Management of Controlled Substances in Dental Practice

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Disclaimer

Dr. O’Neil is not representing or speaking on the behalf of the DEA
Management of Controlled Substances in Dental Practice

After participating in this seminar, dental practitioners will be able to:

• Identify regulations most commonly violated by dental practitioners

• Discuss record keeping requirements for prescribing, dispensing and storage of controlled substances

• Discuss due diligence activities necessary to minimize diversion and abuse of controlled substances by patients and staff
Suggested References

www.deadiversion.usdoj.gov

Practitioner’s Manual:

Title 21, United States Codes
Comprehensive Drug Abuse Prevention and Control Act of 1970
(Controlled Substances Act) is the LAW

Title 21, Code of Federal Regulations Part 1300 to End
is the REGULATIONS

Violations of Laws or Regulations

- Criminal investigation (federal, state)

- Civil action through USAO

- Administrative actions (DEA, state boards such as Board of Pharmacy)

- Referral to other State Regulatory Agency (insurance boards)
DEA Administrative Actions

• Letter of Admonition
• Memorandum of Understanding
• Voluntary Surrender of Registration
• Order To Show Cause
• Immediate Suspension
• Revocation of Registration
Prescribing for Personal Use (Pain vs. Addiction)

“There is nothing in the law that say I can’t write a prescription for myself”

- Outside of Professional Practice
- No Doctor-Patient Relationship
- No Patient Chart / Treatment Plan
- Prosecution on a State Level for Violation of the CSA
Pharmacist’s Responsibility

but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Title 21, Code of Federal Regulations Section 1306.04(a)
Regulations Often Violated by Dental Practitioners... and How to Prevent Violations

<table>
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<tr>
<th>Violation</th>
<th>Description</th>
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<td>Prescribing outside the scope of practice</td>
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<td>Failing to maintain required documents</td>
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<td>Failing to dispose of controlled substances according to regulations</td>
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<td>Failing to store controlled substances according to regulation</td>
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<td>Failing to maintain inventory records according to regulation</td>
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<tr>
<td>Prescribing without a <em>documented</em> established dental provider-patient relationship</td>
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<tr>
<td>Failing to maintain up-to-date registration documentation</td>
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<td>Healthcare or insurance fraud</td>
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Regulations Often Violated by Dental Practitioners... and How to Prevent Violations - Scope of Practice

- Defined by State Dental Practice Act
- Often varies from State to State

Example: chronic pain
  - anxiety disorders
  - non-dental pain

Example: Purchasing controlled substances for dispensing
  - purchases-dentists cannot obtain controlled substances in bulk with a prescription and then dispense the controlled substances in separate amounts. Must purchase with a DEA 222 form or invoice

  (dispensing does not equal administering)
Prescribing without a Documented Established Dental Patient Relationship

- If controlled substance records are not available or records are illegible ..... They essentially don’t exit

- Prescribing for office staff members
  - handle documentation as any other patient

- Prescribing to immediate family members
  - handle documentation as any other patient

- “Curb side consults” should be avoided
Record Keeping Requirements for Prescribing / Dispensing Controlled Substances

• Maintain records for the purchase of ALL controlled substances.

• These records must be maintained, “readily retrievable,” and available for inspection by the DEA, state law enforcement, or regulatory entities responsible for these inspections.
Federal law requires the DEA registration-registrant information, authorized power of attorney letters with all DEA Forms 222 and the most recent biennial inventory records be kept on site for immediate review.

Other records maintained at another location, such as invoices for Schedule III through V purchases, should be retrievable in no less than 2 business days.
Any purchase of a controlled substance to be administered or dispensed to a patient requires a practitioner to maintain purchase and disposal records. Such records are required to be maintained for a period of two years. Some states may require such records to be maintained for five years.

- Biennial inventory must be done on the same day

- Designate a single office staff to help manage this critical paper trail
Record Keeping Requirements

Documentation, or more specifically lack of documentation

- DEA Form 222 is the form used to purchase or transfer a Schedule II controlled substance to and from a practitioner to their suppliers or reverse distributors. The form is required to have the date of purchase or transfer along with the quantities that are purchased or transferred by the practitioner.

- Invoices are required for purchases or transfers of Schedule III through Schedule V controlled substances. The same documentation, such as quantity received or shipped and the date received or shipped, is required by those regulations on controlled substances.

- Perpetual Inventory is not required by federal laws and regulations, but it may be used to maintain an inventory of controlled substances that are purchased, dispensed or administered; disposed of as waste; or on-hand. If a dental practitioner purchases controlled substances for office use, the practitioner should maintain such method of inventory. Perpetual implies the “total count” of a controlled substances onsite is known in real time or near real time.
Record Keeping Requirements

Document legitimate medical purpose in the chart

- Federal *and* State regulations
- Documenting patient, medication, drug dose, quantity in patient chart
A Good Medical Chart will Contain the Following:

• Initial Evaluation
• Patient Medical History
• Referral Letter (Pain Management)
• Medical Tests and Evaluations
• Detail Treatment Plan
• Prescribed Drugs, indication, instructions, Sig, qty
The Prescription / Pad

• Treat Them Like a Loaded Weapon

• Use Carbonless Copy

• Sequentially Numbered Rx

• Maintain Copy in Patient Chart

• Limited Access & Secured Storage

• **Sign and date the day of the issuance** (no predating or signatures before day of issuance, no electronic signatures)
Storage of Controlled Substances

- Stored in a locked, well-constructed metal cabinet or safe (ideally a 2 “lock” system...in a locked room/closet then in a locked cabinet...all with limited patient/personnel access

- Access be limited to only a few individuals.

- The dental practitioner under whose DEA registration number the controlled substances were purchased holds full responsibility for storage.

- Any diversion of such controlled substances will also be the responsibility of that dental practitioner.

- Consider keeping prescription pads in the same place
Storage of Controlled Substances

Federal law requires inventory every 2 years
• Should be the same date
Disposal of Controlled Substances: 
2 Considerations

1. Disposal of controlled substances by the dental practitioner should be done by a DEA-registered reverse-distributor

   • expired, contaminated or defective controlled substances

2. If a reverse distributor is not used, the DEA requires DEA form 41 be completed, submitted and approved BEFORE destruction.

   NOT flushing or destruction by dentist or office staff
Due Diligence Practices to Deter Prescription Drug Diversion

- Background checks on Employees
- Patient intake
- Document *every* patient- Drug, dose, qty, indication
- Ideally keep perpetual inventory of CS
- Write legibly/don’t copy and paste histories, etc.
- Storage of medication and Prescriptions
- Dedicate a single staff to maintain records...then follow-up on your own periodically
- Lock-Up Rx
- Use PDMP
- Reporting known or suspected criminal activity
Summary
Future ADA/PCSS-O Webinars

• April 22, 2015, 2:000 PM (Central): Safe Prescribing for the addicted or non-addicted

• If interested in participating in the April 22, 2015 webinar, please send an email to SiwekA@ada.org with the subject heading “April 22”.