FEDERAL ADMINISTRATIVE SANCTIONS:

Exclusion & Civil Money Penalties

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Agenda

- OIG Enforcement Update
- CMS Role in Enforcement
- Questions

Notes on Enforcement Trends – Summary of Settlements

- In 2017, the U.S. government recovered more than $3 billion in FCA settlements and judgments.
- 2/3 of settlement dollars came from the healthcare and life sciences industry
- OIG recovered approx. $4.13B in FY 2017, investigating 826 individuals or entities.

UPDATE ON DOJ POLICIES

The Brand Memo

- Then-U.S. AAG Rachel Brand Memo (1/25/18)
  - No. 3 at DOJ
  - Leader of the Regulatory Reform Task Force
- Establishes that guidance documents should not be used to change the law or to impose new standards to determine compliance with the law.
- Recognizes the benefits of the notice-and-comment process that is ordinarily required for rulemaking.
- Applies when DOJ Civil is enforcing FCA.

The Brand Memo

Sets forth proper use of guidance documents:

- To explain or paraphrase legal mandates from applicable statutes and regulations.
- To establish evidence of knowledge of the mandate.

Tax Deductibility of FCA Settlements – Section 13306 of the Tax Act

- Section 13306 of the Tax Cuts and Jobs Act amends 26 U.S.C. 162 to expand prohibition on deducting "fines or penalties."
- Now prohibits deduction of "any amount paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry by such government or entity into the potential violation of any law."
- Exceptions:
  - Exception for amounts constituting restitution or paid to come into compliance with law. 26 U.S.C.A. § 162 (f)(2)
  - Limitation on restitution exception: amounts paid as reimbursement for investigation costs or litigation costs are not deductible. 26 U.S.C.A. § 162 (f)(2)(B)
- 26 U.S.C. 6050X – Government agency must report the deductible amount to the IRS at the time of any settlement agreement
  - The report must include (1) total amount of the settlement; (2) the amount that constitutes restitution; and (3) the amount paid for the purpose of coming into compliance with the law involved in the investigation/litigation
- Important to classify properly in settlement negotiations with DOJ and OIG

FCA Implications of Opioid Crisis

- **Opioid Fraud and Abuse Detection Unit**
  - DOJ pilot program formed August 2017: uses data analytics to identify providers for investigation of their opioid prescription practices; funds 12 AUSAs (including one based in TN) for three years to focus only on opioid-related health care fraud.
- **OIG Work Plan: Steady addition of opioid-related items**
- **Prescription Interdiction & Litigation Task Force**
  - Launched by DOJ March 2018, explicitly states it will utilize FCA to pursue pain management clinics, drug-testing facilities, and physicians that prescribe opioids.
  - Task force ordered to examine existing opioid lawsuits by governments and identify where DOJ can provide assistance.
- **High government spending on opioids**
  - Medicare drug program spent more than $4 billion on opioids in 2016.
- **Opioid focus in largest-ever enforcement action (June 2018)**
  - Of 601 defendants, 162 (76 physicians) charged related to opioids, other narcotics
  - Of 2,700 individuals excluded from federal health care programs from July 2017 through June 2018, 587 providers excluded related to opioid diversion and abuse.

FCA Implications of Opioid Crisis

- ***Insys Therapeutics, Inc.*** **(Multiple Cases)**
  - Insys reached settlement-in-principle with DOJ in August 2018, agreeing to pay **$150 million** and up to **$75 million** more based on "contingent events" for FCA and Anti-Kickback violations.
  - Alleged violations include paying kickbacks to induce fentanyl prescriptions and causing Medicare to pay for non-covered uses of drug.
  - In an example of individual liability, former employee pled guilty to criminal charges; four actions remain pending against 14 defendants.
  - Cases: *U.S., et al., ex rel. Guzman v. Insys Therapeutics, Inc., et al.*, Case No. 13-cv-5861; *U.S. ex rel. Andersson v. Insys Therapeutics, Inc.*, Case No. 14-cv-9179; *U.S. ex rel. John Doe and ABC, LLC v. Insys Therapeutics, Inc., et al.*, Case No. 14-cv-3488; *U.S. ex rel. Erickson and Lueken v. Insys Therapeutics, Inc.*, Case No. 16-cv-2956; and *U.S. ex rel. Jane Doe, et al. v. Insys Therapeutics, et al.*, Case No. 16-cv-7937

Opioid Fraud and Abuse Detection Unit

- AG Sessions announced 8/2/17
- Pilot program that utilizes data to identify and prosecute individuals that are contributing to the prescription opioid epidemic.
- Funds 12 experienced AUSAs in opioid "hot-spots" for a three-year term to focus solely on investigating and prosecuting health care fraud related to prescription opioids.
- Focuses on pill mill schemes, and pharmacies that unlawfully divert or dispense.
- The District of Nevada selected as one of 12 districts nationally to participate in pilot program.

Prescription Interdiction & Litigation (PIL) Task Force

- AG Sessions announced 2/27/18.
- Coordinates DOJ's efforts and criminal and civil law enforcement tools to combat the opioid epidemic.
- Includes senior officials from offices of the US AG, DAG, AAG, EOUSA, Civil Division, Criminal Division, and DEA.
- Particular focus on manufacturers and distributors, and a turning of the traditional off-label enforcement focus towards marketing that the government deems "misleading".
- Will leverage the AKS and FCA to further target opioid manufacturers and distributors (e.g., *Galena Biopharma* $7.55M+ settlement 2017)

OIG ENFORCEMENT UPDATE

Goals of OIG-initiated litigation

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

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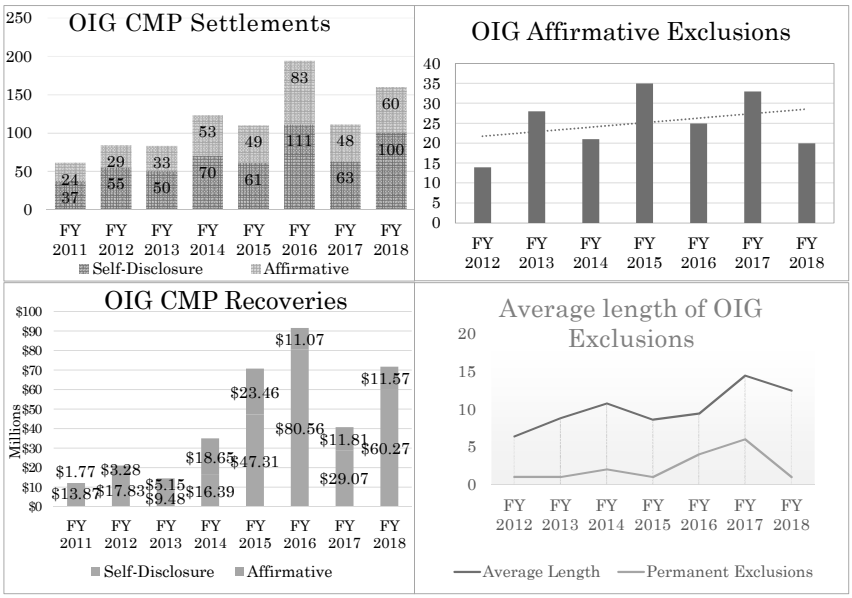
OIG CMPL and Exclusion Actions



Opioids

- OIG Data Brief, Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing, and Toolkit
- Exclusions examples:
  - Cindy Scott, R.N., A.P.R.N. for 10 years
  - Dr. Vinod Sharma for 3 years
  - Dr. Michael Esposito for 15 years
  - Dr. Stephen Latman for 10 years
- Sober home operators, prescribers, and pain management centers

OIG Exclusion Litigation

- *Bestcare Laboratory Services, LLC and Karim Maghareh v. The Inspector General*, DAB CR5166 (2018)
  - *Bestcare* and owner *Maghareh* excluded for fifteen years under OIG's (b)(7) authority
  - ALJ considered on merits after hearing
  - Parallel to civil FCA matter (*United States of America ex rel. Drummond v. BestCare Laboratory Services, LLC, et al.*, No. 08-02441, 2018 U.S. Dist. LEXIS 56499 (S.D. Tex. April 3, 2018))
  - BestCare billed Medicare as if trained personnel had traveled to collect blood samples from inpatient/homebound patients, but instead used commercial airline flights to ship samples

Individual Accountability

- *First Initiative, LLC,* and owner *Shameika Amin*, 50 year exclusion
- *Anthony D. Vertino, Psy.D.*, 20 year exclusion
- *Scott Warantz*, 5 year exclusion
- IDTF owners:
  - *CHJ Diagnostic, Inc.*, and owner *Andranik Tovmasyan*, 5 year exclusion
  - *Prohealth Neurodiagnostic, Inc.*, and owner *Arsen Oganesyan,* 5 year exclusion
  - *Olive Sleep & EEG, Inc.*, and owner *Mariam Unjughulyan*

Other Recent Results

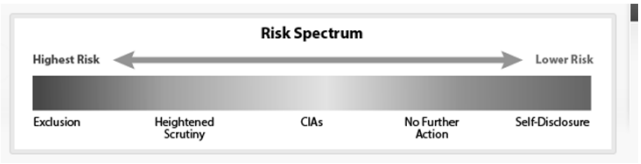
- Ambulance: 23 settlements, over $4.4 million
- Hospital E&M cases: 4 settlements, $2.6 million
- Pelvic Floor Therapy cases: 6 settlements resulting $2.79 million and 32 years of exclusion (total)
- Millennium Lab spin-offs: 11 CMPL settlements and 1 FCA settlement, over $14 million
- Drug pricing cases: 11 settlements, over $18.1 million
- Grant fraud settlements: *St. Charles Health Council, Sonata Biosciences*
- AnMed Health (EMTALA): $1.2 million, largest EMTALA settlement ever

Patient Assistance Programs

- Rescission of OIG Advisory Opinion No. 06-04
- Letter to PhRMA
- First CIAs with specific provisions overseeing PAPs

OIG Fraud Risk Indicator

- Outlines the OIG's assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud



- Makes **public** all health care providers that refuse to agree to enter into a CIA in connection with a FCA settlement
- https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp

New Regulations

New CMPL Regulations codifying authorities created by ACA

- CMPs, assessments, and exclusion for:
  - Failure to grant OIG timely access to records;
  - Ordering or prescribing while excluded;
  - Making false statements, omissions, or misrepresentations in an enrollment application;
  - Failure to report and return an overpayment; and
  - Making or using a false record or statement that is material to a false or fraudulent claim.

New Regulations

- Amended the definition of "remuneration" in the CMP regulations by interpreting and incorporating certain statutory exceptions for:
  - Copayment reductions for certain hospital outpatient department services;
  - Certain remuneration that poses a low risk of harm and promotes access to care;
  - Coupons, rebates, or other retailer reward programs that meet specified requirements;
  - Certain remuneration to financially needy individuals; and
  - Copayment waivers for the first fill of generic drugs.
- Added New Safe Harbors

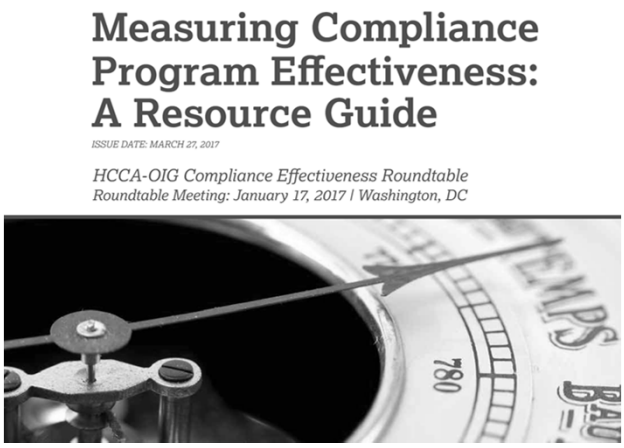
Other Updates on OIG Authorities

- CMP Authorities
  - Grant and Contract Fraud
    - HHS given statutory authority to impose civil money penalties, assessments, and/or exclusion upon individual/entities engaging in fraudulent conduct involving HHS grants, contracts and other agreements.
  - Information Blocking
    - OIG given authority to impose civil money penalties upon parties (health information technology developers, health care providers, and other) that engage in information blocking
- Inflation Adjustment (83 FR 51369, Oct. 11 2018)

Additional Anti-Kickback Updates

- **Proposed Rule: "Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection"**
  - Submitted by OIG and HHS to OMB in July 2018
  - Follows suggestion to revisit the AKS safe harbor for drug rebates in May 2018 Trump Administration drug pricing plan, "American Patients First"
- ***Jack Carrel et al. v. AIDS Healthcare Foundation*, Case No. 0:14-cv-61301-KMW (11th Cir., August 6, 2018)**
  - Appeals court affirms safe harbor protection for referral fees paid to employees.
  - Nonprofit AIDS Healthcare Foundation, Inc. did not violate AKS by paying employees for referring HIV patients to AHF for Ryan White Act services.
  - Government filed statement of interest in support of AHF's motion to dismiss, citing "significant interest in the property interpretation and correct application" of the FCA and AKS.

Compliance Resources



Compliance Program Effectiveness: What it ***is***

- **Structured Around HCCA Seven Elements**
- **Compilation of Questions Used by Experienced Compliance Professionals**
- **A ToolKit**
- **Stimulus**

Compliance Program Effectiveness: What it *is not*

- **NOT a Checklist**
- **NOT a Standard**
- **NOT a Guarantee**

CMS ROLE IN ENFORCEMENT

CMS's Role In Enforcement

- Uses Enrollment/Revocation authorities to remove fraudulent providers from Medicare program.
- Proactively identifies "potentially fraudulent" billing through predictive modeling and other means.

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CMS Program Integrity Functions

- Pre and Post-payment medical review.
- Overpayment collections.
- Enrolls and screens new providers / suppliers.
- Supports OIG and DOJ in False Claims Act, enforcement and criminal prosecutions.
- Coordinates investigative efforts with law enforcement.

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CMS Program Integrity Functions

- Oversees CMS contractors that pay claims and investigate problematic billing by providers and suppliers:
  - the Uniform Program Integrity Contractors (UPICs)
  - the Medicare Administrative Contractors (MACs)
  - the Recovery Auditor Contractors (RACs)
  - the Medicare Drug Integrity Contractor (MEDIC)
  - the Zone Program Integrity Contractors (ZPICs)
  - the Medicaid Integrity Contractors (MICs)

The Final 60-Day Overpayment Rule:

- Final Rule Effective March 14, 2016
  - 81 Fed. Reg. 7654 (February 12, 2016)

- Key Concepts:
  - Identification of an Overpayment
  - The Reasonable Diligence Standard
  - Credible Information
  - Time Within Which to Exercise Reasonable Diligence
  - Look back Period

When Have You Identified an Overpayment?

- "Identification" triggers the 60-day clock to report and repay.
- Area of uncertainty before the final rule.

- According to CMS, identification occurs when provider has or should have, through the exercise of reasonable diligence, determined that it received an overpayment *and* quantified the amount.

In Other Words…

- CMS says "identification" includes:
  - Provider has actual knowledge of the overpayment
  - No actual knowledge, but provider should have known but failed to exercise "reasonable diligence"
    - Mere notification of a possibility does not trigger the clock
    - Notification does trigger the obligation to exercise "reasonable diligence"

What is "Reasonable Diligence"?

- Under the Rule, "reasonable diligence" includes:
  - Proactive compliance activities conducted in good faith
  - Timely, good faith investigation of "credible information" of a potential overpayment

When Do You Need to Conduct an Audit/Investigation?

- When you have "credible information" – information that supports a reasonable belief that an overpayment may have been received.
- CMS says credible information can come from:
  - contractor overpayment determinations
  - hotline complaints
  - unusually high profits or wRVUs
  - probe samples
  - a single overpaid claim!!!

How Far Do You Have to Look Back?

Look back Period

- ***Proposed Rule:*** Ten years from receipt of overpayment
- ***Final Rule:*** Six years from receipt of overpayment
- Providers need to review audit findings and determine whether there are overpayments going back the full six years.

United Healthcare Insurance Company, et al., v. Alex M. Azar II, Secretary of the Department of Health and Human Services, et al., Civil Case No. 16-157 Sept 7, 2018.

- Medicare Advantage 60-day overpayment rule vacated
- A Medicare Advantage plan "identifies" an overpayment when it has actually determined an overpayment occurs or when it should have determined when an overpayment occurred through the exercise of reasonable diligence.
- Discrepancy between the knowingly standard for a federal False Claims Act violation and the requirement that an overpayment is identified when a Medicare Advantage should have determined an overpayment existed through an exercise in reasonable diligence.
- 2014 proposed rule included an "actual knowledge" standard to determine an overpayment and did not include either an "exercise in reasonable diligence" standard to determine an overpayment or "conducting proactive compliance activities" under that standard, CMS arbitrarily and capriciously imposed a more burdensome standard without adequate notice or a chance to comment.
- Could have spillover effect to Fee-For-Service 60-day Rule

Regulatory Sprint to Coordinated Care

Regulatory Sprint

- Regulatory Sprint is focused on:
  - "Regulatory requirements or prohibitions that may act as barriers to coordinated care."
  - "Assessing whether those regulatory provisions are unnecessary obstacles to coordinated care."
  - "Issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care."
- Four-agency task force: CMS, HHS (OIG), OCR, SAMHSA
  - Examining obstacles to coordinated care related to Stark, AKS, HIPAA, Part 2
- Spearheaded by Deputy Secretary Hargan

Regulatory Sprint

- CMS issued RFI in June 2018 seeking comment on **Stark Law** to allow CMS to assess and address impact and burden of Stark and whether the law prevents or inhibits care.
  - 20 specific requests seeking input on current novel financial arrangements, applicability of exceptions, need for additional exceptions
  - Allows general comment on definitions *(e.g.*, "fair market value," "group practice")
  - Comments were due August 24, 2018
- OIG issued second RFI in August 2018 seeking comment on potential new safe harbors to **Anti-Kickback Statute** and exceptions to **CMP Law** to remove obstacles to coordinated, value-based care:
  - Care coordination and value-based care
  - Beneficiary engagement (*e.g.*, incentives, cost-sharing waivers)
  - Other regulatory topics (current waivers, cybersecurity, etc.)
  - Intersection of Stark and AKS
  - Comments due October 26, 2018

Questions?