Prescribing and Dispensing Profile

California

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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

A Schedule II prescription for a patient in a skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice may be dispensed upon an oral or electronically transmitted prescription

- If oral, the pharmacist shall immediately reduce the prescription to writing

Prescription may be dispensed on the oral order of a practitioner if failure to issue a prescription could result in loss of life or intense suffering as long as:

- The order otherwise contains all information required
- The prescriber provides a written prescription within seven days

Practitioner may dispense a Schedule II substance directly to a patient in an amount not to exceed a 72 hour supply where the patient is not expected to require an additional amount beyond the 72 hours

Prescriptions shall not be filled more than six months after originally written

No refills allowed

Schedule III, IV and V Prescribing Limitations (not related to pain clinics)

Prescriptions for Schedule III – V substances may be dispensed upon written, oral, or electronic transmission

Prescriptions for controlled substances, except those in Schedule II, may be refilled without the authorization of the prescriber if the prescriber is unavailable to authorize the refill and if failure to refill the prescription would result in an immediate hazard to the patient's health and welfare or might result in intense suffering

- Only an amount sufficient to maintain the patient until the prescriber can be contacted
- Must notify the prescriber within a reasonable time

Prescription may be dispensed on the oral order of a practitioner if failure to issue a prescription could result in loss of life or intense suffering as long as:

- The order otherwise contains all information required
- The prescriber provides a written prescription within seven days

Prescriptions shall not be filled or refilled more than six months after originally written

No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply

Miscellaneous Prescribing/Dispensing Requirements

It is unprofessional conduct for a physician to prescribe, dispense, or furnish dangerous drugs without an appropriate prior examination and medical indication unless any of the following apply:

- The physician was designated to serve in the absence of the patient's physician and the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of his or her practitioner, but in any case no longer than 72 hours
- The physician transmitted the order for drugs to a registered nurse or a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:
  - The practitioner has consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records
  - The practitioner was designated as the practitioner to serve in the absence of the patient's physician
- The physician was a designated practitioner serving in the absence of the patient's physician and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription strength or amount or for more than one refill
- The physician was prescribing for expedited partner treatment of a sexually transmitted disease

Physicians may prescribe for, furnish to, or administer controlled substances to his or her patient when a patient is suffering from a condition other than addiction to a controlled substance, when the physician in good faith believes the condition requires the treatment, and only in a quantity and duration as are reasonably necessary

Prescriptions must meet the following requirements:

- Signed and dated by prescriber in ink
- Contain the prescriber's address and telephone number
- Contain the name and address of the ultimate user or research subject
- Refill information, such as the number of refills ordered and whether the prescription is a first time request or a refill
- The name, quantity, strength, and directions for use

Prescribing/Dispensing Limitations for Dentists

Dentists may prescribe for, furnish to, or administer controlled substances to his or her patient when a patient is suffering from a condition other than addiction to a controlled substance, when the physician in good faith believes the condition requires the treatment, and only in a quantity and duration as are reasonably necessary

Prescribing/Dispensing Limitations for Optometrists

Optometrists may prescribe for, furnish to, or administer controlled substances to his or her patient when a patient is suffering from a condition other than addiction to a controlled substance, when the physician in good faith believes the condition requires the treatment, and only in a quantity and duration as are reasonably necessary

Optometrists may prescribe select pharmaceutical agents for specified conditions as set out in Business & Professions Code § 3041

Pain Clinic/Pain Management Regulations

No physician or surgeon shall be subject to disciplinary action for prescribing, furnishing, dispensing, or administering of drugs for the treatment of intractable pain in compliance with law

Physicians may prescribe for, or dispense or administer to, a person under his or her treatment for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain

- Must exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist

Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances

All physicians shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients

- One-time requirement of 12 credit hours

Physicians and optometrists are encouraged to take a course in pharmacology and pharmaceuticals

Optometrists who are certified to use therapeutic pharmaceutical agents must obtain 35 hours of continuing education in the diagnosis, treatment, and management of ocular disease in a combination of prescribed areas, including pain management

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

This section deals only with the conditions that qualify a patient for the use of medical marijuana or a therapeutic research program and the attendant physician responsibilities. For complete information on state medical marijuana and therapeutic research programs, please visit the NAMSDL website at www.namsdl.org.

Serious medical conditions include:

- AIDS, anorexia, arthritis, cachexia, cancer, chronic pain, glaucoma, migraine, persistent muscle spasms, including, but not limited to, spasms associated with multiple sclerosis, seizures, including, but not limited to, seizures associated with epilepsy, severe nausea
- Any other chronic or persistent medical symptom that either substantially limits the ability of a person to conduct one or more major life activities or, if not alleviated, may cause serious harm to the patient's safety or physical or mental health

Patients must provide written documentation by the attending physician in the person's medical records stating that the person has been diagnosed with a serious medical condition and that the medical use of marijuana is appropriate

- Physicians must verify that medical records submitted by a patient to a county health department for purposes of obtaining an identification card are true and correct
- Patient must provide updated written documentation annually

Patients are limited to possession of no more than eight ounces of dried marijuana; however, may possess more if a physician recommends that this quantity does not meet the patient's needs

Physician shall not be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes

California Marijuana Research Program

- Encourages the University of California to conduct research into the safety and efficacy of marijuana and, if found valuable, develop medical guidelines for the appropriate administration and use of marijuana

PMP Requirements for Mandatory Registration and Access

A health care provider authorized to prescribe, order, administer, furnish, or dispense Schedule II – IV controlled substances shall, on or before July 1, 2016, or upon receipt of a federal DEA registration, whichever is later, submit an application to access information in the PMP

Patient Referral to Treatment

Nothing specified in statute or regulation.

Board Guidelines

Guidelines for Prescribing Controlled Substances for Pain, Medical Board of California (Nov. 2014)

The guidelines offer treatment considerations for differing populations or scenarios, including:

- Acute pain
  - Opioids should only be used when the severity of the pain warrants the choice and after determining that non-opioid pain medications or therapies wouldn't provide adequate pain relief
  - Number dispensed should be for a short duration and no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition
  - Neither long and intermediate duration opioids nor extended release/long-acting opioids should be used except in situations where monitoring and assessment for adverse effects can be conducted
- Cancer pain
  - Opioids are appropriate to consider for cancer patients with moderate to severe pain
  - Other cancer survivors with moderate-to-severe pain may additionally or alternatively benefit from the use of non-opioid treatments
- Worker's compensation patients
  - Some evidence suggests that early treatment with opioids may delay recovery and a return to work
  - In addition to applying the same methods of assessment, creation of treatment plans, and monitoring, physicians should also consider the psycho-social dynamics inherent in worker's compensation cases
- Patients with a history of substance use disorder
  - In patients who are actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by the risks and such therapy should not be prescribed outside of highly controlled settings
  - Potential risks in other patients may be minimized by more frequent and intense monitoring, authorization of limited prescription quantities, and consultation or co-management with an addiction specialist
  - Clinicians should use the CURES PMP to identify patients receiving drugs from multiple sources
  - If the patient's medical history, self-report, or scores on a screening assessment suggest an above-average risk of substance abuse, clinicians should consider:
    - Exhausting all non-opioid pain management methodologies prior to considering opioid therapy
    - Consulting with a specialist in addiction medicine
    - Creating a written treatment plan and patient agreement and obtaining their signed informed consent
    - Closely monitoring and assessing pain, function, and aberrant behaviors
    - If the patient is in long-term opioid therapy, drug testing, if possible
    - If misuse or abuse is suspected or confirmed, initiate a non-confrontational in-person meeting, present options for referral, opioid tapering or discontinuation or switching to non-opioid treatments
      - Avoid abandoning the patient or abruptly stopping opioid treatments

Board Guidelines, cont'd.

- Patients prescribed benzodiazepines
  - When prescribed in combination with opioids, these patients are at an increased risk of respiratory depression, particularly elderly patients
  - Should consider a trial of benzodiazepine tapering

Patient evaluation and risk stratification

- When considering the long-term use of opioids for chronic, non-cancer pain, physicians should conduct a comprehensive clinical assessment including, but not limited to:
  - Completing a medical history and physical exam
  - Performing a psychological evaluation including the risk of addictive disorders
  - Establishing a diagnosis and medical necessity
  - Exploring non-opioid therapeutic options
  - Evaluation of the benefits and risks
  - Being cognizant of aberrant or drug seeking behaviors
  - Undertaking drug testing
  - Reviewing the CURES PMP report for the patient

Treating physicians should seek consultations with, or refer patients to, a pain, psychiatry, or addiction or mental health specialist as needed

- Should be familiar with treatment options for opioid addiction

Treatment plan and objectives

- Goals of pain treatment include:
  - Reasonably attainable improvement in pain and function
  - Improvement in pain-associated symptoms
  - Avoidance of unnecessary or excessive use of medications

Counseling patients on overdose risk and response

- It is important to educate patients and family/caregivers about the danger signs of respiratory depression

Initiate an opioid trial

- Alternative treatments should be considered before initiating opioid therapy for chronic pain
- Opioid treatment should be presented as a therapeutic trial or test for a defined period of time and with specific evaluation points
- Board recommends that physicians proceed cautiously (yellow flag warning) once the morphine equivalent dose (MED) reaches 80 mg/day
  - Referral to an appropriate specialist should be considered when higher doses are contemplated
- Patients should be seen more frequently while the treatment plan is being initiated and opioid dose adjusted

Board Guidelines, cont'd.

Ongoing patient assessment

- Consider the 5-As method for chronic pain management assessment:
  - Analgesia – the patient is experiencing a reduction in pain
  - Activity – demonstrating an improvement in functionality
  - Adverse – not experiencing side effects
  - Aberrance – patient is complying with the pain management agreement and there are no signs of medication abuse or diversion
  - Affect – the patient's behavior and mood are appropriate

Compliance monitoring strategies include:

- CURES PMP report should be requested frequently for patients who are being treated for pain as well as addiction
- Drug testing
- Pill counting

Discontinuing opioid therapy

- Discontinuation may be required for many reasons, including:
  - Resolution or healing of the painful condition
  - Intolerable side effects
  - Failure to achieve anticipated pain relief or functional improvement
  - Evidence of non-medical or inappropriate use
  - Failure to comply with monitoring
  - Failure to comply with pain management agreement
  - Exhibition of drug seeking behaviors
- If therapy is discontinued, a physically dependent patient should be provided with a safely-structured tapering regimen
- If complete termination of care is necessary, physicians should treat the patient until he or she has had an opportunity to find an alternative source of care and ensure that the patient has adequate medications to avoid unnecessary risk from withdrawal symptoms
- If patient is dismissed for not honoring treatment agreements, consider referral to addiction resources, including a 12-step program

Physicians must maintain adequate and accurate medical records which includes, but is not limited to:

- Patient's medical history
- Results of the physical examination and all laboratory tests
- Patient consent
- Pain management agreement
- Results of risk assessment
- Description of treatments provided, including all medications prescribed or administered
- Results of ongoing monitoring of patient progress
- Notes on evaluations by and consultations with specialists

Board Guidelines, cont'd.

- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors
- Authorization for release of information to other treatment providers as appropriate or legally required
- Results of CURES PMP data searches

Guidelines include numerous appendices that include tools and suggestions for treatment of patients with pain management needs