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Preparing for DEA audits
Avoiding Legal Pitfalls
Practice Tips

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DEA Registration

Problems arise when:

- Opening a new practice (within or outside of the state of practice)
- Physical expansion
- Merger or sale
- Affiliation with a hospital

DEA Registration (Summary)

- A separate registration is required for every principal place of business, unless a registrant is only prescribing at a second location.
- If a registrant maintains supplies of controlled substances, administers, or directly dispenses controlled substances at that second location, a separate registration must be obtained.
- No separate registration is required for an agent or employee of any registrant if acting in the usual course of the employment.
- Can administer or dispense under another practitioner's registration as an employee or an agent but must be licensed individually to prescribe.

Record-Keeping requirements

- 21 CFR Parts 1300-1321
- 21 USC Sections 801-971
- Incorporate in the Policies & Procedures

Most commonly cited record-keeping violations

- Failure to Maintain Complete and accurate records in violation of 21 USC 842(a)(5)
- Failure to perform adequate inventory
- Failure to properly maintain CS records 21 CFR 1304.04(f)
- Prescriptions missing dates and patients' addresses in violation of 1306.08

Other commonly cited record-keeping violations

- Prescription forms lacking various security features (as required under state laws), 21 USC 842(a)(2)
- Theft/loss not reported in timely manner as required by 21 CFR 1301 (b)
- Improper filled Forms 222 in violation of 1305.13
- Missing POA (or failure to properly execute) in violation of 1305.12 (d)

Failure to exercise corresponding responsibility in violation of 1306.04

- Provider ignored the red flags present when dispensing CS, such as long travel, cash payments, early refills, cocktail prescriptions, prescription patterns
- Prescriptions written by problematic prescribers
- Failure to run PDMP reports

Avoiding Corresponding Responsibility Issues

- Execute lock-in agreements with patients
- Train staff
- Perform due diligence in relation to each patient (Document it!)
- "Do-not-fill" policy for some of the "problematic" prescribers
- Running PDMP on all existing (periodically) and new patients
- Review and Update Policies & Procedures on dispensing CS

Red Flags cited in DEA reports

- Excessive filling (compared to similarly situated pharmacy)
- Unusual combination of CS
- Patients obtaining CS from multiple practitioners
- Filling CS prescriptions for patients with the address of a drug treatment facility
- Customers paying in cash
- Filling prescriptions without obtaining a PDMP report.
- Early refills

Monetary Penalties

- Violations of 21 USC 842(a)(1)-(2) are subject to a penalty of $64,820.
- Violations of 21 USC 842(a)(5) = $15,040
- An average DEA audit of an independent pharmacy discovers hundreds of record-keeping violations.
- DOJ files a complaint in US District Court to recover civil penalties = settlements.

Surrendering DEA registration

- DIs tactics to coerce the surrender
- Partial surrender: CIIs only
- Collateral consequences

Trinity Pharmacy case

- All the record-keeping issues discussed above plus
  - Filling CS Rx by pharmacy interns
  - Not following prescriber's instructions on filling CS
  - Failure to identify a pharmacist who filled the CS Rx.

CALJ concluded: *"the evidence demonstrated a culture in the Respondent pharmacy of ignoring regulations deemed inconvenient…this pharmacy is dangerous, and the owners have given not even the smallest indication to the Agency that there is any inclination to change."*

Zion Clinic Pharmacy case

- DI commenced investigation based on excessive ordering (41,700 dosage units of hydromorphone in 2012)

- "Dispensing of controlled substances despite the presence of red flags of diversion that Zion failed to clear prior to dispensing the drugs."

- Defines "Willful blindness"

Administrative Enforcement by OIG

- Trend of auditing NIH and HIS hospitals for sufficient opioid controls
- OIG's automated assessment tools to assess technical security

FDA's Involvement in Opioid Crisis

- Guidelines "Abuse-Deterrent Opioids—Evaluation and Labeling"
- Naloxone
- Risk Evaluation and Mitigation Strategies (REMS)

Practice Tips

- PDMP verification is a must on all new patients. On the existing patients, run PDMP every 4-6 months.
- Verify prescribers' DEA registrations
- Train pharmacists on "red flags"
- Document due diligence!
- Consider e-prescribing
- Ensure TelePharmacy compliance

Industry's Efforts to Curb Opioid Epidemic

- Patient lock-in contract
- Capping the amount of opioids to be dispensed (Walmart, CVS)
- Free counseling to its patients on proper opioid use, possible overdose, and addiction
- Opioid disposal solution
- Caremark reimbursement changes
- Further reducing manufacturing quotas