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**Subject:** Management of Chronic Opioid Protocol

**Purpose:** To provide standardized tools and a highly reliable process for caring for patients who require chronic opioid use.

**Procedure:**

The following protocol should be initiated for non-palliative long-term patients for whose Schedule II and III opioid use *exceeds 90 days or if opioid use exceeding 90 days is anticipated* at the initiation of therapy and when prescribing any patient an extended release hydrocodone without Abuse Deterrent Formulations (i.e. Zohydro) of any duration. Protocol initiation for Schedule IV opioids is strongly recommended but not required.

(NOTE WELL: VMPS Requirements extend beyond this definition; See VPMS Section of Protocol)

**Prescription Agreement (Appendix A)**

1. The provider will review and discuss the prescription agreement with the patient and obtain signatures.
2. The prescription agreement will be scanned into PRISM utilizing Consent document type with "Opioid Agreement" as the description.
3. Prescription agreements will be reviewed and updated as needed.
4. Form is available from Print Shop in hard copy or as letter "FA AMB PRESCRIPTION AGREEMENT" in the PRISM system.

**Informed Consent (Appendix B)**

1. The provider will review and discuss the informed consent with the patient and obtain signatures.
2. The informed consent will be scanned into PRISM utilizing Consent document type, with "Opioid Consent" as the description.
3. Informed consent will be discussed and updated as needed.
4. Form is available from Print Shop in hard copy or as letter "FA AMB INFORMED CONSENT" in the PRISM system.

**Problem List**

1. Problem list will be updated to include "Chronic Pain Syndrome (338.4)" as a permanent problem.
2. Add .PAINMANAGEMENT (Appendix C) to the Overview section. Update all fields.
3. Prescription Agreement and Informed Consent must be indicated in the overview section of the problem.
4. Ensure problem list contains appropriate diagnosis explaining location/pain syndrome.
5. Document aberrant patient behaviors in .PAINMANAGEMENT

**Health Maintenance**

1. The use of “Chronic Pain Syndrome (338.4)” and “Chronic Pain (338.29)” on the problem list will automatically add the Chronic Opioid Management Modifier which consists of:
  - a. Opioid Informed Consent – One time occurrence, no interval
  - b. Opioid Prescription Agreement – One time occurrence, no interval
  - c. Vermont Prescription Monitoring System – Interval defaults to annual
  - d. Urine Drug Screen – Interval defaults to annual
  - e. Pill Count – Interval defaults to annual
  - f. Functional Assessment – Interval defaults to annual
  - g. Current Opioid Misuse Measurement (COMM) – Interval defaults to annual
2. For patients not meeting the criteria of the protocol, yet have Chronic Pain on their problem list, the Chronic Opioid Management Modifier may be removed. See Appendix U.

**Laboratory Testing**

**Urine Drug Screen**

1. Urine drug screens will be completed by utilizing Urine Drug Screen 6 (D6VAL) and appropriate confirmation tests. The frequency of this testing should be guided clinically and it is strongly recommended that this testing be performed at a minimum annually for all patients under this protocol. Frequency may be adjusted as needed.
2. D6VAL will include Urine Creatinine, Specific Gravity Range and temperature of sample to provide screening for possible tampering/adulteration of sample.
  - a. Results will include the following validation statements to support provider assessment:
    - i. Normal Physiologic Urine Creatinine and Specific Gravity Range
    - ii. Suggest Dilute Specimen
    - iii. Suggest Adulterated Specimen
3. Urine sample will be collected using Urine Drug Screen Collection procedure.
4. In the event a urine drug screen needs to be complete externally (i.e. utilization of “Blue Water Process”), results will be scanned into PRISM for future reference. Results do not require manually entry. Urine Drug Screen Health Maintenance Topic will need to be overridden.
5. In the event a provider determines that a Urine Creatinine and Specific Gravity Range are not needed, LAB678 will be utilized which does not include Urine Creatinine or Specific Gravity Range with the drug screen.

To Screen for Drugs of Abuse	Urine Drug Screen 6 (D6)	Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Cannabinoids, Opiates (Only Heroin, Codeine and Morphine)
To Screen for Drugs of Abuse - <b>RECOMMENDED</b>	Urine Drug Screen 6 Validity (D6VAL)	Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Cannabinoids, Opiates (Only Heroin, Codeine and Morphine) <b>AND</b> urine temperature and measurement of specific gravity and creatinine to assess for dilution or adulteration
To Confirm Use of Current Prescription	Opioid Confirmation	Codeine, Hydrocodone, Morphine, Oxycodone, Oxymorphone, Hydromorphone
Items not included in above	Must request each separately	Methadone Confirmation, Fentanyl Confirmation, Buprenorphine Confirmation

**Note Well:** Contact Laboratory for concerns with false positives (H-2 blockers and cannabinoids) false negatives (clonazepam and benzodiazepines) and unusual metabolic pathways (small amount of hydromorphone from morphine)

6. The following link will be utilized to guide clinical interpretation of drug screens. UVM MEDICAL CENTER Laboratory will serve as a resource to the provider and confirmation testing will be at the discretion of the provider. <http://www.pharmacomgroup.com/udt/udt5.pdf>

### **Prescription Refills**

1. Prescription Refills will be provided according to the Prescription Agreement.
2. Prescriptions should be written in increments of 7 to prevent weekend request. (7, 14, 21 or 28 days)
3. Advance planning for refills is strongly recommended to prevent prescribing by multiple providers.
4. Refills will be addressed during office visits (minimum every three months).
5. Prescription refills will not be provided by the on call physician. If the prescribing provider is going to be out of the office, he/she will designate a provider for hand off as appropriate.
6. When writing the prescriptions in PRISM, use the "start", "end" and "fill" dates appropriately.
7. "Earliest Fill Date" will be populated on the order and display at the end of the "Sig" on the printed prescription.
8. Recommend that Fill Date be the same as Start Date, however the prescription may be refilled up to 72 hours prior to start date per provider discretion.
9. For prescriptions that are written as replacements due to loss or theft of medication or prescription, "Replacement Prescription" will be checked in the order and the language will automatically display on the printed prescription.
10. Clinical staff processing refills will complete the following:
  - a. Review of Prescription Agreement
  - b. Review of fill date/do not fill before start date
  - c. VPMS Process as indicated

### **Prescription Pick Up**

1. Patient or Parent/Guardian must present proof of identification at time of prescription pick up.
2. Patient identification will be scanned into PRISM. Do not scan parent/guardian/designee ID into patient's record.
3. Patient or Parent/Guardian and staff member will complete log indicating pick up (Appendix D).
4. Per Informed Consent, patient may identify a designee for prescription pick up.
5. It is recommended that a patient pick up a prescription. In the event a prescription needs to be mailed, prescriptions must be mailed to the patient's local pharmacy for pick up.
  - a. Prescriptions reported as lost in the mail may not be replaced.

### **Pill Counts**

1. Prescribing provider will inform the patient that pill counts may be requested at any time as noted in Prescription Agreement.
2. Pill counts will be obtained when requested by the provider at an office visit and at random times (both in and out of office). Out of office pill counts may be completed in collaboration with the patients Primary Care Provider.
3. Frequency of pill counts will be determined and tracked utilizing Health Maintenance functionality.
  - a. Recommend completion, at a minimum, annually.
4. It is recommended that patients bring all their medications to every visit, in the original bottles.
5. If the patient is selected via randomization, the patient is informed of the request for random pill count via telephone encounter and a nurse visit is scheduled the same business day.
  - a. See Registry section of this protocol for randomization process.
6. The patient, a licensed staff member and a staff witness (may be clinical or support staff) must be in the room when the pill count is conducted. All three are considered witnesses.

7. The nurse will perform hand hygiene before/after the pill count and wear gloves.
8. For pill counts from a prescription bottle, a sterile tray and plastic knife (same as used in a pharmacy) will be used to complete the process and may be ordered through Mediclik.
9. For pill counts from a prescription bottle, empty the medication out onto the tray
10. For pill counts from bubble packs, verify integrity of packaging.
11. Verify by color/shape/size/imprint on the pill and that the pill represents what is on the prescription bottle/bubble pack.
  - a. The following web link may be used for verification: <http://www.rxlist.com/pill-identification-tool/article.htm>
12. The nurse will check the date the prescription was filled and calculate quantity left based upon sig.
13. Document completion of pill count in the patient's record chart using the Pill Count Flowsheet (Appendix E). This documentation will be pulled into a note using .PILLCOUNT.
14. For pill counts from a prescription bottle, return medication to the original container
15. Return prescription bottle/bubble packs to patient in front of patient and witness.
16. For pill counts **conducted outside of a provider office visit**, send results to PCP for review by routing the nurse visit encounter to the provider.
  - a. A discrepancy will be sent to the provider as high priority.
  - b. Reason for Visit will be documented as "Pill Count".
17. For pill counts **conducted during a provider visit**:
  - a. Staff will discuss need for pill count during session huddle (Primary Care) or with provider in advance of the visit to facilitate completion of pill count prior to provide interaction with the patient.
  - b. For pill counts which fail to match, in addition to documenting in the visit encounter, the provider will be notified verbally by the staff completing the count.
18. Upon completion of pill count, Health Maintenance Topic will be satisfied.

## Patient Assessment

### Initiation of Therapy

1. Complete initial assessment tool
  - a. SOAPP-R (Appendix F)

### Continuation of Therapy

1. Level of function will be evaluated at each functional follow up visit.
2. Each functional follow-up visit should include a functional evaluation with documentation of the "5 A's": Analgesia, Activities of daily living (i.e., physical psychological and social functioning), Adverse Effects, Affect and Aberrant drug-related behaviors.
  - a. .5AS (Appendix G)
  - b. To occur with every visit, which is at a minimum every three months
3. Screening for Aberrant Behavior:
  - a. COMM (Appendix N)
4. A re-evaluation should be done annually and will be tracked utilizing Health Maintenance functionality. In addition to using the "5 A's" documentation tool for re-evaluation, the following tools are recommended for annual use, as appropriate:
  - a. Functional Assessment:
    - i. SF – 8: For general functional assessment if no other specific tool available (Appendix H)
    - ii. Oswestry Neck: For functional assessment related to chronic neck pain (Appendix I)
    - iii. Revised Oswestry Low Back Pain: For functional assessment related to chronic back pain (Appendix J)
    - iv. Roland Morris – RDQ: For functional assessment of chronic, non-specific low back pain (Appendix K)
    - v. CDAI: Clinical Disease Activity Index for Arthritis (Appendix L)
    - vi. FIQR: For functional assessment related to fibromyalgia (Appendix M)

b. Adverse Effects (Appendix R)

- i. Recommended use with concerns, dose changes and annually

Titration of Therapy (Appendix O)

1. OPIOID WITHDRAWAL

**Prescribing Practice Evaluation**

Within each Health Care Service:

1. Provider prescribing practices will be reviewed as part of their Ongoing Professional Practice Evaluation (OPPE) process.
2. Physicians, residents and non-physician providers' prescribing practice will be adequately monitored through panel management reports.
3. Residents: All notes are reviewed by their preceptor.

**Panel Management**

1. Three separate reports will be available for review by the prescribing provider on a quarterly basis.
  - a. *Identification of Patients for Protocol*
    - i. Primary Care Opioid – PC – Identification Crystal Report
      1. Report compiled by PCP for patients with 3 or more opioid prescriptions by provider's department, with an active opioid prescription on file and who do not have Chronic Pain Syndrome on their problem list
        - a. Data to be reported over a rolling year
        - b. Report to be reviewed during Provider/CCA Weekly Meetings
        - c. Confirm or add appropriate diagnosis explaining location/pain syndrome
          - i. Add "Chronic Pain Syndrome" to the problem list and mark as a permanent problem.
          - ii. Add PAINMANAGEMENT to the Overview section and update all fields to the Overview section as appropriate.
    - ii. Specialty Care
      1. Report compiled by Authorizing Provider for patients with 3 or more opioid prescriptions by provider's department, with an active opioid prescription on file and who do not have Chronic Pain Syndrome on their problem list
        - a. Data to be reported over a rolling year
        - b. Provider to initiate protocol (Addition of Chronic Pain Syndrome to the Problem List and adding PAINMANAGEMENT to the Overview section) or complete a voice to voice hand off to the patient's Medical Home.
  - b. *Any Patient on an Opioid without Abuse Deterrent Formulation*
  - c. *Patients on Protocol*
    - i. Randomization of patients for pill counts and urine drug screens will occur via the report.
    - ii. Report data elements:
      1. Number of patients prescribed for (By PCP in Primary Care, by prescriber in Specialty Care)
      2. Amount of opioids prescribed (Rx my Dept. Authorized, Unique Auth Provs, Current Med, Total Rx Last Year)
      3. Last Urine Drug Screen (date)
      4. Last PCP visit (date)
      5. Pain score (result and date)
      6. Last VPMS Query (date)

7. Prescribing Agreement (y/n)
  8. Consent present (y/n)
  9. Completion of Functional Assessment (date)
  10. Completion of COMM (date)
  11. Pill Count (date)
  12. Prevalence of "red flags"
    - a. 4 or more prescribers
    - b. Methadone/Suboxone/Buprenorphine use for pain
    - c. High dose Rx (> 100mg morphine equivalents)
- iii. Action to take with report:
1. Review and complete Health Maintenance Topics as appropriate
  2. If patient has not been seen by prescribing provider within past 6 months, schedule appointment for follow up.
  3. Review "red flags" and missing data elements

### **Vermont Prescription Monitoring System (VPMS)**

1. Prescribers must query VPMS in the following four circumstances?
  - a. At least annually for patients who are receiving ongoing treatment with Opioid Schedule II, III or IV controlled substance
  - b. When starting a patient on a Schedule II, III or IV controlled substance for non-palliative long-term pain therapy of 90 days or more
  - c. The first time the provider prescribes an opioid Schedule II, III or IV controlled substance written to treat chronic pain
  - d. Prior to writing a replacement prescription for a Scheduled II, III or IV controlled substance
    - i. Replacement prescriptions are defined as "an unscheduled prescription request in the event that the document on which a patient's prescription was written or the patient's prescribed medication is reported to the prescriber as having been lost or stolen.
2. VPMS query will be documented in the patient's record using .VPMSQUERY and the health maintenance topic will be updated appropriately.

### **Opioids without Abuse Deterrent Formulations (ADF)**

1. When prescribing an opioid without ADF (i.e. Zohydro), in addition to the protocol, the following steps must occur:
  - a. Clear documentation that an opioid without an ADF is needed to manage severe pain that requires daily, around-the-clock long-term opioid treatment, and that alternative treatment options are ineffective, not tolerated or would be inadequate to provide sufficient management of pain.
  - b. In addition to completing the prescription agreement and informed consent, discuss with the patient the increased risks associated with ADFs such as life-threatening respiratory depression, potentially fatal overdose especially in children, neonatal opioid withdrawal symptoms and potentially fatal overdose when interacting with alcohol.
  - c. Urine drug screens must be completed at least every 120 days. Adjust Health Maintenance Urine Drug Screen modifier accordingly.
  - d. Additional VPMS considerations:
    - i. Query must be completed at least every 120 days for patients prescribed 40mg or more per day. Adjust Health Maintenance VPMS modifier accordingly.
  - e. Determine a maximum daily dose of a not-to-exceed value for the prescription to be transmitted to the pharmacy.
  - f. Prescriptions must be filled within 7 days that do not exceed 30 days in duration.

### **Multidisciplinary Rounds**

1. On at least a quarterly basis, multidisciplinary rounds are recommended at the site level.
2. The following individuals will be included in the process when applicable:
  - a. MD Site Leader
  - b. Practice Supervisor
  - c. Prescribing Providers
  - d. Behavioral Health Practitioner
  - e. Clinic RN
  - f. CHT Team (LCSW)
  - g. Hub and Spoke representation
3. Site Registry of patients will be reviewed for the following:
  - a. Discrepancies
  - b. Joint assessment of coping and engagement in treatment
  - c. Joint assessment of risk of opiate use
  - d. Treatment plans developed
  - e. Identification of patterns of abuse/addiction
  - f. Options for patient to be presented back to patient
  - g. Review levels of individual patient surveillance
  - h. Identification of resources needed for patient

**Monitoring Plan:** Practice Supervisor and MD Site Leader are responsible for ensuring protocols are followed. Audits as determined by the UVM MEDICAL CENTER Opioid Task Force

**Related Policies/Procedures:**

State of Vermont VPMS Process

Department of Health Emergency Rule Regulating Use of Zohydro

- Appendix A: Prescription Agreement
- Appendix B: Informed Consent
- Appendix C: Pain Management Smart Phrase
- Appendix D: Prescription Pick Up Log
- Appendix E: Pill Count Flowsheet
- Appendix F: SOAPP-R
- Appendix G: 5A's Smart Phrase
- Appendix H: SF- 8
- Appendix I: Oswestry Neck
- Appendix J: Revised Oswestry Low Back Pain
- Appendix K: Roland Morris - RDQ
- Appendix L: CDAI
- Appendix M: FIQR
- Appendix N: COMM
- Appendix O: Titration of Therapy Clinical Guidelines
- Appendix P: VPMS Smart Phrase
- Appendix Q: Opioid Withdrawal Smart Phrase
- Appendix R: Adverse Effects Document
- Appendix S: Documentation Tool Grid
- Appendix T: Urine Drug Screen Collection Procedure
- Appendix U: Removing Chronic Opioid Modifier
- Appendix V: Urine Collection Temperature Cup Instructions
- Appendix W: Tip Sheet for Reordering Controlled Substances

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