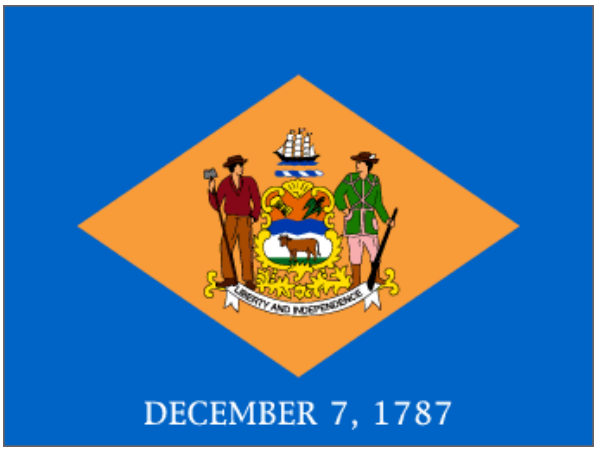
Prescribing and Dispensing Profile

Delaware



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II prescriptions may only be dispensed on the written prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in an emergency so long as they are in compliance with federal law
  - Must be promptly reduced to writing

Schedule II prescriptions for terminally ill patients or patients in a long term care facility shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuation of the medication

Schedule II prescriptions become void if not dispensed within seven days of the original date of the prescription unless the original prescriber authorizes the dispensing past the seven day period

- Such prescriptions may be dispensed up to 100 dosage units or a 31 day supply, whichever is greater
  - Except that prescriptions for Schedule II substances for patients either having a medically documented terminal illness or patients in long term care facilities may be filled in partial quantities, to include dosage units

No refills of Schedule II prescriptions allowed

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

Schedule III and IV prescriptions may only be dispensed on the written or oral prescription of a practitioner

Schedule V substances shall not be distributed or dispensed other than for a medical purpose

- No Schedule V cough preparation containing codeine, dilaudid, or any other narcotic cough preparation may be dispensed without the written or oral prescription of a practitioner

Schedule III prescriptions become void if not dispensed within seven days of the original date of the prescription unless the original prescriber authorizes the dispensing past the seven day period

- Such prescriptions may be dispensed up to 100 dosage units or a 31 day supply, whichever is greater

Schedule III and IV prescriptions may not be filled or refilled more than six months after originally written or refilled more than five times, unless renewed by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

In order to be lawful, a prescription must be issued pursuant to a patient-practitioner relationship

- A patient-practitioner relationship means, with respect to prescribing drugs for a patient, that the practitioner is a licensed practitioner who:
  - Has conducted at least one in-person medical evaluation of the patient and performed a medical history and physical examination sufficient to establish a diagnosis and to identify the underlying conditions of, or contraindications to, the treatment recommended or provided
  - Personally knows the patient and the patient's general health status through an existing patient-practitioner relationship
  - Provides treatment in consultation with or upon referral of another practitioner who has an existing patient-practitioner relationship with the patient and who has agreed to supervise the patient's treatment, including follow-up care and use of the prescribed medications
  - Provides treatment to the patient through on-call or cross-coverage situation for another practitioner who has an existing patient-practitioner relationship with the patient
  - Provides continuing medications on a short-term basis for a new patient prior to the first appointment
  - Provides treatment based upon admission orders for a newly hospitalized patient

No prescriber who is not the owner of a pharmacy or who is not in the employ of such owner may dispense more than a 72 hour supply of Schedules II – V controlled substances except a practitioner who confines his/her activities to dispensing complimentary packages of controlled substances to the practitioner's own patients in the regular course of his or her practice without payment of a fee or remuneration of any kind, whether direct or indirect

Prescriptions must contain the following information:

- Date issued
- Full name and address of patient
- Name, address, telephone number, and registration number of prescriber
- Name and strength of drug prescribed
- Quantity
- Directions for use

Prescribing/Dispensing Limitations for Dentists

No separate statutes or regulations related to prescribing and dispensing limitations for dentists.

Prescribing/Dispensing Limitations for Optometrists

No separate statutes or regulations related to prescribing and dispensing limitations for optometrists.

Pain Clinic/Pain Management Regulations

Board has adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" but these regulations shall control if there are any inconsistencies between the model and the regulations

The Board will consider inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved

- Allegations of inappropriate treatment of pain will be evaluated on an individual basis
  - Board will take disciplinary action against a practitioner for deviating from these regulations unless contemporaneous medical records document reasonable cause for deviation
  - Practitioner's conduct will be evaluated by the outcome of pain treatment, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life
- Inappropriate pain treatment may result from:
  - Practitioner's lack of knowledge about pain management
  - Fears of investigation or sanction by federal, state, and local agencies

The following criteria must be used when evaluating the treatment of chronic pain but may also be applicable to treatment of acute pain:

- A medical history and physical examination of patient must be obtained and documented in the medical record
  - Evaluation must document:
    - Etiology, the nature and intensity of the pain, current and past treatments
    - Underlying or coexisting diseases or conditions
    - Effect of the pain on physical and psychological function, and history of substance abuse
    - The presence of one or more medical indications for the use of controlled substances
- A written treatment plan is required and must state the goals and objectives that will be used to determine treatment success and if further diagnostic evaluations and other treatments are planned
  - Treatment success can be judged by pain relief, improved physical and psychosocial function
  - Treatment plan must address whether treatment modalities or a rehabilitation program are necessary
  - Practitioner must adjust drug therapy after beginning treatment to meet the individual needs of the patient
- Practitioner must discuss the risks and benefits of the use of controlled substances with the patient
- If the patient is a high risk for abuse or has a history of substance abuse, the practitioner must use a written agreement outlining the patient responsibilities, including:
  - Drug testing when required
  - Number and frequency of refills
  - Reasons for which drug therapy may be discontinued
  - Requirement that patient receive prescriptions from one licensed practitioner and one pharmacy where possible

Pain Clinic/Pain Management Regulations, cont'd.

- Practitioner shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Review should include, at a minimum, the following:
  - Continuation or modification of controlled substances for pain management
  - Satisfactory response to treatment as indicated by patient's decreased pain, increased level of function, or improved quality of life
    - Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered
  - If patient's response is unsatisfactory, the practitioner shall assess the appropriateness of the continued use of the current treatment plan
- Practitioner shall refer the patient as necessary for additional evaluation and treatment
- Practitioner shall keep accurate and complete medical records which include:
  - Medical history and physical examination
  - Diagnostic, therapeutic, and laboratory results
  - Evaluations and consultations
  - Documentation of etiology
  - Treatment objectives
  - Discussion of risks and benefits
  - Informed consent
  - Treatments
  - Medications, including date, type, dosage, and quantity prescribed
  - Instructions and agreements
  - Periodic review
- Records should remain current and be maintained readily available for review. Should include documentation appropriate for each visit's level of care, including:
  - Interim history and physical exam
  - Vital signs as clinically appropriate
  - Assessment of progress
  - Medication plan

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

Nothing specified in statute or regulation.

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.

Debilitating medical condition means:

- Cancer, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, decompensated cirrhosis, amyotrophic lateral sclerosis, agitation of Alzheimer's disease, post-traumatic stress disorder, or the treatment of these conditions
- A chronic or debilitating disease or medical condition or its treatment that produces 1 or more of the following: cachexia or wasting syndrome; severe, debilitating pain, that has not responded to previously prescribed medication or surgical measures for more than 3 months or for which other treatment options produced serious side effects; intractable nausea; seizures; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis

If the patient's qualifying debilitating medical condition is post-traumatic stress disorder, the physician must also be a licensed psychiatrist

Physician must issue written certification that it is the physician's professional opinion that the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana

- Can only be made in the course of a bona fide physician-patient relationship
  - Bona fide relationship cannot be limited to authorization for the patient use of medical marijuana or consultation for that purpose
- Physician must complete an assessment of the patient including his/her medical history and current medical condition
- Must specify the qualifying patient's debilitating medical condition
- Certifications must be issued within 90 days immediately preceding the date of a patient's application for registry identification card

Physician shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by any professional licensing board solely for providing written certifications or for otherwise stating that, in the physician's professional opinion, a patient is likely to receive therapeutic benefit from the medical use of marijuana or for refusing to provide such certifications or statements

- Physician is still obligated to exercise a professional standard of care for evaluating or treating a patient's medical condition

PMP Requirements for Mandatory Registration and Access

All prescribers and dispensers holding a registration to prescribe, distribute, dispense, or deliver controlled substances shall be registered with the PMP

If a dispenser has a reasonable belief that a patient may be seeking a controlled substance for any reason other than treatment of a medical condition, the dispenser must obtain a PMP report

Before prescribing a Schedule II – V controlled substance for a patient, a prescriber or his/her designee shall obtain a PMP report for the patient when the prescriber has a reasonable belief that the patient may be seeking the substance, in whole or in part, for any reason other than treatment of a medical condition

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

The Medical Examining Board has adopted the Federation of State Medical Boards' "Model Policy for the Use of Controlled Substances for the Treatment of Pain."