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# PRESCRIBING CONTROLLED SUBSTANCES: MANAGING THE RISKS

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While scrutiny of controlled substance prescribing has increased, there are three proven strategies to manage the risks associated with prescribing controlled substances:

- 1) Collecting information
- 2) Communicating
- 3) Carefully documenting

## **COLLECTING INFORMATION**

### About the Patient:

- Perform, and document, a complete initial patient evaluation, including medication history
- Review your state's Prescription Monitoring Program (PMP) prior to prescribing
  - If the report shows prescriptions not reported by the patient, address the issue clinically with the patient.
    - Do not abandon by terminating without notice
    - Do not report the entries to law enforcement

### About the Medications:

- Stay up-to-date with the medications you prescribe
- Read the labels for the medications you prescribe
- Subscribe to FDA's MedWatch (1) for notification of medication safety alerts
- Be familiar with FDA's REMS for the medications you prescribe (2)

### About Treatment / Standard of Care:

- Stay current with and follow:
  - Applicable federal and state laws related to prescribing controlled substances
  - Applicable federal and state regulations
  - Guidance from regulatory agencies such as
    - DEA
    - State licensing board
  - Guidance from others such as

- Federation of State Medical Boards
- Professional organizations – APA, AACAP, etc.
- Complete appropriate CME courses related to prescribing controlled substances
- Follow universal precautions when prescribing opioids (3)
  - Make a diagnosis with an appropriate differential
  - Conduct a patient assessment, including risk for substance abuse disorders
  - Discuss the proposed treatment plan with the patient and obtain informed consent
  - Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician
  - Initiate an appropriate trial of opioid therapy, with or without adjunctive medications
  - Perform regular assessment of patient and function
  - Reassess the patient’s pain score and level of function
  - Regularly evaluate the patient in terms of the “5 A’s”: Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect
  - Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly
  - Keep careful and complete records of the initial evaluation and each follow-up visit

About Abuse and Diversion:

- Recognize the drug abuser – from the DEA (4)
  - Common characteristics
    - Unusual behavior in waiting room
    - Assertive personality, often demanding immediate attention
    - Unusual appearance
    - Unusual knowledge of controlled substances and/or textbook symptoms
    - Evasive or vague answers to questions regarding medical history
    - Reluctant or unwilling to answer questions regarding medical history
    - No regular doctor; no health insurance
    - Will request a specific medication and is reluctant to try a different one
    - No interest in the diagnosis; fails to keep appointments for further diagnostic tests or refuses to see a consultant
    - Exaggerates medical problems and/or simulates symptoms
    - Cutaneous signs of drug abuse
  - Common modus operandi:

- Must be seen right away
  - Wants an appointment toward end of office hours
  - Calls or comes in after regular business hours
  - Traveling through town, visiting friends or relatives
  - Feigning physical problems
  - Feigning psychological problems
  - States that certain medications to no work or is allergic to them
  - Lost or stolen prescription
  - Requests refills more than originally prescribed
  - Pressures by eliciting sympathy or guilt
  - Utilizes a child or elderly person when seeking stimulants or narcotics
- Recognize doctor shoppers – red flags – from the Tucson DEA (5)
    - Symptom incompatible with reported injury
    - Visits physician some distance from home
    - History of problems with no medical records
    - Multiple accidents
    - Insists on drug of choice
    - Loss of prescription or medication
    - Fails to have testing done
    - Takes more meds than directed
    - Requests meds early
    - Obtains meds from multiple prescribers
    - Prescriptions are filled at multiple pharmacies
  - When confronted by a suspected drug abuser – from the DEA (4)
    - DO:
      - Perform a thorough examination appropriate to the condition
      - Document examination results and questions asked of the patient
      - Request picture ID
      - Confirm telephone number
      - Confirm current address at each visit
      - Write prescriptions for limited quantities
    - DON'T:
      - Take the patient's word for it if suspicious
      - Dispense meds just to get rid of drug-seeking patients

- Prescribe, dispense, or administer controlled substances outside the scope of your professional practice or in the absence of a formal practitioner-patient relationship

## **COMMUNICATING**

### With the Patient:

- Ensure adequate on-going monitoring of the patient and progress toward treatment goals
- Consider standardized assessment tool
  - Especially pain management (6)
  - Especially for buprenorphine treatment (7)
- Ensure adequate on-going monitoring of the medications – efficacy, side effects, etc.
- Informed consent
  - Nature of proposed medication
  - Risks and benefits of proposed medication, including
    - Severe risks, even if infrequent
    - Frequent risks, even if not severe
    - Potential for tolerance, dependence, addiction, overdose
    - Potential for driving impairment
  - Alternatives to proposed medication
  - Risks and benefits of alternative treatments
  - Risks and benefits of doing nothing
  - Prescribing policies
  - Reasons for which medication may be changed or stopped
- Use resources to assist with patient understanding
  - Medication guides
    - FDA (8)
    - Professional organizations, such as AACAP (9)
  - FDA’s “Patient Counseling Document for Opioids” (10)
- Your office policies related to prescribing controlled substances, such as:
  - Only one prescriber
  - Only one pharmacy
  - No replacement of lost or stolen prescriptions
  - Prohibition on dose or frequency increases by patient
  - Use of PMP
  - Random pill counts

- Random drug screening
- Etc.
- Consider the use of a treatment agreement, especially for pain management, which could include:
  - Intended benefits / goals of using controlled substances
  - Risks of the treatment, including tolerance, dependence, abuse, addiction
  - Prescription management – how patient can keep medications secure, etc.
  - Office policies
  - Termination for
    - Non-adherence
    - Aberrant behavior
  - Etc.
- Ensure the security of your prescriptions – from the DEA (11):
  - Use tamper-resistant prescription pads
  - Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use
  - Write out the actual amount prescribed in addition to giving a number to discourage alterations
  - Use prescription blanks only for writing a prescription and not for notes
- Discuss proper disposal of unused medication

#### With Others:

- Ensure communication between all involved in the patient's care (such as covering physician, other treaters, etc.)
- Communicate with family members as authorized by the patient
  - In emergency situations, remember that safety of the patient or others is an exception to confidentiality, so no authorization is required
  - You can listen to what third parties want to tell you without breaching patient confidentiality, as long as you are not disclosing information

#### **CAREFULLY DOCUMENTING**

- Document your treatment decision-making process
  - Documentation allows your work to be understood
- Record should contain:
  - Medication log

- Evaluation
- Medical indication for prescribing
- Treatment plan – initial and updated
- Informed consent – including patient education materials
- Ongoing assessment
  - Adherence to treatment plan
  - Medication monitoring
  - Aberrant behavior
- Referral / consultation, if necessary
- Treatment agreement, if used
- Assessment forms, if used

**Sources:**

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