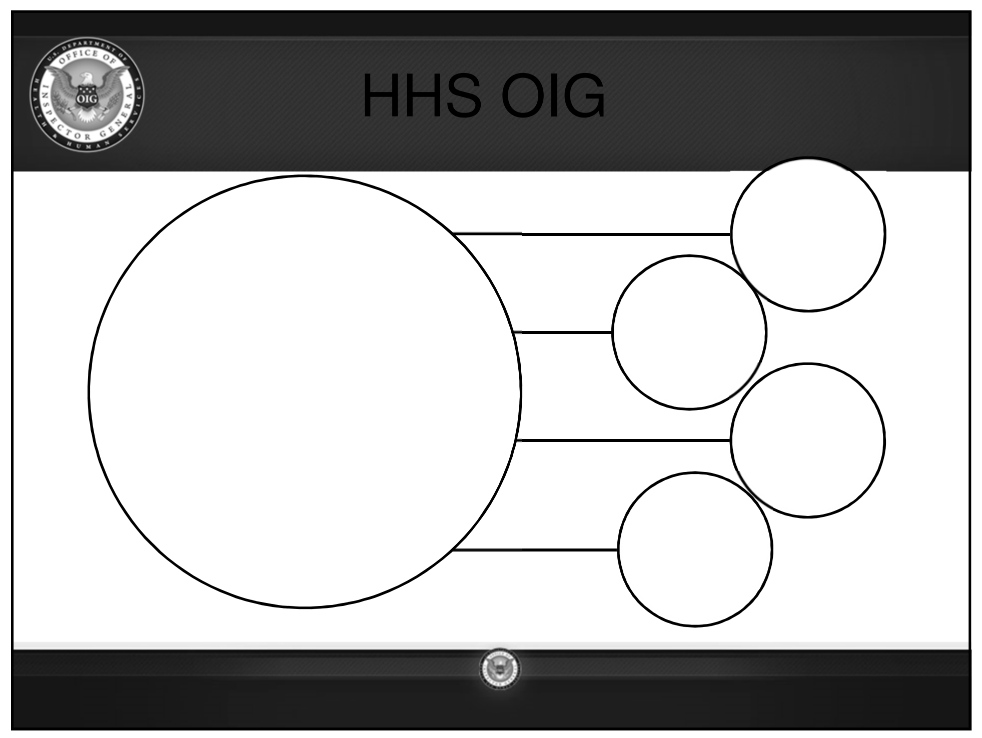
HHS Office of Inspector General

OIG Update

- Prioritizing HHS Oversight
- Priorities
- Other Areas
- Fraud Risk Indicator
- Administrative Enforcement and Guidance

2

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
FDA
U.S Food and Drug Administration
INDIAN HEALTH SERVICE
PHS · 1955
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
U.S. PUBLIC HEALTH SERVICE
1798
NIH
U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
ADMINISTRATION FOR
CHILDREN & FAMILIES


HHS OIG

OIG Outputs – 2013-2017

- $24.4 Billion in Expected Investigative and Audit Recoveries
- 1,607 Audit and Evaluation Reports
- 4,581 Criminal Actions
- 3,221 Civil Actions
- 18,222 Exclusions

Desired Outcomes

- Healthier People
- Lower Costs
- Better Care
- More Efficient System

Identifying Risk Areas

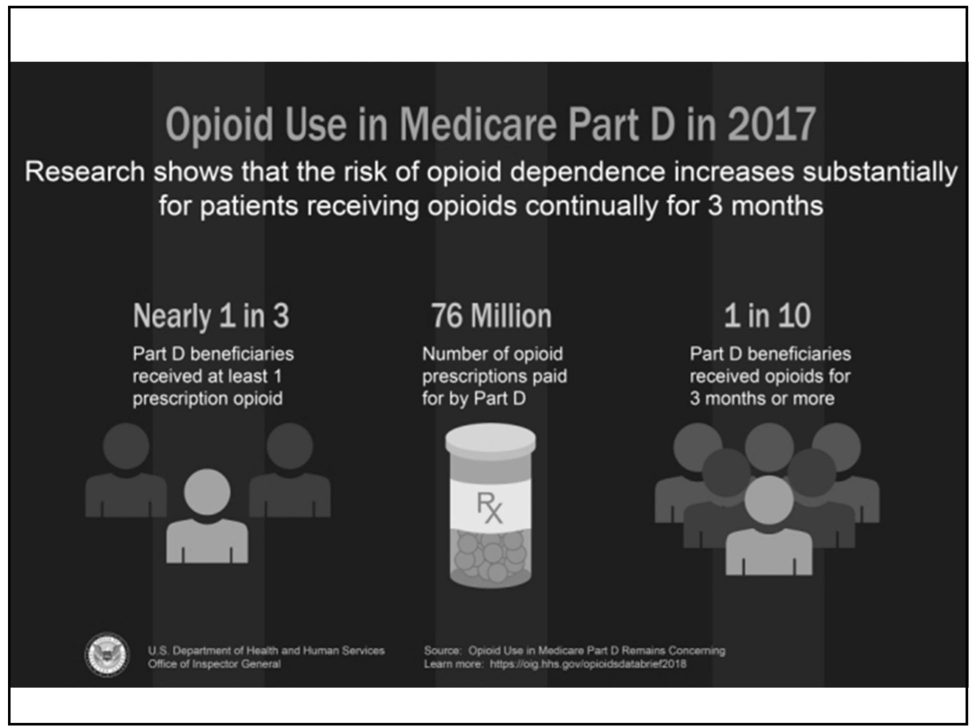
- Program Vulnerabilities
- Data Analytics
- Hotline, Qui Tams, Tips
- OIG Collaboration

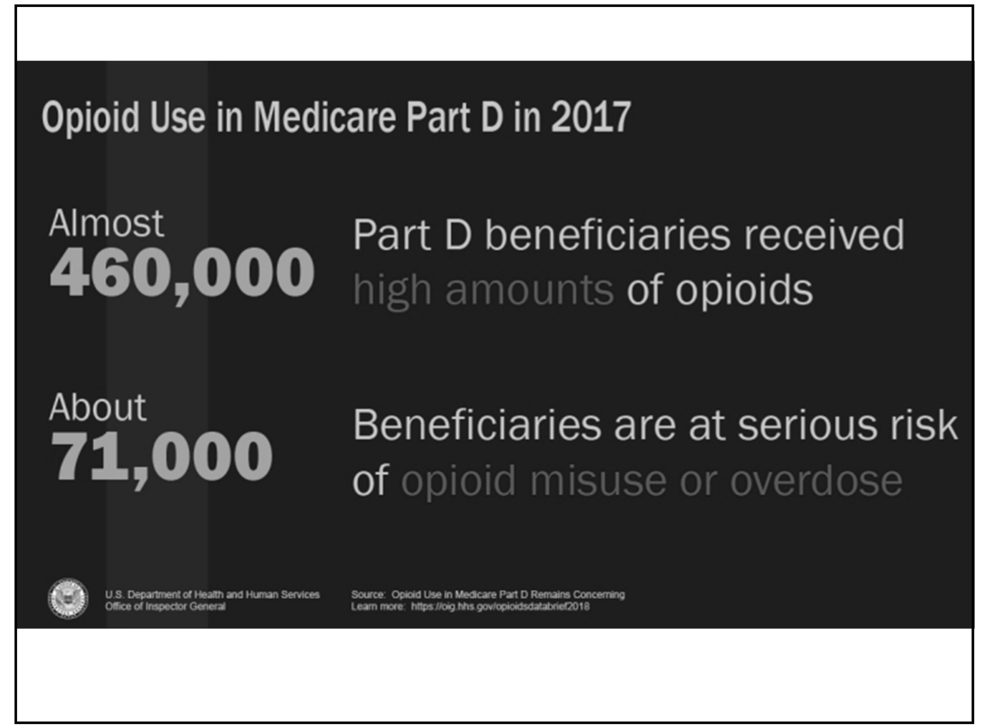
OIG-Identified Risks

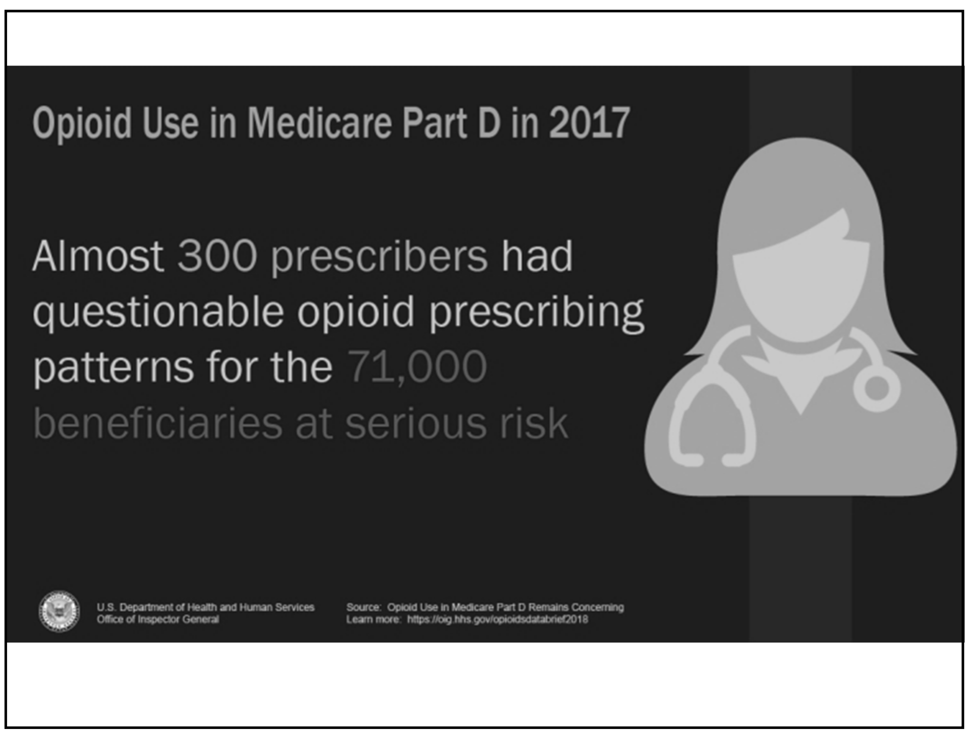
- HHS Top Management Challenges
- Work Plan
- Semi-Annual Report, HCFAC Report
- Audits, Evaluations, Investigative Results
- Website -- oig.hhs.gov

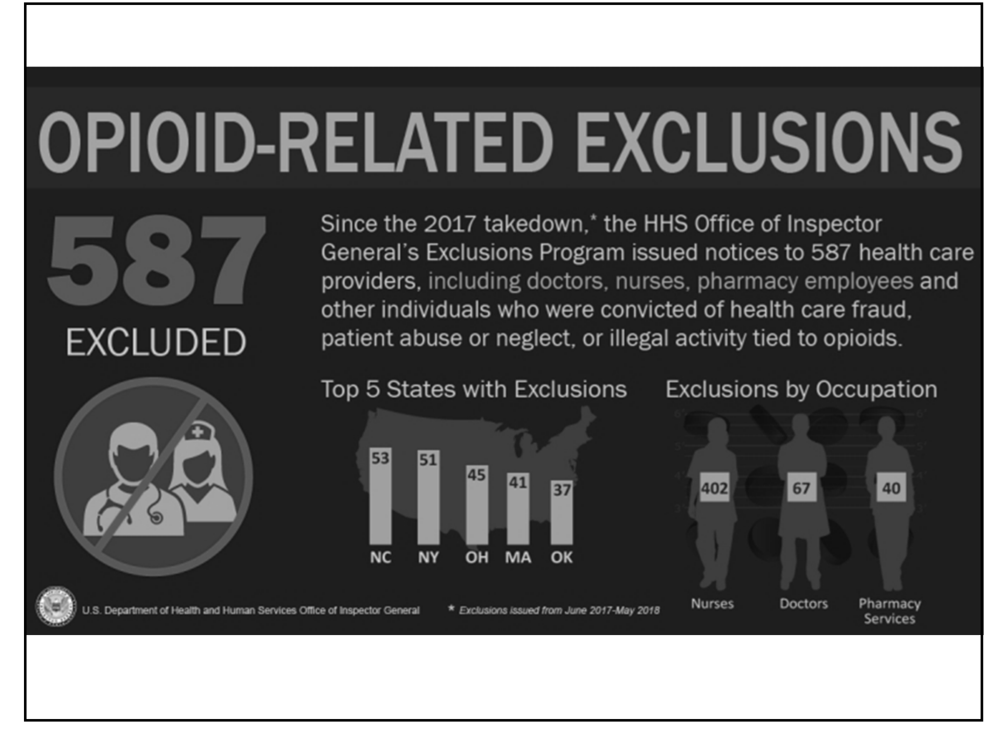
Opioids

- OIG Role
- HHS Program Improvement
- Identify and Hold Wrongdoers Accountable
- Share/Collaborate with Partners


Opioid Use in Medicare Part D in 2017
Research shows that the risk of opioid dependence increases substantially for patients receiving opioids continually for 3 months
Nearly 1 in 3
Part D beneficiaries received at least 1 prescription opioid
76 Million
Number of opioid prescriptions paid for by Part D
1 in 10
Part D beneficiaries received opioids for 3 months or more
U.S. Department of Health and Human Services
Office of Inspector General
Source: Opioid Use in Medicare Part D Remains Concerning
Learn more: https://oig.hhs.gov/opioidsdatabrief2018


Opioid Use in Medicare Part D in 2017
Almost 460,000
Part D beneficiaries received high amounts of opioids
About 71,000
Beneficiaries are at serious risk of opioid misuse or overdose
U.S. Department of Health and Human Services
Office of Inspector General
Source: Opioid Use in Medicare Part D Remains Concerning
Learn more: https://oig.hhs.gov/opioidsdatabrief2018


Opioid Use in Medicare Part D in 2017
Almost 300 prescribers had questionable opioid prescribing patterns for the 71,000 beneficiaries at serious risk
U.S. Department of Health and Human Services
Office of Inspector General
Source: Opioid Use in Medicare Part D Remains Concerning
Learn more: https://oig.hhs.gov/opioidsdatabrief2018


OPIOID-RELATED EXCLUSIONS
587
EXCLUDED
Since the 2017 takedown,* the HHS Office of Inspector General's Exclusions Program issued notices to 587 health care providers, including doctors, nurses, pharmacy employees and other individuals who were convicted of health care fraud, patient abuse or neglect, or illegal activity tied to opioids.
Top 5 States with Exclusions
53
51
45
41
37
NC
NY
OH
MA
OK
Exclusions by Occupation
402
67
40
Nurses
Doctors
Pharmacy Services
U.S. Department of Health and Human Services Office of Inspector General
* Exclusions issued from June 2017-May 2018

Opioids

Toolkit:

Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose

Home and Community Based Services

- Home Health
- Hospice
- Group Homes
- Personal Care Services

Home Health

- Vulnerable Area
  - Medical Necessity
  - Kickbacks
- OIG Multi-Disciplinary Approach
- OCIG Industry Outreach
- Focus on Geographic Hot Spots

Vulnerabilities in Hospice Care

Over the past decade, hospice use has grown steadily.
Medicare paid $16.7 billion for hospice care in 2016.

SINCE 2006:

81%
Increase in spending for hospice care

43%
Increase in the number of hospices

53%
Increase in the number of hospice beneficiaries

U.S. Department of Health and Human Services
Office of Inspector General

Source: *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity*
LEARN MORE: https://oig.hhs.gov/hospiceportfolio2018

Hospice

Portfolio:

Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity

Joint Report

U.S. Department of Health and Human Services
Office of Inspector General,
Administration for Community Living, and
Office for Civil Rights

Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight

January 2018

Personal Care Services

- MFCU focus
  - 38% of MFCU indictments involve PCS providers or attendants
- Beneficiary abuse and neglect
- Financial fraud

Skilled Nursing Facilities

- Failure to Report Abuse/Neglect
- Grossly Substandard Care
- Disaster Preparedness
- Unnecessary Therapy

Managed Care

- Providers
  - Impact on patients and programs
- Plans
  - Patient Access to Services
  - Payment Denials
  - Risk Adjustment
    - CMS Proposed Rule – October 26, 2018

Audits

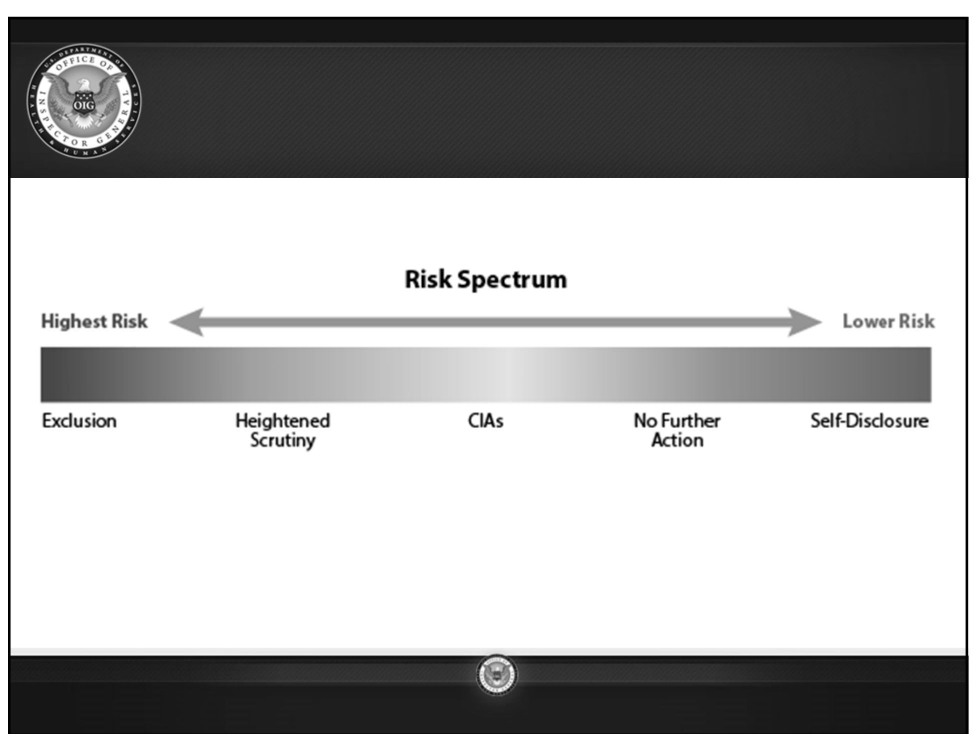
- Focus on Quality and Safety
- Compliance Reviews
  - HHAs, Hospitals, Hospice, SNF
  - Risk-Based
- Part B
  - Ambulance, Orthotics, Psychotherapy, etc.
- Part C
  - RADV

Strike Force Locations
Detroit
Chicago
Brooklyn
Newark/Philadelphia
Washington, DC
Appalachian Region
Los Angeles
Dallas
Baton Rouge
Houston
New Orleans
Tampa/
Orlando
Miami

2018 Takedown
BY THE NUMBERS
601 Defendants Charged, Including:
165 Medical Professionals
$2 Billion in Losses
587 Exclusions Issued
58 Federal Districts
30 Medicaid Fraud Control Units
350 OIG Agents

False Claims Act

- Primary Remedy for Civil Fraud
- Retrospective
- OIG Exclusion – 1128(b)(7) of SSA
- Prospective
- Parallel Process
- Exclusion Criteria



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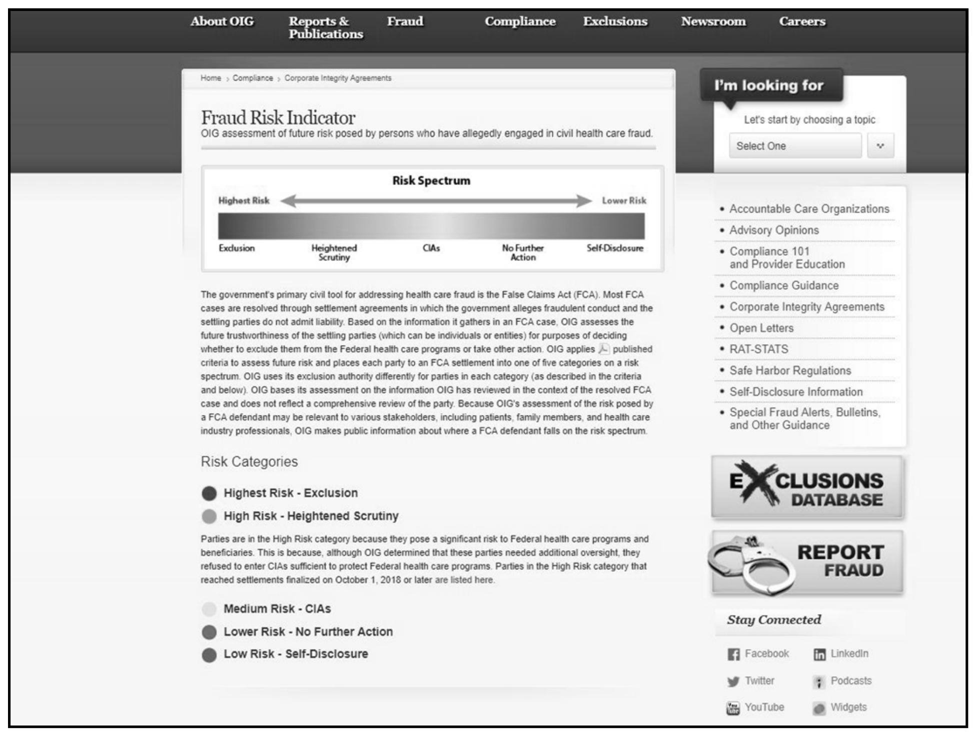
Fraud Risk Indicator
OIG assessment of future risk posed by persons who have allegedly engaged in civil health care fraud.
Risk Spectrum
Highest Risk
Lower Risk
Exclusion
Heightened Scrutiny
CIAs
No Further Action
Self-Disclosure
The government's primary civil tool for addressing health care fraud is the False Claims Act (FCA). Most FCA cases are resolved through settlement agreements in which the government alleges fraudulent conduct and the settling parties do not admit liability. Based on the information it gathers in an FCA case, OIG assesses the future trustworthiness of the settling parties (which can be individuals or entities) for purposes of deciding whether to exclude them from the Federal health care programs or take other action. OIG applies published criteria to assess future risk and places each party to an FCA settlement into one of five categories on a risk spectrum. OIG uses its exclusion authority differently for parties in each category (as described in the criteria and below). OIG bases its assessment on the information OIG has reviewed in the context of the resolved FCA case and does not reflect a comprehensive review of the party. Because OIG's assessment of the risk posed by a FCA defendant may be relevant to various stakeholders, including patients, family members, and health care industry professionals, OIG makes public information about where a FCA defendant falls on the risk spectrum.
Risk Categories
Highest Risk - Exclusion
High Risk - Heightened Scrutiny
Medium Risk - CIAs
Lower Risk - No Further Action
Low Risk - Self-Disclosure
I'm looking for
Let's start by choosing a topic
Select One
Accountable Care Organizations
Advisory Opinions
Compliance 101 and Provider Education
Compliance Guidance
Corporate Integrity Agreements
Open Letters
RAT-STATS
Safe Harbor Regulations
Self-Disclosure Information
Special Fraud Alerts, Bulletins, and Other Guidance
EXCLUSIONS DATABASE
REPORT FRAUD
Stay Connected



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Risk Categories
Highest Risk - Exclusion
High Risk - Heightened Scrutiny
Parties are in the High Risk category because they pose a significant risk to Federal health care programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter CIAs sufficient to protect Federal health care programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later are listed here.
Medium Risk - CIAs
Lower Risk - No Further Action
Low Risk - Self-Disclosure
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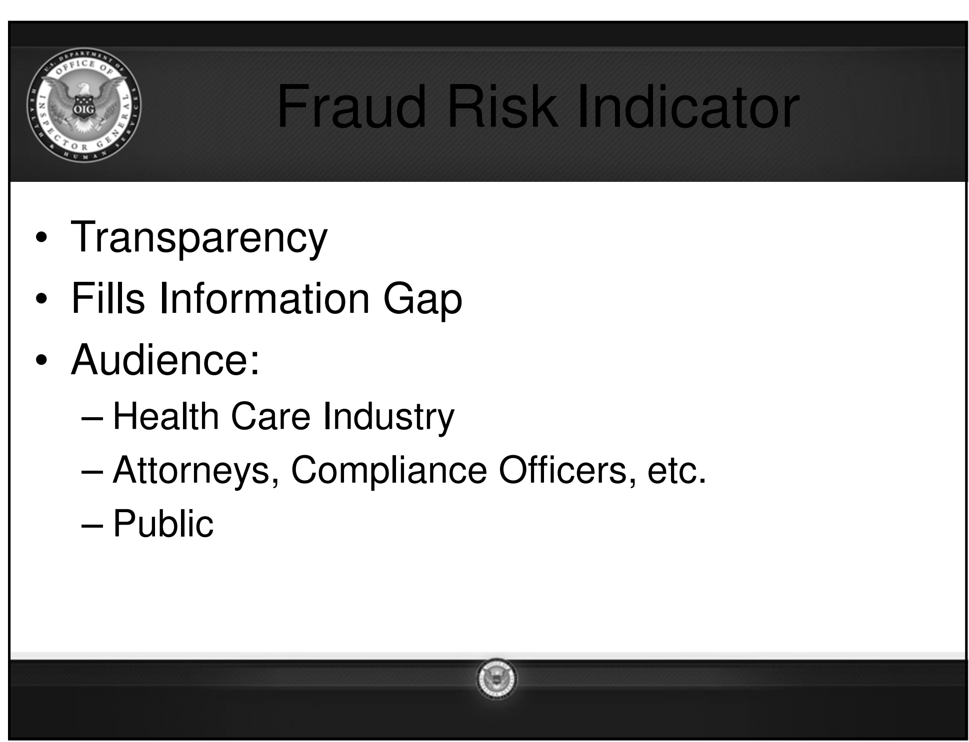
High Risk - Heightened Scrutiny
Parties are in the High Risk category, and subject to heightened scrutiny, because they pose a significant risk to Federal health care programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter CIAs sufficient to protect Federal health care programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later are listed below.
Provider
Date Settled
City/State
Press Release
I'm looking for
Let's start by choosing a topic
Select One
Accountable Care Organizations
Advisory Opinions
Compliance 101 and Provider Education
Compliance Guidance
Corporate Integrity Agreements
Open Letters
RAT-STATS
Safe Harbor Regulations
Self-Disclosure Information
Special Fraud Alerts, Bulletins, and Other Guidance


Fraud Risk Indicator
• Transparency
• Fills Information Gap
• Audience:
– Health Care Industry
– Attorneys, Compliance Officers, etc.
– Public

Corporate Integrity Agreements

- Increased Focus on Risks
- Refined Claims Reviews
  - Medical Necessity
  - Risk-Based
  - Provider-Specific
  - Hospitals and other types of providers
- Board/Executive Responsibility

Self-Disclosure Protocol

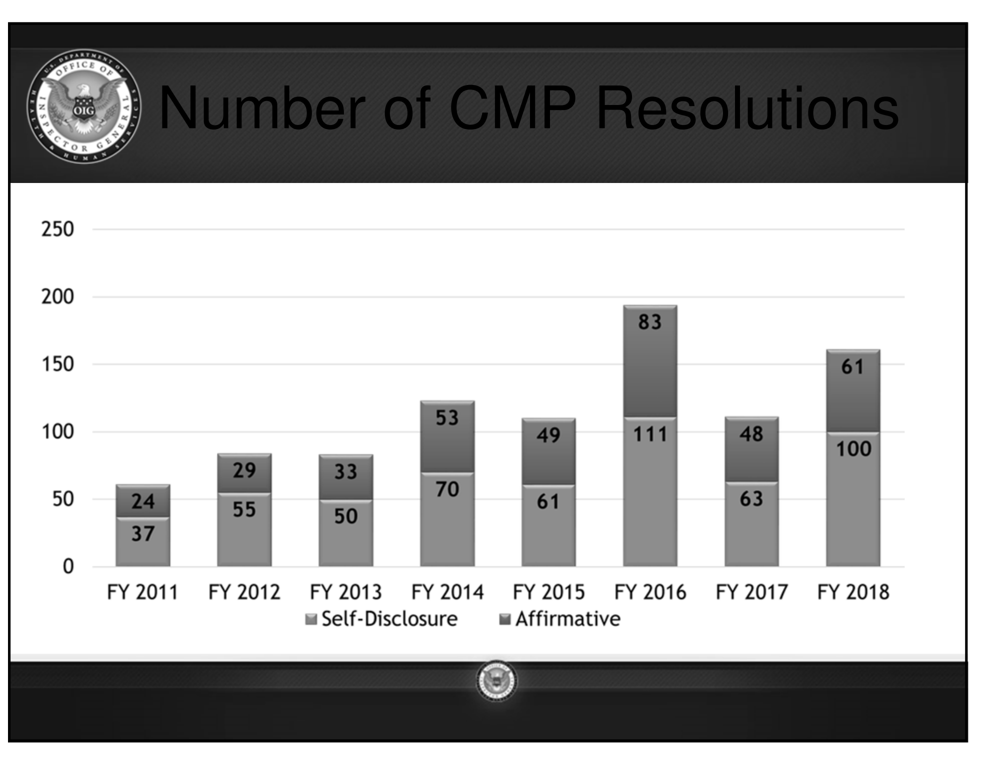
- Evidence of Commitment to Compliance
- Benefits:
  - Faster Resolution
  - Less Disruption
  - Lower Payment
  - Exclusion Release

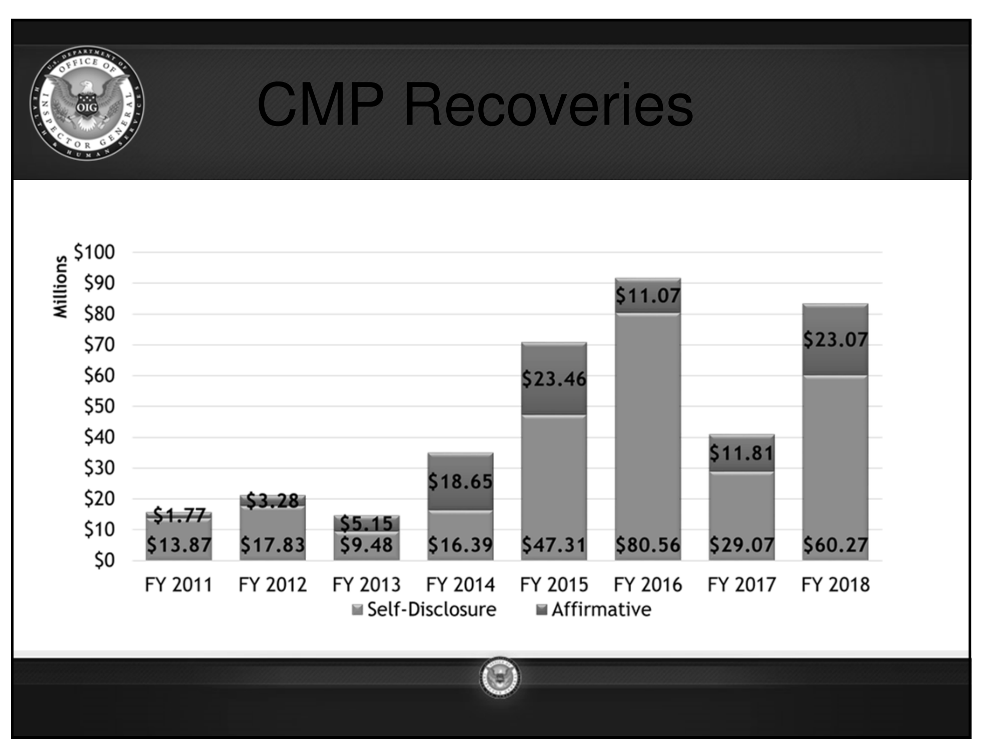
OIG Administrative Enforcement

- Exclusion
  - Derivative
  - Affirmative
- Civil Money Penalties
  - Alternative Remedy
  - Expansion to Grants/Contracts
  - Increased Penalties
- Process

Goals of OIG Administrative Enforcement

- Protect patients
- Amplify OIG priorities/guidance
- Hold individuals accountable
- Complement DOJ enforcement
- Focus on Kickbacks
  - Payers and Recipients
  - Narrow grey areas
  - Level the playing field


Number of CMP Resolutions
250
200
150
100
50
0
24
37
29
55
33
50
53
70
49
61
83
111
48
63
61
100
FY 2011
FY 2012
FY 2013
FY 2014
FY 2015
FY 2016
FY 2017
FY 2018
Self-Disclosure
Affirmative

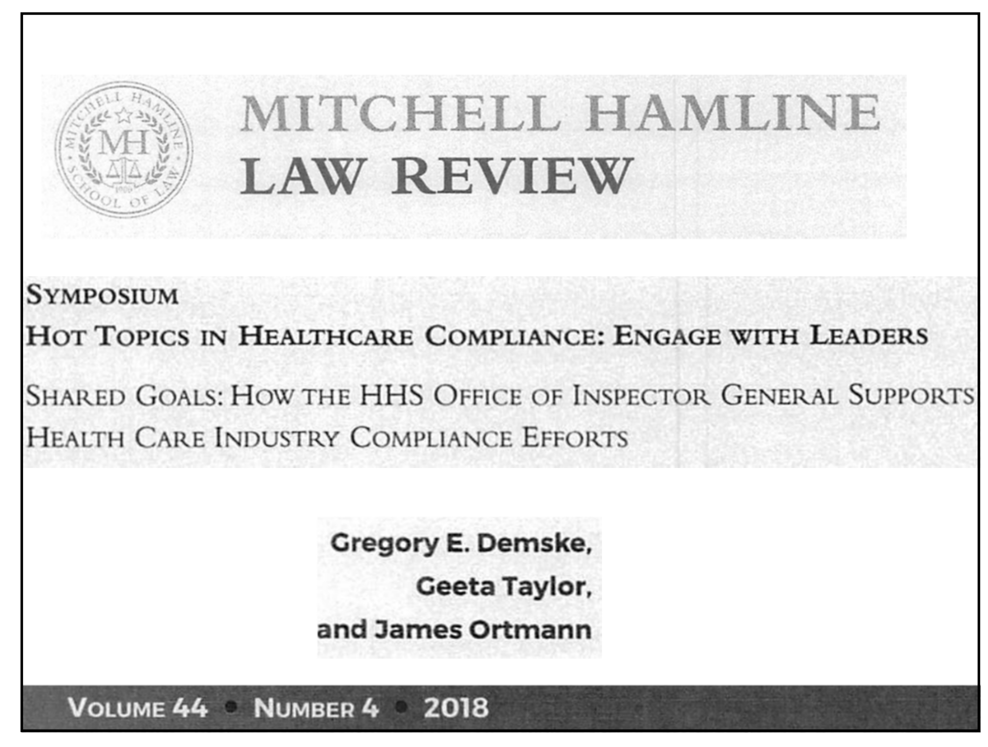

CMP Recoveries
Millions
$100
$90
$80
$70
$60
$50
$40
$30
$20
$10
$0
$1.77
$13.87
$3.28
$17.83
$5.15
$9.48
$18.65
$16.39
$23.46
$47.31
$11.07
$80.56
$11.81
$29.07
$23.07
$60.27
FY 2011
FY 2012
FY 2013
FY 2014
FY 2015
FY 2016
FY 2017
FY 2018
Self-Disclosure
Affirmative

OIG Litigation

- BestCare and Maghareh
  - August 2018
  - 15-year exclusions
  - TRO Denied
- Dr. Kallini
  - October 2018
  - $4.9 Million
  - 20-year exclusion

Guidance

- Anti-Kickback Statute (and More)
- Safe Harbor Regulations
- Advisory Opinions
- Risk Areas
- Compliance Best Practices
- Regulatory Sprint to Coordinated Care
  - RFI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HOT TOPICS IN HEALTHCARE COMPLIANCE: ENGAGE WITH LEADERS
SHARED GOALS: HOW THE HHS OFFICE OF INSPECTOR GENERAL SUPPORTS HEALTH CARE INDUSTRY COMPLIANCE EFFORTS
Gregory E. Demske,
Geeta Taylor,
and James Ortmann
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