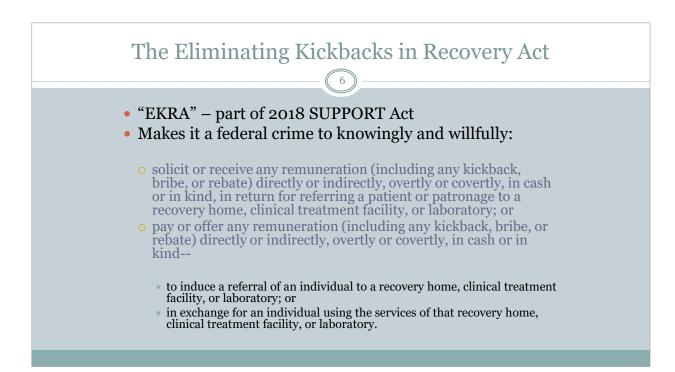


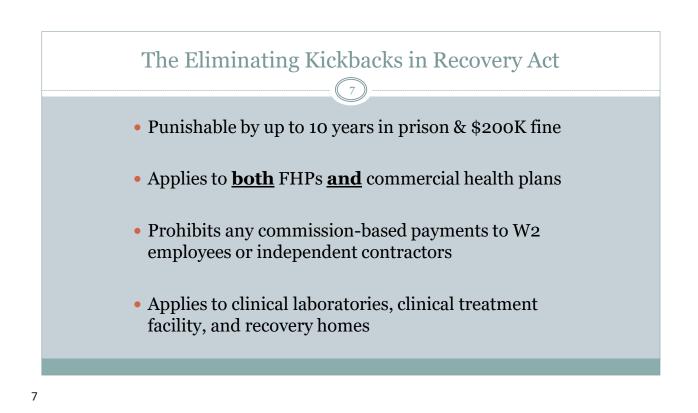
- Prohibits knowingly & willfully paying, offering, soliciting or receiving remuneration in return for referral
- <u>**Criminal**</u>, civil & administrative remedies (including damages + penalties + exclusion)
- Predicate to FCA liability
- Safe Harbors & exceptions similar to Stark exceptions (space & 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

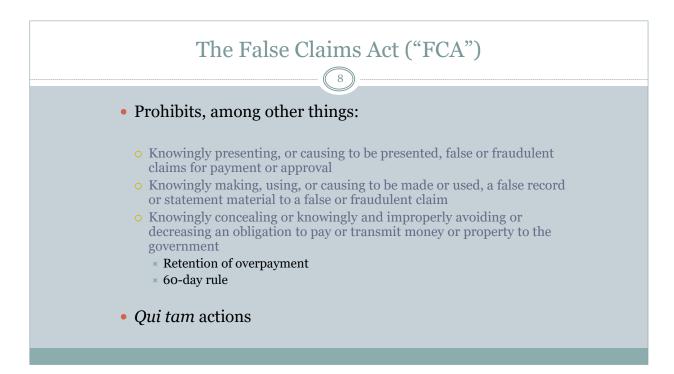
The Anti-Kickback Statute

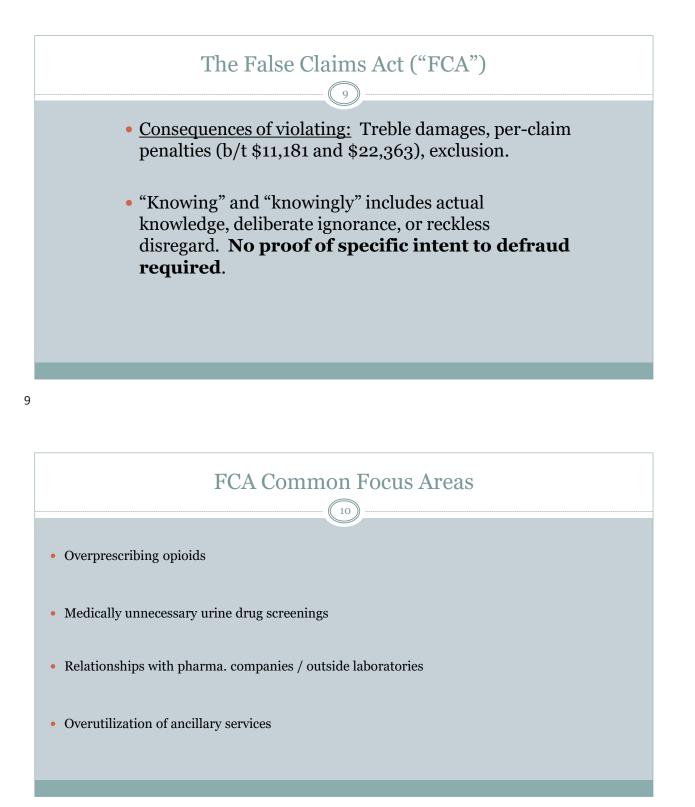
- **2016:** Ill. psychiatrist pleads guilty to receiving kickbacks from two pharma. companies in exchange for prescribing antipsychotic medication. Sentenced to 9 months.
 - Remuneration under sham "consulting agreement"
 - Defendant also agreed to restitution of \$600K

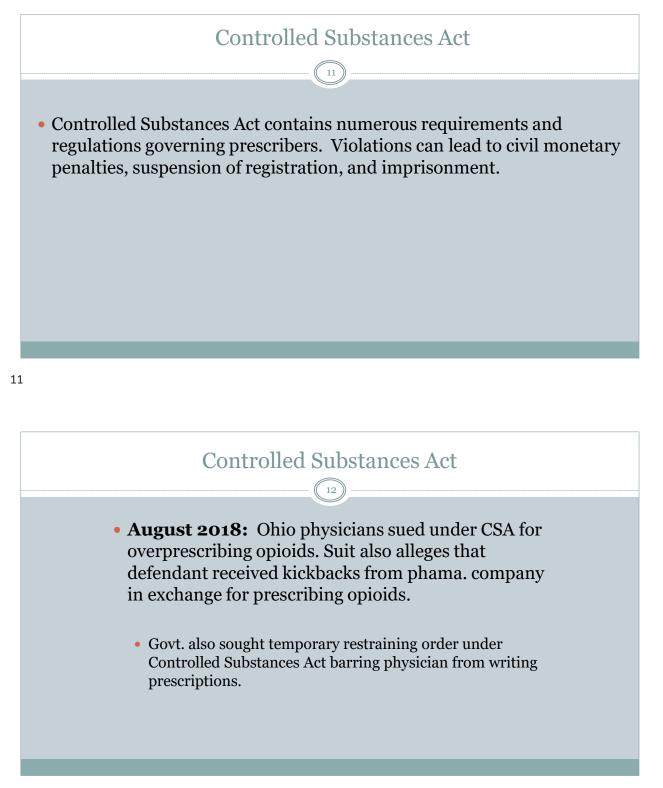


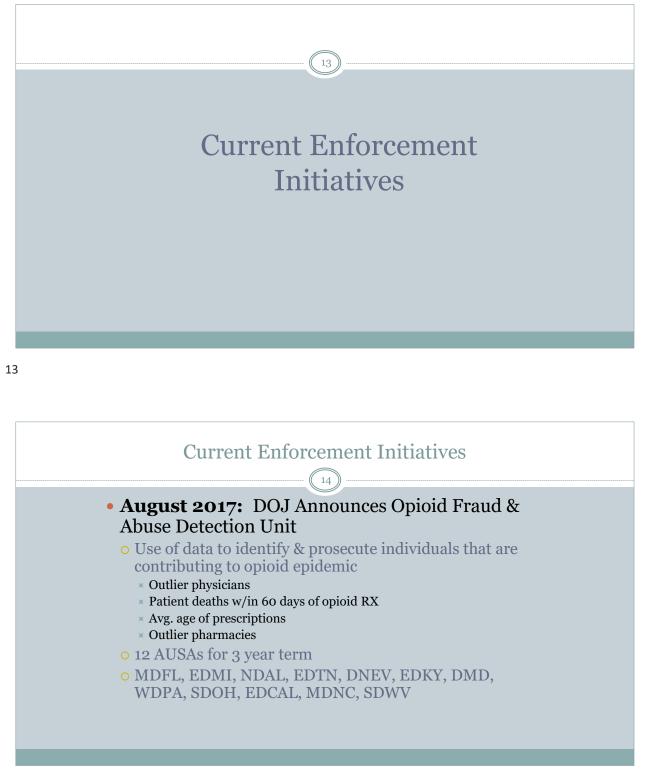
















Current Enforcement Initiatives

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:

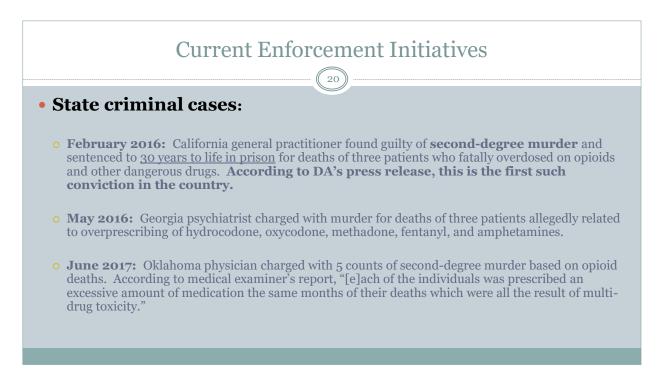
- DEA announces that during 45-day period in Feb. and March 2018, DEA surfed its enforcement and administrative resources to identify & investigate prescribers and pharmacies that dispensed disproportionately large amounts of drugs.
- DEA used agents, investigators, and analysts to analyze 80 million 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).

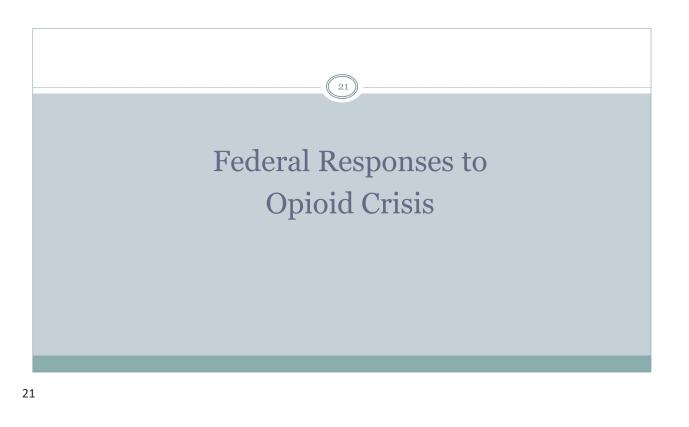


Current Enforcement Initiatives

• 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)
- o 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





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.

Federal Responses to the Crisis

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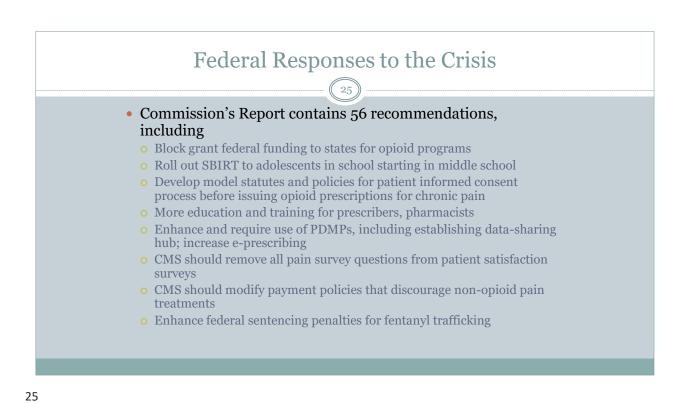
• CDC Guidelines (March 2016)

- 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.

Federal Responses to the Crisis

Commission on Opioids (March 2017)

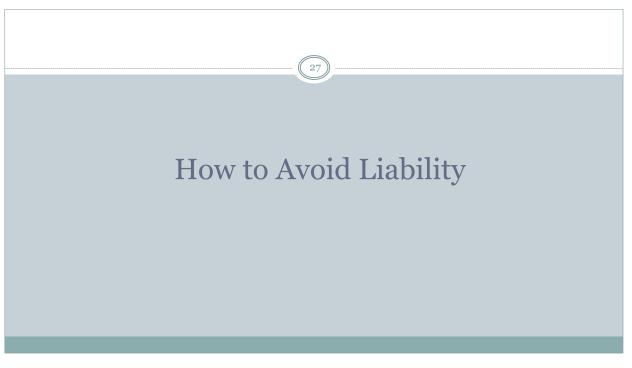
- Chaired by Gov. Christie
- August 1 draft report urged Pres. Trump to declare a national public health emergency to unlock emergency funding, expand treatment
- o Trump stated his intent to issue declaration on August 10; did so on October 26
- Commission's final report issued November 1, 2017





• 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
- o 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



How to Avoid Liability

- 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
- o Oversee compliance with such policies by physicians/other prescribers and pharmacy managers
- o Review, update, and train on policies about checking PDMP
- o Educate physicians and staff about drug-seeking behavior, how to respond
- o Provide physicians and staff tools to educate patients about risks of opioids
- o Establish relationships with SUD treatment centers and practitioners in the community
- o Maintain naloxone on hand, and train staff on its use

How to Avoid Liability

• 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
- o Must store Schedule II-V in securely locked, substantially constructed cabinet.

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.
 - o 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

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

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.

