View from the Trenches: The Government's Opioid Fraud and Abuse Initiatives

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Introduction

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- How the crisis developed and has evolved
- Federal statutes & regulations
- Current enforcement initiatives
- Federal responses to the crisis
- How to avoid liability

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Federal Statutes & Regulations

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The Anti-Kickback Statute

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- Prohibits **knowingly & willfully** paying, offering, soliciting or receiving remuneration in return for referral
- **Criminal**, civil & administrative remedies (including damages + penalties + exclusion)
- Predicate to FCA liability
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, sale of practice, bona fide employment, physician recruitment, etc.)
- Applies to **all** federal healthcare programs except FEHBP
- "One Purpose" rule

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The Anti-Kickback Statute

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- **2016:** Ill. psychiatrist pleads guilty to receiving kickbacks from two pharma. companies in exchange for prescribing antipsychotic medication. Sentenced to 9 months.
  - Remuneration under sham "consulting agreement"
  - Defendant also agreed to restitution of $600K

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The Eliminating Kickbacks in Recovery Act

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- "EKRA" – part of 2018 SUPPORT Act
- Makes it a federal crime to knowingly and willfully:
  - solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
  - pay or offer any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
    - to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
    - in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory.

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The Eliminating Kickbacks in Recovery Act

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- Punishable by up to 10 years in prison & $200K fine
- Applies to **both** FHPs **and** commercial health plans
- Prohibits any commission-based payments to W2 employees or independent contractors
- Applies to clinical laboratories, clinical treatment facility, and recovery homes

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The False Claims Act ("FCA")

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- Prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - Retention of overpayment
    - 60-day rule
- *Qui tam* actions

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The False Claims Act ("FCA")

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- Consequences of violating: Treble damages, per-claim penalties (b/t $11,181 and $22,363), exclusion.
- "Knowing" and "knowingly" includes actual knowledge, deliberate ignorance, or reckless disregard. **No proof of specific intent to defraud required**.

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FCA Common Focus Areas

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- Overprescribing opioids
- Medically unnecessary urine drug screenings
- Relationships with pharma. companies / outside laboratories
- Overutilization of ancillary services

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Controlled Substances Act

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- Controlled Substances Act contains numerous requirements and regulations governing prescribers. Violations can lead to civil monetary penalties, suspension of registration, and imprisonment.

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Controlled Substances Act

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- **August 2018:** Ohio physicians sued under CSA for overprescribing opioids. Suit also alleges that defendant received kickbacks from phama. company in exchange for prescribing opioids.
  - Govt. also sought temporary restraining order under Controlled Substances Act barring physician from writing prescriptions.

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Current Enforcement Initiatives

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Current Enforcement Initiatives

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- **August 2017:** DOJ Announces Opioid Fraud & Abuse Detection Unit
  - Use of data to identify & prosecute individuals that are contributing to opioid epidemic
    - Outlier physicians
    - Patient deaths w/in 60 days of opioid RX
    - Avg. age of prescriptions
    - Outlier pharmacies
  - 12 AUSAs for 3 year term
  - MDFL, EDMI, NDAL, EDTN, DNEV, EDKY, DMD, WDPA, SDOH, EDCAL, MDNC, SDWV

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Current Enforcement Initiatives

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- **September 2017:** 41 State AGs announce joint investigation of manufacturers & distributors of opioids.
- **January 2018:** AG Sessions announces DEA surge to focus on pharmacies and prescribers who dispense unusual or disproportionate amount of drugs.
- **February 2018:** New Jersey AG announces creation of new office within AG Office dedicated exclusively to opioid issues.

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Current Enforcement Initiatives

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- **February 27, 2018:** DOJ announces creation of **Prescription Interdiction & Litigation (PIL) Task Force**.
  - PIL will "aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufactures and distributors."
  - PIL will use all criminal & civil tools available to hold distributors such as **pharmacies, pain mgmt. clinics, drug testing facilities, and individual physicians** accountable for unlawful actions.

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Current Enforcement Initiatives

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- **Individual US Attorney's Offices get involved:**
  - **April 6, 2018:** USA Bill Powell (NDWV) announces creation of **Health Care Crimes Task Force,** which will investigate and prosecute opioid diversion, healthcare fraud, and other illegal activities in healthcare field.
    - Taskforce comprised of USAO, HHS-OIG, DEA, FBI, DCIS, WV Insurance Commission Fraud Unit, and W.V. MFCU.
- **DEA Surge:**
  - DEA announces that during 45-day period in Feb. and March 2018, DEA surfed its enforcement and administrative resources to identify & investigate prescribers and pharmacies that dispensed disproportionately large amounts of drugs.
  - DEA used agents, investigators, and analysts to analyze 80 million transaction reports from DEA-registered manufacturers and distributors, as well as reports submitted on suspicious orders and drug thefts and information shared from agency partners.
  - Reported results include 28 arrests, 54 other enforcement actions including search warrants and administrative inspection warrants, and 283 administrative actions of other types (including inspections, letters of admonition, memoranda of agreement/understanding, surrenders for cause of DEA registrations, orders to show cause, and immediate suspension orders).

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Current Enforcement Initiatives

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- **June 2018:** DOJ announces largest HCF enforcement action in DOJ history:
  - 601 individuals charged, including 165 doctors, nurses and other licensed medical professional
  - 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics
  - Thirty state MCFUs participated in takedown
  - Since July 2017, 2700 individuals excluded (587 for opioid diversion and abuse)

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Current Enforcement Initiatives

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- **April 2019:** "Appalachian Regional Prescription Opioid" (APRO) Strike Force Takedown
  - Criminal charges against 60 individuals, including 53 medical professionals (including 31 doctors, 7 pharmacists, 8 NPs)
  - 11 federal districts
  - Illegal prescribing & distributing of opioids and other dangerous narcotics
  - HHS also announces that since June 2018, it has excluded over 2,000 individuals

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Current Enforcement Initiatives

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- **State criminal cases:**
  - **February 2016:** California general practitioner found guilty of **second-degree murder** and sentenced to 30 years to life in prison for deaths of three patients who fatally overdosed on opioids and other dangerous drugs. **According to DA's press release, this is the first such conviction in the country.**
  - **May 2016:** Georgia psychiatrist charged with murder for deaths of three patients allegedly related to overprescribing of hydrocodone, oxycodone, methadone, fentanyl, and amphetamines.
  - **June 2017:** Oklahoma physician charged with 5 counts of second-degree murder based on opioid deaths. According to medical examiner's report, "[e]ach of the individuals was prescribed an excessive amount of medication the same months of their deaths which were all the result of multi-drug toxicity."

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Federal Responses to Opioid Crisis

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Federal Responses to the Crisis

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- CDC Guidelines (**March 2016**)
  - Non-pharmalogic therapy and non-opioid pharmalogic therapy preferred. Consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to patients.
  - Before starting opioid therapy, establish treatment goals with all patients & consider how opioid therapy will be discontinued if benefits do not outweigh risks.
  - Before starting and periodically during opioid therapy, discuss with patients known risks & realistic benefits.

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Federal Responses to the Crisis

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- CDC Guidelines (**March 2016**)
  - When starting opioid therapy, prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
  - When opioids are started, prescribe lowest effective dosage. Carefully reassess evidence of individual benefits and risks when considering increasing dosage.
  - When opioids used for acute pain, prescribe lowest effective dose of immediate-release opioids and prescribe no greater quantity than needed for expected duration of pain severe enough to require opioids. 3 days or less will often be sufficient, more than 7 days rarely needed.
  - Evaluate benefits & harms with patients within 1-4 weeks of starting opioid therapy for chronic pain or dose escalation. Evaluate benefits 7 harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harm of continued use, reduce dose or taper and discontinue.

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Federal Responses to the Crisis

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- Commission on Opioids (**March 2017**)
  - Chaired by Gov. Christie
  - August 1 draft report urged Pres. Trump to declare a national public health emergency to unlock emergency funding, expand treatment
  - Trump stated his intent to issue declaration on August 10; did so on October 26
  - Commission's final report issued **November 1, 2017**

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Federal Responses to the Crisis

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- Commission's Report contains 56 recommendations, including
  - Block grant federal funding to states for opioid programs
  - Roll out SBIRT to adolescents in school starting in middle school
  - Develop model statutes and policies for patient informed consent process before issuing opioid prescriptions for chronic pain
  - More education and training for prescribers, pharmacists
  - Enhance and require use of PDMPs, including establishing data-sharing hub; increase e-prescribing
  - CMS should remove all pain survey questions from patient satisfaction surveys
  - CMS should modify payment policies that discourage non-opioid pain treatments
  - Enhance federal sentencing penalties for fentanyl trafficking

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Federal Responses to the Crisis

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- Opioid Commission recommendations
  - Payors should remove reimbursement and policy barriers to SUD treatment, like patient limits, prior authorizations, and fail-first protocols
  - Enable DOL to fine insurers and funders who violate Mental Health Parity Act
  - Use medication-assisted treatment for pre-trial detainees; establish drug courts in all 93 federal judicial districts
  - HHS should develop new guidance for EMTALA compliance for stabilizing SUD patients
  - Offer employers and EAPs information to address employee SUDs
  - Fast-track (a) research into pain management, overdose medications and prevention and treatment of SUDs, and (b) FDA review of SUD-prevention technology

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How to Avoid Liability

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How to Avoid Liability

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- Follow guidance re: prescribing opioids for chronic pain (e.g., CDC guidelines)
- Create/implement prescribing policies and update medical record documentation requirements based upon applicable laws
- Oversee compliance with such policies by physicians/other prescribers and pharmacy managers
- Review, update, and train on policies about checking PDMP
- Educate physicians and staff about drug-seeking behavior, how to respond
- Provide physicians and staff tools to educate patients about risks of opioids
- Establish relationships with SUD treatment centers and practitioners in the community
- Maintain naloxone on hand, and train staff on its use

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How to Avoid Liability

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- Ensure compliance with DEA diversion regulations
  - All DEA registrants must provide **effective controls and procedures** to guard against theft & diversion of controlled substances. Factors to be used to determine adequacy of security controls:
    - Location of premises and relationship such location bears on security needs
    - Type of building and office construction
    - Type and quantity of controlled substances stored on premises
    - Type of storage medium (e.g., safe, vault, etc.)
    - Control of public access to facility
    - Adequacy of registrant's monitoring system (e.g., alarms, etc.)
    - Availability of local police protection
  - Must store Schedule II-V in securely locked, substantially constructed cabinet.

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How to Avoid Liability

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- Ensure compliance with DEA diversion regulations
  - Do not employ anyone who has: (1) been convicted of felony, (2) been denied a DEA registration; (3) had a DEA registration revoked; (4) surrendered a DEA registration for cause.
  - Notify DEA immediately upon discovery of thefts or significant losses.
  - Additional DEA advice:
    - Keep blank prescriptions in safe place;
    - Write out actual amount prescribed in addition to giving # to discourage alterations;
    - Never sign prescription blanks in advance
    - Use tamper-resistant prescription pads

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How to Avoid Liability

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- Ensure compliance with DEA diversion regulations
  - Follow all DEA diversion recordkeeping requirements.
    - Must maintain a complete & accurate record of controlled substance inventory;
    - Must use proper disposal methods for out-of-date, damaged, or otherwise unusable or unwanted controlled substance, including samples

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How to Avoid Liability

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- Implement a compliance program
- Elements of an effective **compliance program**:
  - Conducting internal monitoring and auditing;
  - Implementing compliance and practice standards;
  - Designating a compliance officer or contact;
  - Conducting appropriate training and education;
  - Responding appropriately to detected offenses and developing corrective action;
  - Developing open lines of communication; and
  - Enforcing disciplinary standards through well-publicized guidelines.

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Questions?

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