
PRESCRIBING CONTROLLED SUBSTANCES: MANAGING THE RISKS

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:

1. www.fda.gov/medwatch
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