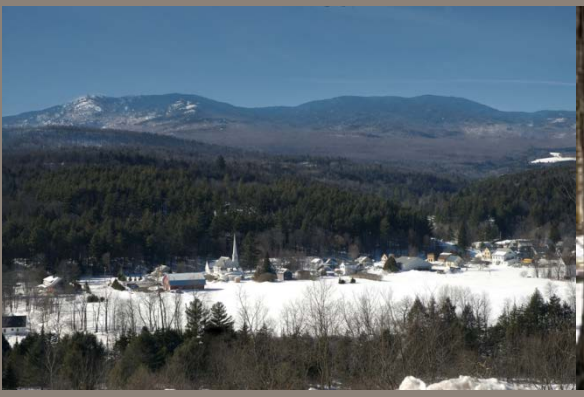
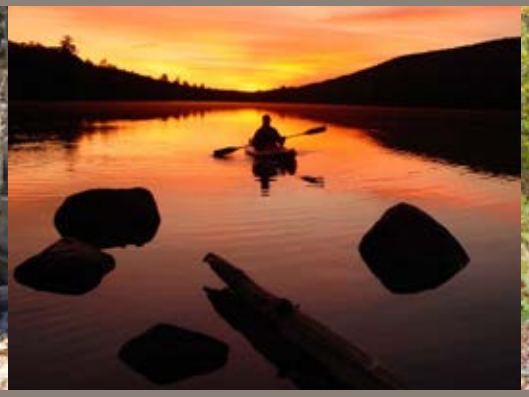





OPIOID PRESCRIBING RULES

VERMONT
DEPARTMENT OF HEALTH

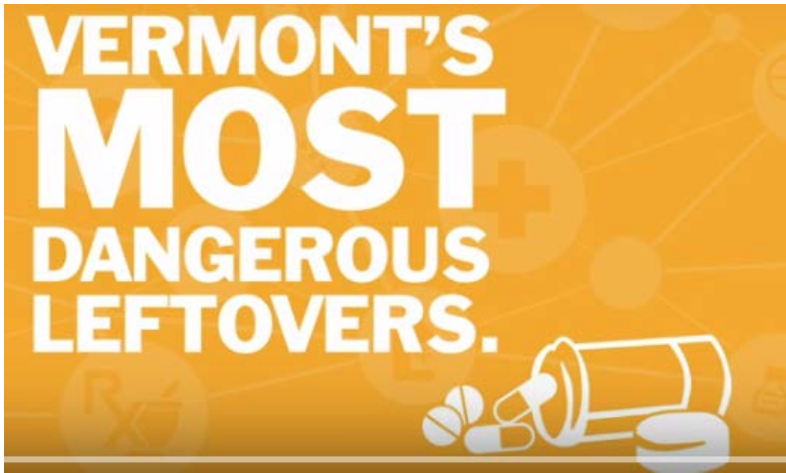
April 20, 2017 – Rutland Regional Medical Center

Outline

- Introduction and Universal Precautions
  - Shayla Livingston, MPH, Health Department *10 Minutes*
- Acute Pain
  - Michael J. Kenosh, MD, RRMC *20 Minutes*
- Chronic Pain
  - Michael J. Kenosh, MD, RRMC *10 minutes*
- VPMS
  - Hannah Hauser, MSW, VPMS Program Manager *5 Minutes*
- Questions
  - *15 Minutes*

The Problem

- As many as four out of five heroin users begin by abusing prescription drugs
- Of those who abuse prescription opioids, seven out of 10 received these drugs through methods of diversion
- Opioids are overprescribed. They are prescribed:
  - Too often
  - At too high a dose
  - For too long
- Prescribers play a role in the supply and use of opioids in communities.



Patient-level surveys of opioid use after surgery

- Dartmouth Hitchcock researchers examined opioid prescribing patterns after general surgery outpatient procedures. Results:
  - Wide variation in quantity provided for each operation
  - An average of only 28% of pills were used
  - To satisfy 80% of patient needs, could reduce prescription amounts by 43%

1: Hill M, McMahon M, Stucke R, & Barth R. Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures. *Annals of Surgery*. 2016; doi: 10.1097/SLA.0000000000001993

Patient-level surveys of opioid use after surgery

- UVM study (Nov. 2016), after general and orthopedic surgery, same wide variation found even within a practice. Results:
  - 7% did not receive an opioid
  - Of the 93% who received an opioid
    - 12% did not fill the prescription
    - 30% that filled the prescription didn't use any
    - The overall median proportion used = 26%

High-Level Overview of Rules

Note that providers should read the full rules which can be found here:

http://www.healthvermont.gov/about-us/laws-regulations/rules-and-regulations

Rule(s) Governing the Prescribing of Opioids for Pain

- adopted pursuant to Act No. 75 of the Acts of the 2013 Session (8/01/15); adopted pursuant to Sections 14(e) and 11(e) of Act 75 (2013) and Sections 2(e) and 2a of Act 173 (2016). (7/01/17.)
- legal requirements for the appropriate use of opioids in treating pain in order to minimize opportunities for misuse, abuse, and diversion, and optimize prevention of addiction and overdose
- prescription limits for acute pain only apply to the first prescription written for a given course of treatment, and do not apply to refills. The prescribing limits under this rule do not apply to palliative care, or end of life care.

Universal Precautions

- First consider non-opioid and nonpharmacologic treatments
- Upon first prescription prescribers must:
  - discuss risks and safe storage and disposal
  - provide a patient education sheet, and
  - receive an informed consent for all first opioid prescriptions
- Co-prescribe naloxone for prescriptions over 90 MME or if also on benzodiazepines
- Check the prescription monitoring system for everyone's first prescription exceeding 10 pills or a replacement prescription

4.0 Universal Precautions

- Any opioid, Schedule II, III, or IV, for the first time during a course of treatment to any patient
  - Consider Non-Opioid and Non-Pharmacological Treatment
  - Query the Vermont Prescription Monitoring System (VPMS)
  - Provide Patient Education and Informed Consent

4.0 Universal Precautions

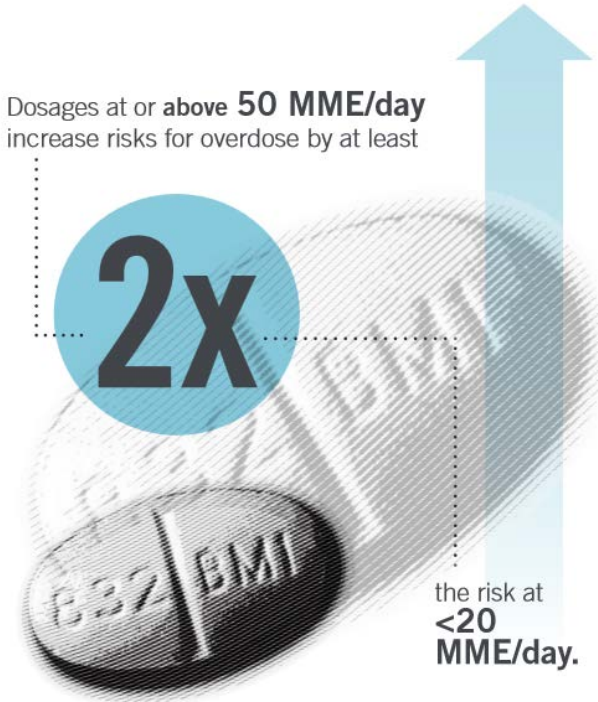
- Provide Patient Education and Informed Consent
  - in-person discussion with the patient (parent, guardian, or legal representative) regarding potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal
  - Prior to prescribing, shall provide the patient with the Department of Health patient education sheet published on the Health Department website, or a written alternative
  - signed informed consent
    - Information on potential for misuse, abuse, diversion, and addiction; risks of life-threatening respiratory depression; fatal overdose from accidental exposure, especially in children; neonatal opioid withdrawal syndrome; and fatal overdose when combining with alcohol and/or other psychoactives (benzodiazepines and barbiturates)

4.0 Universal Precautions

- Provide Patient Education and Informed Consent
  - signed informed consent with no ability to delegate before every initial opiate prescription for acute pain

Opioid Prescribing for Acute Pain

- First prescription to opioid naïve patients :
  - Consider non-opioid treatment
  - Prescribe minimum needed for pain
  - 350 MME (50 MME per day for 7 days) limit
  - Transfer of care
  - Avoid long-acting opioids



Prescribing Opioids for Acute Pain

- Framework smallest doses for the shortest periods of time
- limits found in Figures 1.0 and 2.0 are maximums
- Maximums are averages, not absolute daily limits. This may allow larger doses at the start of the prescription with smaller doses at the end as the patient tapers
- limits apply to patients who are opioid naïve and are receiving their first prescriptions not administered in a healthcare setting
  - [decision making required by the rule would be too complicated to manage for medications that would be administered where there is minimal risk of diversion in a hospital]
  - has not used opioids for more than seven consecutive days during the previous 30 days.

MME Limits for First Prescription for Opioid Naïve Patients Ages 18+

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate pain	24 MME/day	0-3 days: **72 MME** 1-5 days: **120 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy
Severe pain	32 MME/day	0-3 days: **96 MME** 1-5 days: **160 MME**	6 hydrocodone 5mg or 4 oxycodone 5mg or 4 hydromorphone 2mg	many non-laparoscopic surgeries, maxillofacial surgery, total joint replacement, compound fracture repair
For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe up to 7 days so long as the reason is documented in the medical record.				
Extreme Pain	50 MME/day	7 day MAX: 350 MME	10 hydrocodone 5mg or 6 oxycodone 5mg or 6 hydromorphone 2mg	similar to the severe pain category but with complications or other special circumstances

Exemptions: active and aftercare cancer treatment, palliative care, end-of-life and hospice care, patients in skilled and intermediate care nursing facilities, multi-system trauma, complex surgical interventions such as spinal surgery, persons released from an in-patient care setting with uncontrolled pain, patients on medication-assisted treatment for substance use disorder, patients who are not opioid naïve (have had opioids within past 30 days)

Opioid Prescribing for Minors

Teens who used opioids for legitimate reasons in high school had a 33% increased risk for future misuse compared to their peers.[1]

- Consult with pediatrician before prescribing in ED
- Opioids as last resort for minor injuries
- Limits the first prescription to a total of 72 MME (24 MME for 3 days)

[1]Miech R, Johnston L, O'Malley PM, Keyes KM, Heard K. Prescription Opioids in Adolescence and Future Opioid Misuse. Pediatrics. 2015;136(5):e1169-e1177.

MME Limits for First Prescription for Opioid Naïve Patients Ages 0-17

Pain	Average Daily MME *(allowing for tapering)*	Prescription TOTAL MME based on expected duration of pain	Common average DAILY pill counts	Commonly associated injuries, conditions and surgeries
Minor pain	No Opioids	0 total MME	0 hydrocodone 0 oxycodone 0 hydromorphone	molar removal, sprains, non-specific low back pain, headaches, fibromyalgia, un-diagnosed dental pain
Moderate to **Severe** pain	24 MME/day	0-3 days: **72 MME**	4 hydrocodone 5mg or 3 oxycodone 5mg or 3 hydromorphone 2mg	non-compound bone fractures, most soft tissue surgeries, most outpatient laparoscopic surgeries, shoulder arthroscopy

Exemptions: active and aftercare cancer treatment, palliative care, end-of-life and hospice care, patients in skilled and intermediate care nursing facilities, multi-system trauma, complex surgical interventions such as spinal surgery, persons released from an in-patient care setting with uncontrolled pain, patients on medication-assisted treatment for substance use disorder, patients who are not opioid naïve (have had opioids within past 30 days)

Prescribing Opioids for Acute Pain

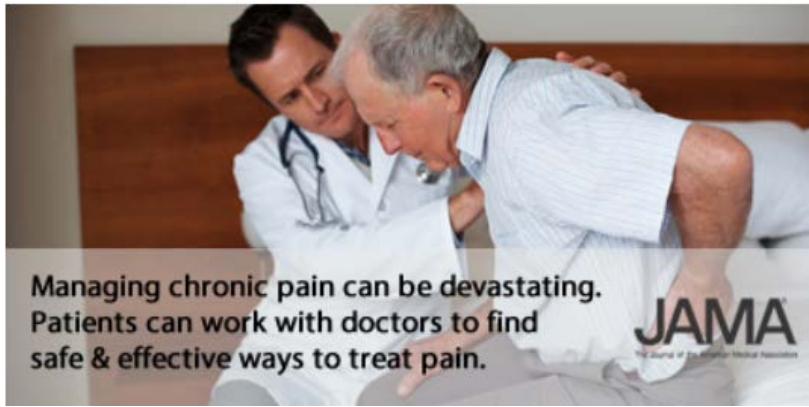
- Long-acting opioids are not indicated for acute pain; reason must be justified in the patient's medical record
- prior to ending care for acute pain, if not primary care provider, ensure a safe transition of care by making a reasonable effort to contact the primary care provider with any relevant clinical information concerning the patient's condition, diagnosis and treatment [that is not limited to sending medical records/a discharge summary]
- prior to prescribing, shall make a reasonable effort to consult with child's primary care provider

Exemptions

- Palliative care
- End-of-life and hospice care
- Patients in skilled and intermediate care nursing facilities
- Pain associated with significant or severe trauma
- Pain associated with complex surgery (spinal surgery)
- Pain associated with prolonged inpatient care due to post-operative complications
- Medication-assisted treatment for substance use disorders
- Patients who are not opioid naïve
- Other circumstances as determined by the Commissioner of Health

Opioid Prescribing for Chronic Pain

- Universal precautions apply
- Requires pain management plans and ongoing assessments of opioid effectiveness
- Sets a trigger for revaluation at 90 MME
- Stable patients must be evaluated at least every 90 days



Prescribing Opioids for Chronic Pain

- Schedule II, III or IV opioids for chronic pain (pain lasting longer than 90 days)
- prescribing for the first time during a course of treatment, the Universal Precautions in Section 4.0 apply

Prescribing Opioids for Chronic Pain

- Screening, Evaluation, and Risk Assessment
- Initiating an Opioid Prescription for Chronic Pain
- Referrals and Consultations
- Reevaluation of Treatment
- Exemptions

Screening, Evaluation, and Risk Assessment

- conduct and document a thorough medical evaluation and physical examination
- document supporting diagnoses
- evaluate and document benefits and risks, including the risk for misuse, abuse, diversion, addiction, or overdose including
  - 3.18 "Risk Assessment" for predicting a patient's likelihood of misusing or abusing opioids (SOAPP or "any evidence-based screening tool")
    - Other examples on VDH website

Initiating an Opioid Prescription for Chronic Pain

- consider and document
  - Non-opioid alternatives up to a maximum recommended by the FDA, including non-pharmacological treatments
  - Trial use of the opioid
  - requirements to query VPMS
  - currently or has recently been dispensed methadone or buprenorphine or prescribed and taken any other controlled substance
    - required by law to disclose this information
  - signed Controlled Substance Treatment Agreement

Initiating an Opioid Prescription for Chronic Pain

- Controlled Substance Treatment Agreement
  - functional goals for treatment
  - choice of dispensing pharmacy
  - safe storage and disposal
  - other requirements as determined by the prescriber
    - directly observed urine drug testing and pill counts

- examples of informed consent and Controlled Substance Treatment Agreements will be available on VDH website

Initiating an Opioid Prescription for Chronic Pain

- For the duration of the patient's treatment
  - 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
  - stable patients reevaluated at least every 90 days
  - write maximum daily dose or a "not to exceed" on script

Referrals and Consultations

- Consider a referral to a pain specialist or substance abuse specialist
  - not meeting the goals of treatment despite escalating doses
  - high risk for substance misuse, abuse, diversion, addiction, or overdose as determined by history or screening
  - reasonable grounds to believe, or confirms, misuse of opioids or other substances
  - multiple prescribers and/or pharmacies
  - prescribed multiple controlled substances
  - patient request

Reevaluation

- Controlled Substance Treatment Agreements will be reviewed and documented at least yearly in medical record
- Specific rules relative to exceeding 90 MME/day
- Determine and document as part of the reevaluation:
  - Whether to continue opioids or trial alternatives
  - Obtain pain management, substance abuse or pharmacological consult
  - Acknowledgement that a violation of the agreement may result in consequences

Reevaluation

- Specific rules relative to exceeding 90 MME/day
  - in-person discussion regarding increased risk of overdose
  - reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of adherence
  - potential for the use of non-opioid and nonpharmacological alternatives
  - functional examination of the patient
  - review of Controlled Substance Agreement and Informed Consent
  - assessment of co-morbid conditions affected by treatment with opioids
  - other related actions by the patient that may lead prescriber to modify pain management regimen (risk factors)

Exemptions

- Chronic pain associated with cancer or cancer treatment
- Palliative care
- End-of-life and hospice care
- Patients in skilled and intermediate care nursing facilities

- Acute pain from cancer/cancer care are not exempt from the universal precautions (checking VPMS, informed consent, providing an information sheet) nor from the prescribing limits. Chronic pain may be exempt

Naloxone

- Co-prescribe for MME>90 or concurrent prescription for benzodiazepines

Extended Release (Acute or Chronic)

- In addition to the above, ER hydrocodones and oxycodones not manufactured as Abuse-deterrent Opioids require
  - conduct and document a thorough medical and physical examination
  - diagnoses which support the use
  - evaluate and document benefits and risks including Risk Assessment
  - 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
  - signed Informed Consent
  - signed Controlled Substance Treatment Agreement

Extended Release

- Cont.
  - query VPMS and document
    - review of other prior controlled substances preceding ER
    - query no less frequently than every 120 days for 40 mg or greater of hydrocodone or 30 mg or greater of oxycodone
    - query no less frequently than as described in the Vermont Prescription Monitoring System Rule
  - write a maximum daily dose, or a “not to exceed value”
  - filled within seven (7) days of the date issued and no more than 30-day supply

Extended Release

- Periodic follow-up visits and evaluations at least every 90 days during which the following must be documented
  - whether to continue ER
  - need for a pain management or substance abuse consultation
  - acknowledgement that a violation of the agreement may result in consequences

VPMS Rules: Required Prescriber Queries

- The first time the provider prescribes an opioid
- Starting long-term pain therapy of 90 days or more
- Prior to writing a replacement prescription
- At least annually for patients who are receiving ongoing treatment
- The first time prescriber prescribes a benzodiazepine
- When a patient requests an opioid or a renewal from an Emergency Department or Urgent Care Center

Law Requires Dispensers to query the Vermont Prescription Monitoring System

Dispensers must check the prescription monitoring system when:

- Dispensing an opioid to a **new patient**
- A patient **pays cash** for an opioid, but has insurance
- A patient requests a **refill** of an opioid before it is due
- The dispenser knows the patient is being prescribed an opioid by **more than one prescriber**

Exemption for a hospital-based dispenser dispensing a quantity of an opioid that is sufficient to treat a patient for 48 hours or fewer.

Resources

- Act 173 *An act relating to combating opioid abuse in Vermont*
  - http://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT173/ACT173%20As%20Enacted.pdf
- VDH Rule Governing the Prescribing of Opioids for Pain
  - http://www.healthvermont.gov/sites/default/files/documents/2016/12/REG_opioids-prescribing-for-pain.pdf
- VDH Vermont Prescription Monitoring Rule
  - http://www.healthvermont.gov/sites/default/files/documents/2016/12/REG_vpms-20170701.pdf
- Patient Information Sheet
  - http://www.healthvermont.gov/sites/default/files/documents/2016/12/adap_opioid_patient_informaton.pdf
- Informed Consent Template
  - URL HERE
- Office of Primary Care and Area Health Education Centers (AHEC) Program
  - http://www.med.uvm.edu/ahec/workforceresearchdevelopment/toolkits-and-workbooks/opioid_prescribing

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For patients with severe pain and extreme circumstance, the provider can make a clinical judgement to prescribe up to 7 days so long as the reason is documented in the medical record.		
Severe pain and extreme circumstance	50 MME/day	7 day MAX: 350 MME