701 Best Practices in Controlled Substance Prescribing and Documentation

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McLaren HEALTH CARE

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Agenda

- Best Practices defined
- Overview of laws
- Controlled Medicine Agreements
- Frequency of Visits
- PDMP
- Documentation
- Laboratory-based compliance monitoring
- The prescription
- Consults
- Patient non-compliance
- Medical marijuana
- Best Practices Next Steps

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Best Practices

- A process or method that represents the most effective way of achieving a specific objective, or which has been proven to work well and produce good results, and is recommended as a model.
- This process better equips the provider and their staff to be more organized in their approach to possibly complex needs of the patient.
- Requires committed office staff, providers, and leadership.

Does your organization have a Best Practice for controlled substances?

Yes

No

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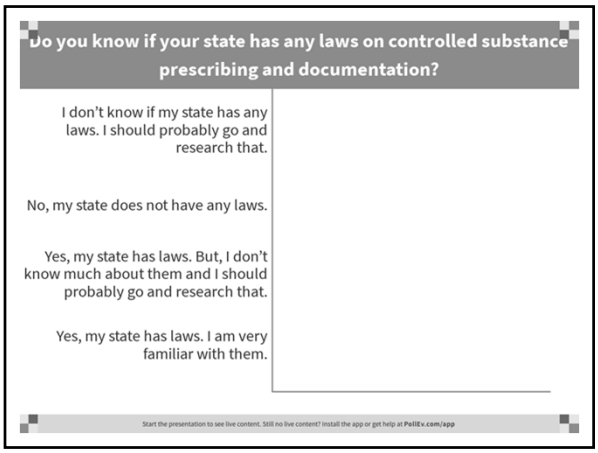

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Overview of Recent Laws

- Per the CDC, 47 states have laws that limit controlled substance prescriptions with time limitations (hours, days) or dosage limitations (dosage units or number of pills)
- Michigan requires opioid education for initial opioid prescription, limits on opioids for acute pain, registering for and checking PDMP
- Florida limits prescribing (acute pain 3-7 days & non-acute pain exceptions for more than 7 days), requires 2 hour continuing education on controlled substance prescribing, expanded required use of PDMP
- Arizona requires a red cap put on the prescription bottle for all schedule II's with a warning label on it for overdose/addiction
- Tennessee requires education for prescriptions that are more than 3 days for an opioid or if opioid dosage exceeds 180 MME to woman of childbearing age
- New Jersey limits prescribing to 5 days for initial schedule II, documented discussions, pain agreements for treatment of chronic pain, mandatory CME

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Controlled Medicine Agreements

- Sets the expectations for treatment with a controlled substance
- Helps ensure the patient understands their role and responsibilities
  - How to obtain refills, conditions of medication use
- Informs the patient about conditions whereby controlled substance or treatment could be terminated
- Outlines the responsibilities of the provider
- Recommend a copy for the patient and for the chart

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Controlled Medicine Agreements

McLaren Medical Group
CONTROLLED MEDICINES AGREEMENT

The purpose of this Agreement is to prevent any misunderstandings about certain medicines that you will be taking. This is to assist both you and your doctor in complying with the law regarding controlled medicines.

TERMS OF THE AGREEMENT:

I understand that this Agreement is essential to the trust and confidence necessary in a doctor/patient relationship. I understand that if I break this Agreement, my doctor will stop prescribing controlled medicines.

I understand that this agreement includes all controlled medicines scheduled II-V as categorized by the U.S. Federal regulations. This may include, but is not limited to, drugs referred to as Narcotics, ADD/ADHD Medications, Sleep Medications, Benzodiazepines, etc.

I will communicate fully with my doctor about the character and intensity of my symptoms, the effect of the symptoms on my daily life, and how well the medicine is helping to relieve the symptoms.

I will not use any illegal controlled substances, including marijuana, cocaine, etc., or prescription drugs not prescribed to me, and agree that I will submit to a random blood or urine test if requested by a provider to determine compliance with my program of controlled medication management.

I will not share, sell or trade my medicine with anyone.

I will not attempt to obtain any controlled substances, including opioid medicines, controlled stimulants, or anti-anxiety medicines, from any other doctor without coordination of care between doctors.

I will safeguard my medicine from loss or theft. I understand my doctor may not replace my lost, misplaced, or stolen medicines. If I have trouble with safeguarding my medicine, I understand my doctor will discuss this with me and may elect to remove me from drug therapy, if medically appropriate, or otherwise take additional control measures regarding my supply of controlled medicines. I agree to these additional controls, which I understand include limitations on my supply of controlled medicines.

I agree that refills of my prescriptions for controlled medicines will be made only at the time of an office visit or during regular office hours because an evaluation of my circumstance or condition must be made. No refills will be available outside of normal business hours.

I agree to use ______________ Pharmacy, located at ______________, for filling prescriptions for all of my controlled medicines.

I agree that I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate will result in my being without medicine for a period of time.

I understand that I am required to see my healthcare provider in a face-to-face appointment at least _____ times per year.

I understand that any provisions not followed in this Agreement could be grounds for discharge from care.

I agree to follow the guidelines that have been fully explained to me. All of my questions and concerns regarding these medicines have been adequately answered. A copy of this Agreement has been given to me.

All controlled substances carry the risk of addiction.

This Agreement is entered into on this __________ day of ______________, ________ ____

Patient: ______________ Provider: ______________

Authorized Representative: ______________ Relationship: __________

Witness: ______________

CONTROLLED MEDICINES AGREEMENT

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Controlled Medicine Agreements

McLaren Medical Group
PARENT CONTROLLED MEDICINES AGREEMENT

The purpose of this Agreement is to prevent any misunderstandings about certain medications that your child will be taking. This is to assist both you and your doctor in complying with the law regarding controlled medicines.

TERMS OF AGREEMENT:

I understand that my child's doctor is bound by certain state and federal laws when prescribing controlled medicines. While these laws seem inconvenient to me, I understand that they are ultimately intended to protect my child's safety, health, and privacy.

I understand that this Agreement is essential to the trust and confidence necessary in a doctor/patient relationship. I understand that if I break this Agreement, my child's doctor will stop prescribing controlled medicines for my child.

I understand that this agreement includes all controlled medicines scheduled II-V as categorized by the U.S. Federal regulations. This may include, but is not limited to, drugs referred to as Narcotics, ADD/ADHD Medications, Sleep Medications, Benzodiazepines, etc.

I will communicate with my child's doctor about the character and intensity of my child's symptoms, the effect of the symptoms on my child's daily life, and how well the medicine is helping to control the symptoms.

I will be vigilant in assuring that my child does not use any illegal controlled substances, including marijuana, cocaine, etc., or prescription drugs not prescribed to my child, and agree that my child may be tested for use of controlled substances at any time.

I will not use, share, sell, or trade my child's medication at any time.

I agree that I will administer the medication exactly as the doctor prescribed it and make no changes to the dose, nor discontinue the medication, without instruction from my child's doctor.

I will not attempt to obtain any controlled medications for my child from any other doctor without coordination of care between doctors.

I agree to use ______________ pharmacy, located at ______________, for filing prescriptions for all of my child's controlled medicines.

I will safeguard my child's prescription and my child's medication from loss or theft. I understand that my child's doctor may not replace lost, misplaced, or stolen medicines. If I have trouble with safeguarding my child's medicine, I understand my doctor will discuss this with me and may elect to remove my child from therapy with controlled medicines.

I understand that refills of my child's medication will be made only at the times of office visits, or during regular office hours if I call 5 business days ahead of time with a refill request. I understand that after I have called for a refill request, I should call the office the day I plan to pick it up to be sure that the physician has had the opportunity to write the prescription. I understand that refills are NOT available after office hours, on weekends, or through an on-call physician.

I understand that I may be asked for photo ID when picking up my child's prescription. I understand that I may leave written permission for some other adult designee (over age 18) to pick up my child's prescription and that the designee may be asked to provide photo ID when picking up my child's prescription.

I understand that my child is required to see the healthcare provider in a face-to-face appointment at least _____ times each year.

I understand that any provisions not followed in this Agreement could be grounds for discharge from care.

I agree to follow the guidelines that have been fully explained to me. All of my questions and concerns regarding these medicines have been adequately answered. A copy of this Agreement has been given to me.

This Agreement is entered into on this __________ day of ______________, __________.

Patient: ______________ Provider: ______________

Parent/Guardian: ______________ Relationship: ______________

Witness: ______________

Patient Name

PARENT CONTROLLED MEDICINES AGREEMENT

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Frequency of Visits

- Recommendation is once a month till stable (or 3 visits)
- Then every 1-3 months to evaluate the need for continuation based on the patient's adherence to the recommended regimen, dose of the medication, and how well the patient is doing
- Most providers see patients prescribed a schedule II every month
- Patients with significant psychosocial issues, recovering addicts, exhibition of difficulty with compliance, new pain issue, dosage adjustments should be seen more often, may be even weekly

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Prescription Drug Monitoring Program

- Very useful information, some states require use
- Narcotic, sedative, stimulant scores
- Overdose risk score
- All prescribers
- All pharmacies
- All prescriptions
  - Date written, date filled (including if a refill and what number), quantity, days of medications, payment type

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Documentation – before prescribing

- Accurate and complete records, including
  - Medical history and physical examination
  - Diagnostic, therapeutic and laboratory results
  - Evaluations and consultations
  - Treatment objectives
  - Discussion of risks and benefits
  - Treatments
  - Medications (including date, type, dosage and quantity prescribed)
  - Instructions and agreements
  - Check PDMP

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Documentation – at each visit

- Assessment of pain level
  - Recommend scale 1-10
- Functional level/score
  - Activities of daily living, what is the patient actually doing
- Side effects
  - Constipation
- Affect/mood
  - Depression/anxiety, may need antidepressant or therapy
- Aberrant drug-related behaviors
  - requesting early refills, abnormal drug screen

DOCUMENT, DOCUMENT, DOCUMENT, DOCUMENT, DOCUMENT

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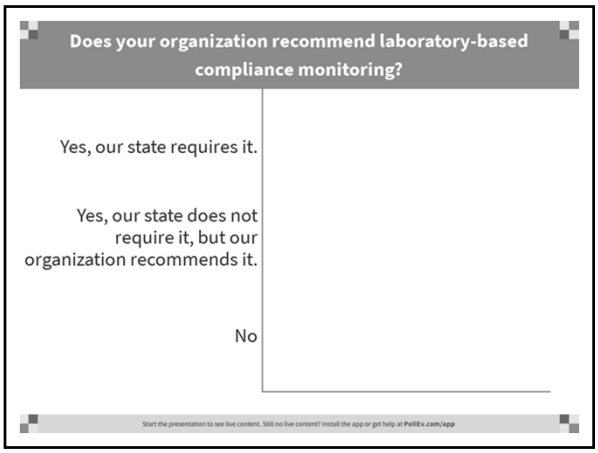
Documentation – controlled substance

- Last time took their controlled substance medication, may need drug testing
- How many are they taking every day, assess for unauthorized dosage increases
- Discuss treatment goals
- Any abnormalities from prior drug testing or from PDMP review
- Proper storage/disposal
- Address any other conflicts/red flags



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Laboratory-based compliance monitoring

- Initially (before prescribing) and then random based on red flags
- Use expanded panel test and indicate specific controlled substance(s) testing for
- Document last time took controlled substance(s)
- Discuss and document any abnormal findings and possibly repeat testing
- Low/medium risk 1-2 times per year
- High risk 2-4 times per year
- Random drug screens recommended

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The Controlled Substance Prescription

- Recommended to avoid concurrent benzodiazepine and opioid prescriptions
- Some states limit prescribing dosage by MME amount and/or days
- DEA requirements:
  - Date, provider's signature, patient's name/address, provider's name/address/DEA number, drug name, strength, dosage form, quantity, directions for use, refills if allowed
  - Schedule II – refills not allowed, can provide multiple prescriptions for up to 90 day supply with instructions for fill by date if allowed by state law
  - Schedule III-V – refills allowed up to five times in six months

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Possible red flags for non-compliance

- Patients seeking early refills
- Requesting higher dosage or other controlled substances by name
- Multiple reports of lost or stolen prescriptions
- Obtaining controlled medicines from multiple providers without the provider's knowledge
- Pressuring or threatening behaviors
- Presence of an illicit or not prescribed drug in the urine drug screen or absence of a prescribed drug in the urine drug screen
- Patient escalating dose on their own
- Deteriorating function of the patient
- Intoxication/impairment
- Using pharmacies other than what is specified in the agreement
- Reports from others to the clinic of the patient's misuse of the drug
- Resistant to other forms of treatment besides controlled substances

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How to handle patient non-compliance

- Recommend asking patient to come in to the office and to bring in their pill bottle. A pill count is done with two staff counting the pills in front of the patient. The PDMP is referenced for how many pills should be remaining.
- Obtain urine drug screen. If patient will not submit, then no further controlled substance is prescribed
- Address abnormal urine drug screens with the patient
- Address multiple providers or pharmacies identified on the PDMP
- Any possible signs of non-compliance, provider should discuss with the patient and document the discussion
- Provider then decides to continue prescribing (possibly adjust/taper dose), no further prescribing or terminate the patient relationship
- Refer the patient for pain management, counseling/psychiatric

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Medical marijuana

- 30 states have legalized medical marijuana, 9 states have approved recreational marijuana
- Marijuana is schedule I under DEA, meaning no recognized medical use and high potential for abuse by federal government
- DEA does not allow providers to prescribe or dispense medical marijuana, but providers can write letters of recommendation
  - McLaren does not allow its providers to recommend medical marijuana citing possible conflict with participation in federal programs that states must comply with all federal laws
- Recommendation is to avoid prescribing any controlled substance while patient is taking illicit drug, including medical marijuana
- No malpractice lawsuits related to medical malpractice, but enforcement by DEA & states for failing to follow requirements
  - If provider does write recommendations, should check with malpractice insurance carrier to see if activity is covered

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Best Practices Next Steps

- Putting Best Practices in to place
  - Support from medical professionals
- Audit for compliance
- Update annually

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Questions?

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