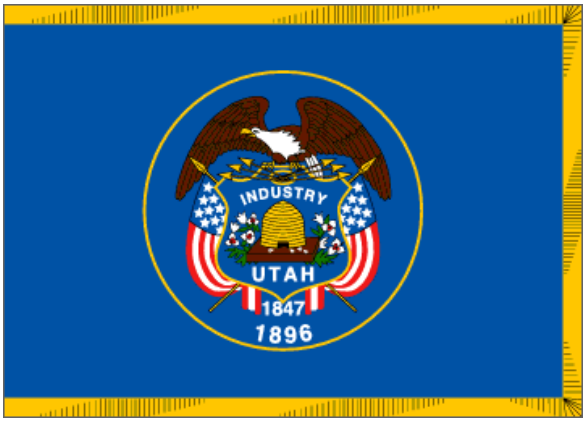
Prescribing and Dispensing Profile

Utah



Research current through November 2015.

This project was supported by Grant No. G1599ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Practitioner may issue an oral prescription for Schedule II substances if:

- The quantity dispensed is only sufficient to cover the patient for the emergency period, not to exceed 72 hours
- The prescribing practitioner has examined the patient within the past 30 days, the patient is under the continuing care of the prescriber for a chronic disease or ailment, or the prescriber is covering for another practitioner and has knowledge of the patient's condition
- A written prescription is delivered to the pharmacist within seven working days

Pharmacist may fill an emergency oral or telephonic prescription from a prescriber if:

- The amount does not exceed a 72 hour supply
- The filling pharmacist reasonably believes that the prescriber is licensed to prescribe the controlled substances or makes a reasonable effort to determine that he is licensed

Schedule II prescriptions must be filled within 30 days after originally issued or within 30 days after the dispensing date, if that date is specified separately from the date of issue

Practitioner may issue multiple prescriptions for Schedule II substances but only in the following circumstances:

- No more than three prescriptions for the same Schedule II substance may be issued at the same time
- No one prescription may exceed a 30-day supply
- A second or third prescription shall include the date of issuance and date for dispensing
- Unless the practitioner determines there is a valid reason to the contrary, the date for dispensing a second or third prescription may not be fewer than 30 days from the dispensing date of the previous prescription

Schedule II prescriptions may not be filled in a quantity to exceed a one month supply

Schedule II records must be maintained separately from all other records

Schedule II prescriptions may not be refilled

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

Prescriptions may be dispensed on the oral prescription of a practitioner

- Must be promptly reduced to writing

Pharmacist may refill Schedule III – V prescriptions on an emergency basis provided:

- Failure to refill the prescription might result in interruption of a therapeutic regimen or create patient suffering
- Either:
  - A natural or manmade disaster prevents the pharmacist from being able to contact the prescriber
  - The pharmacist is unable to contact the prescriber after reasonable effort, the effort should be documented, and said documentation should be available to the department

Schedule III, IV and V Prescribing Limitations (not related to pain clinics), cont'd.

- The quantity of the prescription does not exceed a 72-hour supply, unless the packaging is in greater quantity
- The pharmacist informs the patient that the refill is being provided without prescriber authorization and that such authorization is required for future refills
- The pharmacist maintains a record of the emergency refill
- The pharmacist notifies the prescriber of the refill at the earliest reasonable time

Schedule III and IV prescriptions may only be filled within six months of issuance and may not be refilled more than six months after originally issued or refilled more than five times unless renewed by the practitioner

- No refill may be dispensed until such time has passed since the date of the last dispensing that 80% of the medication in the previous dispensing should have been consumed if taken according to the prescriber's instructions

Schedule III – V records must be maintained separately from all other records

Schedule V prescriptions may not be refilled more than one year after originally issued unless renewed by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

In the interest of a patient's health, a pharmacist may, in an emergency, refill a prescription for a patient

- May only do so if the prescriber is not available promptly to authorize the refill and only if, in the professional judgment of the pharmacist, the prescription should be refilled
- Only sufficient medication as necessary in the emergency may be furnished not to exceed a three-day supply
- Practitioner should be contacted as soon as possible for further instructions

A person other than a pharmacist or the pharmacist's intern may not dispense a controlled substance

- Does not prevent a physician from dispensing drug samples
  - May not be Schedule II drugs, opioids, or benzodiazepines
  - Must be prepackaged by the original manufacturer
  - Must be provided to the physician free of charge and provided to the patient free of any direct or indirect charge
  - Must not exceed a 30-day supply for controlled substances

A medical practitioner may apply for a license as a dispensing medical practitioner if s/he is licensed in good standing and submits an application for licensure as a dispensing medical practitioner

- A dispensing medical practitioner may dispense:
  - A cosmetic drug and an injectable weight loss drug if:
    - The drug was prescribed by the dispensing medical practitioner to the practitioner's patient
    - The dispensing medical practitioner complies with administrative rules
  - A cancer drug treatment regimen

Miscellaneous Prescribing/Dispensing Requirements, cont'd.

- A pre-packaged drug to an employee or dependent of an employee at an employer sponsored clinic if the dispensing medical practitioner:
  - Treats an employee or dependent of an employee of one of an exclusive group of employers at an employer sponsored clinic
  - Prescribes a pre-packaged drug
  - Dispenses the pre-packaged drug at the employer sponsored clinic
  - Complies with administrative rules
- A dispensing medical practitioner:
  - Shall inform the patient:
    - That the drug dispensed may be obtained from a pharmacy unaffiliated with the practitioner
    - Directions for use
    - Potential side effects
    - How to contact the dispensing medical practitioner if the patient has questions or concerns regarding the drug

It is unprofessional conduct for a practitioner to issue an order or prescription for a drug or device without first obtaining information in the usual course of professional practice that is sufficient to establish a diagnosis, to identify conditions, and to identify contraindications to the proposed treatment

Prescriptions must contain the following information:

- Signature of prescriber
- Name, address, and registry number of prescriber
- Name, address, and age of the patient
- Date of issuance
- Name, quantity, and directions for use
- Number of refills

Prescribing/Dispensing Limitations for Dentists

The practice of dentistry includes the administration and prescription of drugs related to and appropriate in the practice of dentistry

Prescribing/Dispensing Limitations for Optometrists

An optometrist may prescribe or administer pharmaceutical agents for the eye and its adnexa, including oral agents, subject to the following condition:

- An optometrist may administer or prescribe a hydrocodone combination drug, or a Schedule III controlled substance if:
  - The substance is administered or prescribed for pain of the eye or adnexa
  - The substance is administered orally or topically or is prescribed for oral or topical use
  - The amount of the substance administered or prescribed does not exceed a 72-hour quantity
  - If the substance is prescribed, it does not include refills

An optometrist may not prescribe or administer a Schedule II substance except for a hydrocodone combination drug

Pain Clinic/Pain Management Regulations

No specific statutes or regulations identified.

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

Controlled substance prescribers shall complete at least 3.5 hours of continuing medical education hours in one or more controlled substance prescribing classes, except dentists who shall complete at least two such hours, that satisfy the following requirements:

- Must satisfy the division's requirements for the continuing education required for the renewal of the controlled substance prescriber's respective license type
- Must be delivered by an accredited or approved continuing education provider
- Must include postcourse knowledge assessment
- Must include content covering the following:
  - The scope of the controlled substance abuse problem in Utah and the US
  - All elements of the FDA Blueprint for Prescriber Education
  - The national and Utah-specific resources available to prescribers to assist in appropriate controlled substance and opioid prescribing
  - Office policies, procedures, and implementation

By rule, controlled substance prescribers must obtain four hours of continuing education

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

Each individual, other than a veterinarian, who has a license to prescribe a controlled substance shall register with the division to use the PMP database

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, Utah Department of Health (2009)

Recommendations

- Opioid recommendations for acute pain:
  - Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief
  - When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition
  - The patient should be counseled to store the medications securely, not share with others, and to dispose of properly when pain has resolved
  - Long duration acting opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted
    - Methadone is rarely, if ever, indicated for treatment of acute pain
  - The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition
    - Patients with acute pain who don't recover in the usual timeframe or otherwise deviate from expected clinical course for their diagnosis should be carefully evaluated
      - Continuation of opioid treatment may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such at the time
      - Diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history reviewed for co-morbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse and history of substance abuse
      - It is recommended that the provider check the PMP at this time

Board Guidelines, cont'd.

- Opioid recommendations for treatment of chronic pain:
  - Comprehensive initial evaluation/assessment of patient
    - Comprehensive evaluation should be performed before initiating opioid treatment
      - Long-term use of opioid medications to treat chronic pain safely requires the commitment of adequate resources to regularly monitor and evaluate outcomes and identify occurrence of adverse consequences
      - The goal of the evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patient's function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes
      - Evaluation should specifically address the following issues:
        - Assess pain and prior treatment of pain
          - Determine the cause of the pain and whether it is acute or chronic
          - Assess previous approaches and trials for appropriateness, adequacy and outcome
        - Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy
          - Obtain history of substance use, addiction, or dependence
          - Identify psychiatric conditions that may affect pain or treatment of pain
          - Identify use of medications that might interact with medications used to treat pain; particular attention should be given to benzodiazepines and other sedative medications
          - Assess social history, including employment, social network, marital history, and any history of legal problems, especially illegal use or diversion of controlled substances
          - Assess for presence of medical conditions that complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea
          - Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher doses; some clinicians recommend that all patients who are considered for long term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered
        - Assess the effects of pain on the person's life and function
  - Consider alternative treatment options
    - Alternatives to opioid treatment should be tried or an adequate trial of such treatments by a previous provider documented before initiating opioid treatment
      - Opioid medications are not the appropriate first line of treatment for most patients
      - Non-opioid analgesics, NSAIDs, antidepressants, antiepileptic drugs, and non-pharmacologic therapies should be tried and the outcomes documented first
    - Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions

Board Guidelines, cont'd.

- Screening for risk of addiction or abuse
  - Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long term for chronic pain
  - Consider using drug screening before initiating long term opioid treatment
  - Prescriber should check the PMP prior to prescribing opioids for chronic pain
- Establish treatment goals
  - A written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function
    - Treatment plan should be tailored to the patient's individual circumstances and the characteristics and pathophysiology of the pain
      - Pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function
      - Non-opioid treatment modalities should be included in the treatment plan whenever possible
  - Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain
    - Complete elimination of pain is an unreasonable goal for most pain conditions
    - Goals should include improvement in tolerability of the pain and in function
    - Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcome and include:
      - Objective physical findings obtained by the examining clinician
        - Improved strength, range of motion, aerobic capacity
      - Functional status at work
        - Increase in physical output, endurance, or ability to perform job functions
      - Functional status at home
        - Increased ability to perform instrumental activities of daily living and frequency and intensity of conditioning
    - Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes and can include:
      - Patient rating of quality of life
      - Psychosocial status
        - Increased social engagement or decreased emotional distress
      - Familial status
        - Improved relationships with or decreased burden on family members
      - Physical status
        - Increased ability to exercise, perform chores, or participate in hobbies
  - Treatment goals should be developed jointly by patient and clinician
    - Engage patients in their own healthcare

Board Guidelines, cont'd.

- Informed consent and formulation of treatment plan
  - Patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement
    - Patients should be informed not to expect complete relief from pain
    - Ensure patient doesn't have any absolute contraindications for opioid prescribing, which include:
      - Allergy to an opioid agent (may be addressed by using a different agent)
      - Co-administration of drug capable of inducing life-limiting drug-drug interaction
      - Active diversion of controlled substances
    - Educate patients and family members about the danger signs of respiratory depression
  - The patient and, when applicable, the family or caregiver, should both be involved in the educational process
    - Educational materials should be provided in written form and discussed in person with the patient
  - Treatment plan, which defines the responsibilities of both patient and clinician, should be documented
    - Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan
      - Could also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber
  - Treatment plan should contain goals of treatment, guidelines for prescriptions refills, agreement to submit to drug testing upon request, and reasons for possible discontinuation of drug therapy
    - Plan should contain the items that were developed jointly by patient and clinician, including follow up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading medication or getting refills early
      - Specific reasons for termination of the agreement and cessation of prescribing may also be set out
    - Optional inclusions in agreement include:
      - Pill counts
      - Prohibition on the use of alcohol or certain other medications
      - Documentation of counseling regarding driving or operating heavy machinery
      - Specific frequencies of drug testing
  - Discuss the involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care
- Initiate opioid therapy as a treatment trial
  - Opioid medication should be initiated as a short term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life
    - Clinician should make clear that treatment with opioids will be stopped if the trial is determined to be unsuccessful
    - Decision to continue beyond the trial period should be based on the balance between the benefits, including function and quality of life, and adverse effects experienced
  - In most cases, the trial should begin with short-acting opioid medication
  - Parenteral administration of opioids is generally discouraged

Board Guidelines, cont'd.

- Titration phase
  - Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted
    - Follow up face-to-face visits should occur at least every 2-4 weeks during the titration phase
      - Frequency of visits should be based on risk stratification and the clinician's judgment
  - When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose should be considered
    - The rate at which dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by going to slowly with the risk of causing harm, including fatal overdose, by going too fast
    - Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration
    - Clinicians who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages
  - During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the PMP at least quarterly
- Maintenance – periodic monitoring and dose adjustments
  - Once a stable dose has been established, regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored
  - Providers should consider performing drug screening on randomly selected visits and any time aberrant behavior is suspected
  - During maintenance phase, the PMP should be checked annually
  - Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals
    - These include reduction in patient's pain scores and improved physical, psychological and social function
    - If treatment goals are not being met despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications
  - Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant
    - Options for adjustment include reducing medication or rotating opioid medication
  - Dosing changes should generally be made during a clinic visit
- Evaluate the treatment trial
  - Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient
  - A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial

Board Guidelines, cont'd.

- Discontinuing opioid treatment
  - An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated
  - Discontinuation of opioid treatment is recommended if any of the following occurs:
    - Dangerous or illegal behaviors are identified
    - Patients claims or exhibits a lack of effectiveness
    - Pain problem resolves
    - Patient expresses a desire to discontinue therapy
    - Opioid therapy appears to be causing harm to the patient, especially if harm exceeds benefit
  - When possible, offer to assist patients in safely discontinuing medications even if they have withdrawn from treatment or been discharged for agreement violations
- Documentation and medical records
  - Clinicians should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior
  - Written treatment plan should document objectives that will be used to evaluate treatment success
    - Objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned
  - Assessment of treatment effectiveness should be documented in the medical record
  - Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record
- Consultation and management of complex patients
  - Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment
    - Prescribers should consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:
      - Patient has a complex pain condition and the clinician wishes to verify the diagnosis
      - Patient has significant co-morbidities
      - Patient is high-risk for aberrant behavior or addiction
      - Clinician suspects development of significant tolerance, particularly at high doses
  - Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment
  - Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or substance use disorder specialist, if available, for recommendations on the treatment plan and possibly assistance in management
  - Patients with coexisting psychiatric disorders should receive ongoing mental health support and treatment while receiving opioid medication for pain control

Board Guidelines, cont'd.

- Methadone
  - Methadone should only be prescribed by clinicians familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring