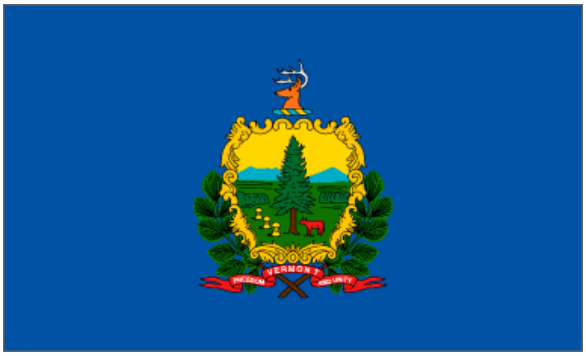
Prescribing and Dispensing Profile

Vermont



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

No Schedule II prescription written without a future fill date may be filled more than 30 days after originally written

A practitioner may issue multiple prescriptions for a Schedule II substance authorizing up to a 90 day supply

- Each prescription must contain the original date of issue and the future fill date
- No Schedule II prescription written to be filled at a future date may be filled more than 90 days after originally written

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

- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - For a narcotic substance to be compounded for the direct administration to a patient by certain methods
  - For a resident of a long term care facility or patient in hospice care
- May be dispensed on the oral prescription of a practitioner in an emergency, provided:
  - The quantity prescribed and dispensed is limited to an amount adequate to treat the patient during the emergency period
  - It must be immediately reduced to writing
  - If the prescribing practitioner is not known to the pharmacist, s/he must make a reasonable effort to determine that the oral authorization came from a legal practitioner, which may include a call back to the practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure the practitioner's identity
  - The prescribing practitioner must cause a written prescription to be delivered to the pharmacy within seven days

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

Schedule V drugs may only be dispensed on the written, oral, or electronic prescription of a practitioner

- Oral prescriptions must be promptly reduced to writing

Prescriptions shall not be refilled unless refilling is authorized by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

A physician, in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense regulated drugs

A prescription or drug order for a legend drug is not valid unless issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to treatment

Miscellaneous Prescribing/Dispensing Requirements, cont'd.

It is unprofessional conduct for a physician to provide, prescribe, dispense or furnish prescription medication to a person in response to a communication transmitted or received by computer or other electronic means, when the licensee fails to take the following actions to establish and maintain a proper physician-patient relationship:

- A reasonable effort to verify that the person requesting medication is in fact the patient, and is in fact who the person claims to be
- Establishment of documented diagnosis through the use of accepted medical practices
- Maintenance of a current medical record
- An electronic, online, or telephonic evaluation by questionnaire is inadequate for the initial evaluation of a patient
- The following are not violations if transmitted or received by computer or other electronic means:
  - Initial orders for newly hospitalized patients
  - Prescribing for a patient of another physician for whom the prescriber has taken the call
  - Prescribing for a patient examined by a licensed advanced practice registered nurse, physician assistant, or other advanced practitioner authorized by law and supported by the physician
  - Continuing medication on a short-term basis for a new patient prior to the patient's first appointment
  - Emergency situations where the life or health of a patient is in imminent danger

Prescriptions shall contain the following information:

- Signature of prescriber and date of issuance
- Full name, address, and date of birth of patient
- Full name, address, facility or practice name where applicable, telephone number, and DEA registration number of prescriber
- Name, strength, dosage form, quantity or stop date, and route of administration of drug prescribed
- Directions for use
- Number of refills

Prescribing/Dispensing Limitations for Dentists

A dentist, in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense regulated drugs

Prescribing/Dispensing Limitations for Optometrists

The board shall certify eligible licensees to use and prescribe therapeutic drugs and may use and prescribe appropriate pharmaceutical agents for diagnosis, management, and treatment of the eye and adnexa

Pain Clinic/Pain Management Regulations

Chronic pain means pain caused by various diseases or abnormal conditions and that continues longer than 90 days.

- Chronic pain does not include pain from cancer or pain experienced during hospice or end-of-life care

Prescriber shall conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record when prescribing opioids for chronic pain

- Prescriber shall document in the patient's medical record any diagnoses which support the use of opioids for the relief of chronic pain
- Prescriber shall evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the patient prior to writing a prescription for opioids
    - Evaluation shall include, but not be limited to, a risk assessment
        - Risk assessment means a process for predicting a patient's likelihood of misusing or abusing opioids in order to develop and document a level of monitoring for that patient

Prior to prescribing opioids for chronic pain, the prescriber shall consider and document in the patient's medical record:

- Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments, have been considered
- Trial use of the opioid
- Any applicable requirements to query the PMP
- That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone from an opioid treatment program or prescribed and taken any other controlled substance
    - Prescriber shall explain that this information is important for the patient's safety and that the patient is required by law to disclose this information

For patients prescribed opioids for chronic pain for 90 days or more, the prescriber shall:

- Receive, and include in the patient's medical record, a signed Informed Consent from the patient that shall include information regarding:
    - The drug's potential for misuse, abuse, diversion, and addiction
    - The risks associated with the drug for life-threatening respiratory depression
    - Potentially fatal overdose as a result of accidental exposure, especially in children
    - Neonatal opioid withdrawal syndrome
    - Potentially fatal overdose when combining with alcohol and/or other psychoactive medication including but not limited to benzodiazepines and barbiturates
- Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient which includes:
    - Functional goals for treatment, dispensing pharmacy choice, and safe storage and disposal of medication
    - Other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance

Pain Clinic/Pain Management Regulations, cont'd.

- Schedule and undertake periodic follow-up visits and evaluations at a frequency determined by the patient's risk factors, the medication dose and other clinical indictors
  - Patients who are stable in terms of the medication dose and its effectiveness in managing chronic pain must be reevaluated no less than once every year
- Write the maximum daily dose or a "not to exceed" equivalent on the prescription for the dispensing pharmacy

The prescriber shall consider referring a patient for a consultation with an appropriate specialist, such as a pain specialist or substance abuse specialist, when:

- The patient is not meeting the goals of treatment despite escalating doses of controlled substances for pain
- The patient is at high risk for substance misuse, abuse, diversion, addiction, or overdose as determined by the patient's history or a screening
- The prescriber has reasonable grounds to believe, or confirms, a patient is misusing opioids or other substances
- The patient is seeing multiple prescribers and/or utilizing multiple pharmacies
- The patient has been prescribed multiple controlled substances

Controlled substance treatment agreements for patients receiving treatment for chronic pain shall be reviewed by the prescriber and patient no less than annually to reevaluate the patient

- Reviews shall be documented in the patient's record
- Based on the reevaluation, prescriber shall determine and document:
  - Whether to continue the treatment of pain with opioids or if there are available alternatives
  - The possible need for a pain management, substance abuse or pharmacological consultation to achieve effective pain management, avoidance of dependence or addiction or taper from the prescribed analgesics
  - Acknowledgement that a violation of the agreement will result in a reassessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription
    - This may occur after consultation with an addictions specialist

Prior to prescribing a dose of opioids, or a combination of opioids, that exceeds 120 MED/day, the prescriber shall document in the patient's medical record:

- A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen
- The potential for the use of non-opioid and non-pharmacological alternatives for treating pain
- A functional status examination of the patient
- A review of the patient's treatment agreement and informed consent, making any necessary revisions, including pill counts and directly observed urine testing to monitor adherence and possible use of other substances
- Any assessment of any co-morbid conditions affected by treatment with opioids
  - This may best be conducted by a mental health or addictions professional
- Any other related actions by the patient that may reasonably lead a prescriber to modify the pain management regimen, including but not limited to:
  - Aberrant behaviors, early refills of controlled substances, or other known risks associated with misuse, abuse, diversion, addiction, or overdose

Pain Clinic/Pain Management Regulations, cont'd.

Prior to prescribing an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid, the prescriber shall:

- Conduct and document a thorough medical evaluation and physical examination as part of the patient's medical record
- Document in the patient's medical record any diagnoses which support the use of an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid for pain relief
- Evaluate and document benefits and relative risks, including the risk for misuse, abuse, diversion, addiction, or overdose, for the individual patient which shall include a risk assessment
- Document in the patient's medical record that the prescription of an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid is required for the management of pain severe enough to require daily, around-the-clock, long-term, opioid treatment for which alternative treatment options, including non-pharmacological treatments, are ineffective, not tolerated, or are otherwise inadequate to provide sufficient management of pain
- Receive, and include in the patient's medical record a signed Informed Consent from the patient, that shall include information regarding:
  - The drug's potential for misuse, abuse, diversion, and addiction
  - The risks associated with the drug for life-threatening respiratory depression
  - Potentially fatal overdose as a result of accidental exposure, especially in children
  - Neonatal opioid withdrawal syndrome
  - Potentially fatal overdose when combining with alcohol
- Receive, and include in the patient's medical record, a signed Controlled Substance Treatment Agreement from the patient which includes:
  - Functional goals for treatment, dispensing pharmacy choice, safe storage and disposal of medication
  - Urine testing (no less frequently than annually with the actual frequency to be determined by the clinician on the basis of the patient's risk assessment and ongoing behavior)
  - Other requirements as determined by the prescriber, such as directly observed urine drug testing and pill counts to reasonably and timely inform the prescriber if the patient is misusing the prescribed substance
- Query the PMP and document it in the patient's record
  - A review of other controlled substances prescribed to the patient prior to the first prescription of an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid
  - A query no less frequently than once every 120 days for any patient prescribed 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone per day of an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid as long as the patient possesses a valid prescription for that amount
- A determination of a maximum daily dose, or a "not to exceed value" for the prescription to be transmitted
- The writing of a prescription that must be filled within seven (7) days of the date issued and does not exceed a 30-day supply

Pain Clinic/Pain Management Regulations, cont'd.

- Prescribers subject to this section shall schedule and undertake periodic follow-up visits and evaluations (no less frequently than every 180 days), during which the following must be documented in the patient's medical record:
  - Whether to continue the treatment of pain with an extended release hydrocodone or oxycodone that is not an abuse-deterrent opioid or if there are available alternatives
  - The possible need for a pain management or substance abuse consultation
  - A provider explanation and a patient acknowledgement that a violation of the agreement will result in a re-assessment of the patient's treatment plan and alteration or institution of controls over medication prescribing and dispensing, which may include tapering or discontinuing the prescription
    - This may occur after consultation with an addictions specialist

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

All licensees shall obtain at least one hour of CME in the topics of hospice, palliative care, or pain management

All licensees who prescribe controlled substances shall obtain at least one hour of CME related to the topic of safe and effective prescribing

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.

Therapeutic use of cannabis

- Program to be administered by the commissioner of health and shall be used only for treating cancer patients and for such other medical uses as are prescribed by the commissioner
- Distribution to a patient shall only take place pursuant to the instructions of a physician

Bona fide health care professional-patient relationship means a treating or consulting relationship of not less than six months' duration, in the course of which a health care professional has completed a full assessment of the registered patient's medical history and current medical condition, including a personal physical exam

- The six month requirement does not apply for patients diagnosed with a terminal illness, cancer with distant metastases, or AIDS

To become a registered patient, a person must be diagnosed with a debilitating medical condition by a health care professional in the course of a bona fide health care professional-patient relationship

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions, cont'd.

Debilitating medical condition, provided that, in the context of a specific disease or condition, reasonable medical efforts have been made over a reasonable amount of time without success to relieve the symptoms, means:

- Cancer, multiple sclerosis, positive status for HIV, AIDS, or the treatment of these conditions, if the disease or the treatment results in severe, persistent, and intractable symptoms
- A disease, medical condition, or its treatment that is chronic, debilitating, and produces severe, persistent, and one or more of the following intractable symptoms: cachexia or wasting syndrome; severe pain; severe nausea; or seizures

Department shall develop a medical verification form to be completed by a health care professional that includes the following:

- A statement that a bona fide health care professional-patient relationship exists or that the debilitating medical condition is of recent or sudden onset, and the patient has not had a previous health care professional who is able to verify the nature of the disease and its symptoms
- A statement that reasonable medical efforts have been made over a reasonable amount of time without success to relieve the symptoms
- A statement that the patient has a debilitating medical condition, including the specific disease or condition which the patient has and whether the patient meets the criteria
- A signature line that certifies the statements are true and correct and the provider is a health care professional as defined by law
- The health care professional's contact information, license number, category of his or her health care profession, and contact information for out-of-state licensing agency, if any

Department shall send verification form to health care professional and confirm the accuracy of the information

- Department may approve patient notwithstanding the six month requirement if the Department is satisfied that the medical verification confirms that the debilitating medical condition is of recent or sudden onset, and that the patient has not had a previous health care professional who is able to verify the nature of the disease and its symptoms

PMP Requirements for Mandatory Registration and Access

Every health care provider who prescribes any Schedule II – IV controlled substance must register with the PMP; this includes:

- All Vermont prescribers of controlled substances and their delegates
- Medical director of the Department of Vermont Health Access
- Health care providers licensed to practice in another state with an active reciprocal agreement for PMP data sharing
- Health care providers licensed to practice in another state who treat Vermont patients
- Vermont's chief medical examiner, and delegate, and medical examiners licensed to practice in another state investigating the death of a Vermont resident

PMP Requirements for Mandatory Registration and Access, cont'd.

Medication assisted treatment prescribers/programs shall register with the PMP

- Reasonable measures to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner shall be taken, including use of the PMP

Health care providers or their delegates shall query the PMP as follows:

- At least annually for patients receiving ongoing treatment with Schedule II – IV controlled substances
- When starting a patient on a Schedule II – IV substance for nonpalliative long-term pain therapy of 90 days or more
- The first time the provider prescribes an opioid Schedule II – IV substance to treat chronic pain
- Prior to writing a replacement prescription for a Schedule II – IV substance
- When prescribing Schedule II – IV substances to treat acute pain for a duration longer than 21 days
- In addition, in an emergency department or urgent care setting:
  - When a patient requests an opioid prescription for chronic pain from an emergency department or urgent care prescriber if the prescriber intends to write a prescription for an opioid
  - When a patient requests an extension of a current opioid prescription for acute pain from an emergency department or urgent care prescriber if the prescriber intends to write a prescription for an opioid
  - Before prescribing an opioid for longer than 10 days
- Prior to prescribing buprenorphine or a drug containing buprenorphine to a Vermont patient for the first time and at regular intervals thereafter
  - No fewer than two times annually thereafter
  - Prior to writing a replacement prescription

All Medicaid participating providers who prescribe buprenorphine or a drug containing buprenorphine to a Vermont Medicaid beneficiary must query the PMP the first time they prescribe such drug and at regular intervals thereafter

- No fewer than two times annually
- Prior to prescribing a replacement prescription

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

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Board Guidelines

Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, Board of Medical Practice (April 2, 2014)

Responsibility for appropriate pain management

- All physicians and other healthcare providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain
- The board considers the use of opioids for pain management to be for a legitimate purpose when based on sound clinical judgment and current best clinical practices, appropriately documented, and of demonstrable benefit to the patient
    - To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the medication, and should demonstrate that the therapy has been adjusted as needed

Preventing opioid diversion and abuse

- The board recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health
- Allegations of inappropriate pain management will be evaluated on an individual basis
- Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk

Guidelines

- Patient evaluation and risk stratification
    - Medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation
        - Evaluation should be completed prior to making the decision to prescribe opioids
        - Nature and extent of evaluation depends on the type of pain and the context in which it occurs
            - Assessment would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning
    - Initial work up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated
    - Social and vocational assessments are useful in identifying supports and obstacles to treatment and rehabilitation
    - Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should also be part of the initial evaluation

Board Guidelines, cont'd.

- Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should also be part of the initial evaluation
- All patients should be screened for depression and other mental health disorders as part of risk evaluation
    - Patients with untreated depression and other mental health problems are at increased risk of misuse or abuse, including addiction and overdose
    - Patients considered to be at high risk should either not be prescribed opioids or should receive consultation from an addiction specialist
    - Patients who have an active substance use disorder should not receive opioid therapy until they are in an established treatment/recovery program or alternatives are established such as co-management with an addiction professional
- Development of treatment plan and goals
    - Goals of treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications
    - Treatment plan and goals should be established as early as possible in the treatment process and revised regularly
    - Treatment plan should contain information supporting the selection of therapies, both pharmacologic and non-pharmacologic
    - Treatment plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered
- Informed consent and treatment agreement
    - Physician should discuss the risks and benefits of the treatment plan with the patient
        - If opioids are prescribed, patient should be counseled on safe ways to store and dispose of medications
    - Use of a written informed consent and treatment agreement is highly recommended
        - Informed consent documents typically address:
            - The potential risks and anticipated benefits of chronic opioid therapy
            - Potential side effects of the medication
            - The likelihood that tolerance to and physical dependence on the medication will develop
            - The risk of drug interactions and over-sedation
            - The risk of impaired motor skills
            - The risk of opioid misuse, dependence, addiction, and overdose
            - The limited evidence as to the benefit of long-term opioid therapy
            - The physician's prescribing policies and expectations, including the number and frequency of refills, as well as the physician's policy on early refills and replacement of lost or stolen medications
            - Specific reasons for which drug therapy may be changed or discontinued
        - Treatment agreements outline the joint responsibilities of physician and patient and are indicated for opioid and other medications that might be abused and typically discuss:
            - The goals of treatment, in terms of pain management, restoration of function, and safety
            - The patient's responsibility for safe medication use
            - The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice
            - The patient's agreement to periodic drug testing
            - The physician's responsibility to be available or have a covering physician available to care for unforeseen problems and to prescribe scheduled refills

Board Guidelines, cont'd.

- Initiating an opioid trial
  - Safer alternative treatments should be considered before initiating opioid therapy
  - Opioid therapy should be presented as a trial or test for a defined period of time, usually no more than 90 days, and with specified evaluation points
  - Physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety
  - When initiating therapy, the lowest possible dose should be given to an opioid naïve patient and titrated to effect
    - Should begin with a short acting opioid and consider rotating to a long-acting/extended release opioid only if indicated
  - A decision to continue treatment beyond the trial period should reflect a careful evaluation of benefits vs. adverse events and/or potential risks
- Monitoring and adapting the treatment plan
  - Physician should regularly review the patient's progress toward treatment goals, including any new information about the etiology of the pain and the patient's overall health and level of function
  - Physicians must use the PMP
  - Patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted
    - As patient is stabilized, follow up visits may be scheduled less frequently
  - At each visit, the results of therapy should be monitored by assessing the 5 A's of chronic pain management
    - Analgesia – whether there has been a reduction in pain
    - Activity – whether the patient has demonstrated an improvement in level of function
    - Adverse – whether there are significant adverse effects
    - Aberrant – whether there is evidence of aberrant substance-related behaviors
    - Affect – the mood of the patient
  - Continuation, modification, or termination of opioid therapy should be contingent on the physician's evaluation of:
    - Evidence of the patient's progress toward treatment objectives
    - The absence of substantial risks or adverse events, such as overdose or diversion
  - Satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life
- Periodic drug testing and response to evidence of aberrant behavior
  - Periodic drug testing may be useful in monitoring adherence to the treatment plan
    - Testing should not be limited to instances when the provider believes there is a problem
  - Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion
  - If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added or substituted for the opioid therapy, or whether a different approach should be employed
  - Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response

Board Guidelines, cont'd.

- Consultation and referral
  - Physician should seek consultation with, or refer the patient to, a pain, psychiatry, addiction, or mental health specialist as needed
- Discontinuing opioid therapy
  - Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use
  - If therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering and withdrawal regimen
  - Providers should not continue treatment unless the patient has received a benefit, including demonstrated functional improvement
- Medical records
  - Every physician who treats patients for chronic pain must maintain accurate, complete, and legible medical records that should include:
    - Copies of the signed informed consent and treatment agreement
    - Patient's medical history
    - Results of the physical exam and all laboratory tests
    - Results of the risk assessment, including results of any screening instruments used
    - A description of the treatments provided, including all medications prescribed or administered
    - Instructions to the patient, including discussions of the risks and benefits
    - Results of ongoing monitoring of patient progress or lack of progress in terms of pain management and functional improvement
    - Notes on evaluations by and consultations with specialists or other providers, and notation by the receiving provider of response to the information and recommendations
    - 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
    - All prescription orders of opioids and other controlled substances