FCM Toolkit for Safe Opioid Prescribing

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

Updated
1/2018

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GUIDELINES FOR THE USE OF OPIOID/NARCOTIC MEDICATIONS FOR CHRONIC NON-MALIGNANT PAIN

Please see the FCM Policy 11/2017

It is **recommended that providers be familiar with the Board of Medicine and CDC guidelines**.

> "Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate."

When opioids are prescribed, they should use the lowest possible doses for the shortest periods possible. **If opioids are prescribed, a 2-3 day supply is recommended rather than a larger quantity.** A **PMP check is required if more than 7 days are prescribed**.

If the prescription of chronic opioids is decided upon for the management of chronic pain, FCM policy should be followed with additional guidance as needed from the Medical Board and CDC. If medications are found to be beneficial without undue risk, guidelines **recommend avoidance of prescribing more than 50 daily MME** (Morphine Mg Equivalents). Patients should be closely **followed in the office at least every 3 months for MME<50 and every 1-2 months for MME>50.**
A recommended goal for patients being prescribed or using >90 MME is to taper downward (goal <50 MME) or consult/refer to pain management.

Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 90 MME/day, or concomitant benzodiazepine or high-risk drug is present.

Concomitant benzodiazepine or sedating medication prescription markedly increases the risk of death. Providers **should not co-prescribe an opioid** with the following medications **all benzodiazepines, sedative hypnotics, carisoprodol (SOMA), tramadol,** promethazine, barbiturates, and quetiapine (Seroquel).

If there are extenuating circumstances, a provider may co-prescribe an opioid, but is required to document a tapering plan to achieve the lowest possible effective dose.

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Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	**Conversion factor***
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Methadone	4-12
Morphine	1

Opioid	Conversion factor*
Oxycodone	1.5

EPIC CSA/SMA workflow

Enter "Controlled Substance Agreement Signed (Z79.899)" as a diagnosis and add to the problem list. This is also a good place to document when the last PMP and Urine Drug Screen were done.

Order "Controlled Substance Agreement" or **"Supervised Medication Agreement"** and have the patient sign and date. One copy should be given to the patient and another copy sent to scan.

The diagnosis "**Controlled Substance Agreement Terminated (Z91.14)**" can be used and added to the problem list if a violation has occurred. Patients will not be automatically dismissed from the practice but will be informed in writing that the practice will no longer be prescribing controlled medications to them. This will be documented in the problem list and FYI section of EPIC. Providers are encouraged to continue to provide medical care to these patients. In extreme circumstances, if the provider believes that the patient needs to be dismissed from the practice, they should contact our Patient Liaison at 540-981-7798 or the Regional Medical Director.

Patients who violate a CSA/SMA will be educated about addiction and given information and resources to obtain addiction and substance abuse treatment and counseling. Resources can include **Substance Abuse and Mental Health Services Administration** 1-800-662-HELP at findtreatment.samhsa.gov and National Institute on Drug Abuse (NIDA) at drugabuse.gov.

The **PMP** is required to be reviewed prior to initiation of opioid therapy (if prescribe 7 days or more). This should then be checked at least every 3 months. This can now legally be scanned and made a part of the patient record. An application is available for provider's nurse/staff to obtain PMP access as a delegate.

The appropriate **Urine drug screen (UDS)** to order is "**Prescription Abuse Monitoring 15 Panel" (A23015)**. This should be performed **at least every 3 months the first year, at least every 6 months after the first year**, and more often as indicated. For assistance in interpreting results, call 1.877.40.RXTOX (**1.877.407.9869**) for the next available **toxicology specialist at Quest**.

EPIC note templates that are encouraged are:

PAIN HPI
Diagnoses, Location(s) and Description of Pain ***
Analgesia Pain severity without medication is {NUMBERS 0-1219207}/10 and is improved with medication to {NUMBERS 0-1219207}/10.
Other medication or non-medication treatments include ***
Activity/Benefit and Treatment Goals
Improved psychosocial function and quality of life {AMB YES NO2100"no"}
Improved physical function, work and daily activities {AMB YES NO2100"no"}
Adverse/Side Effects (sedation, impaired cognition, constipation, etc.) {AMB YES NO2100"no"}
Aberrant Behavior

1. In the past 30 days, have you borrowed pain medication from someone else or taken more than the recommended amount of medication? {AMB YES NO2100"no"}
2. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)? {AMB YES NO2100"no"}

Affect Having depression, anxiety or mood disorder? {AMB YES NO2100"no"}
Concurrent Use of High Risk Meds (Benzodiazepines, muscle relaxants, sleep aids, tramadol)? {AMB YES NO2100"yes"}
If yes, have there been efforts to taper to the least effective dose? {AMB YES NO2100"yes"}

PAIN PLAN
The course of treatment has been reviewed with the patient and has been updated in the medication list/orders.
Narcan will be prescribed when indicated for those with an **MME >90-120** (consider for those with MME>50) (CDC MME Calculator) **and for those at increased risk** for opioid overdose (history of sleep apnea, prior overdose, substance or alcohol use/abuse; concurrent benzodiazepine, sedative hypnotic, tramadol or Carisoprodol use).
The patient is *** benefiting from opioid/drug therapy and the pain relief/improved function benefits currently outweigh the side effects/risks which were discussed with the patient.
An **SMA** (Supervised Medication Agreement) has been completed on *** and informed consent with treatment risks have been discussed with the patient. A signed copy has been scanned into the EMR.
The **PMP** has been checked (**at least every 3 months**) on *** and is *** appropriate.
The **UDS/drug screen** (**at least every 3 months year 1; at least every 6 months thereafter**) has been tested on *** and is *** appropriate.
Additional evaluation or treatments recommended at this time include ***
The patient will follow up in *** (at least every 3) months, sooner if problems, side effects, other symptoms or concerns.

TAPERING INFORMATION FOR MEDICATIONS
A gradual reduction of **benzodiazepines and barbiturates** is slower than opiates. For benzodiazepines the dose should be reduced by less than 10% every 3 days. **Opioids** can be tapered at a higher percentage of 20% every other day. 1 week for opiates and up to 8 weeks for benzodiazepines. If the reduction of more than one medication is indicated and contacts with the patient are limited, it is probably wisest to decrease only one at a time. Provide the patient with a daily taper schedule and ask the patient to call periodically with an update.
Pain Clinical Manual Second edition Margo McCaffery, RN, MS, FAAN, Chris Pasero RN, MSNc, mosby 1999.

ADDITIONAL RESOURCES
Virginia Board of Medicine's Emergency regulations for opioid prescribing
https//www.dhp.virginia.gov/medicine/
Virginia Department of Health Professions PMP sign up and log in
https//virginia.pmpaware.net/login

CDC Factsheet for providers
http//www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf

CDC factsheet for patients
https//www.cdc.gov/drugoverdose/pdf/aha-patient-opioid-factsheet-a.pdf

To refer a challenging patient to a colleague for a second opinion or to transfer care, you can search for practitioners in Virginia that provide Pain Management at
http//www.vahealthprovider.com/search_adv.asp

If you need to refer a patient to a colleague for evaluation or to transfer care, you can search for practitioners that specialize in Addiction Medicine at http//www.vahealthprovider.com/search_adv.asp

A resource for substance abuse treatment options around the state is the sink or swim treatment locator http//drugfreeva.org/grab-a-lifering/

Laws and Regulations Governing the Prescription Monitoring Program
https//www.dhp.virginia.gov/dhp_programs/pmp/pmp_laws.asp

Center for Disease Control's "Guideline for Prescribing Opioids for Chronic Pain"
https//www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

ORT (Opioid Risk Tool)
https//www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

COMM (Current Opioid Misuse Measure)
http//www.opioidprescribing.com/documents/09-comm-inflexxion.pdf

PHQ-2 Depression Screening Tool
http//www.commonwealthfund.org/usr_doc/PHQ2.pdf
http//cde.drugabuse.gov/sites/nida_cde/files/PatientHealthQuestionnaire-2_v1.0_2014Jul2.pdf

PHQ-9 Depression Screening Tool
http//www.aafp.org/afp/2012/0115/p139.html
http//www.opioidprescribing.com/documents/11-phq-9.pdf

ADAPTED FROM POLICY / PROCEDURE
FCM USE OF OPIOID MEDICATIONS FOR CHRONIC NON-MALIGNANT PAIN
CLINICAL STAFF PROCEDURE

ROLE OF CLINICAL STAFF in supporting providers in the care of chronic pain patients with Controlled Substance Agreements
PMP Database Search A PMP Database search is to be initiated at time of CSA/SMA.

1) By Virginia law, PMP searches must be performed at the initiation of any opioid prescription that will last more than 7 days.
2) A **PMP database check** is **required initially and at least every 3 months thereafter**. A **UDS** or similar is **required initially, every 3 months for the first year of treatment and at least every 6 months thereafter.** There must be documented informed consent, alternative treatments and a signed CSA/SMA. If the last prescription was filled by a pharmacy of a state not participating in a shared agreement with Virginia, the medication should be confirmed by a call to the last filling pharmacy.

EPIC CSA/SMA workflow
1) Enter "Controlled Substance Agreement Signed (Z79.899)" as a diagnosis and add to the problem list. This is also a good place to document when the last PMP and Urine Drug Screen were done.
2) Order "Controlled Substance Agreement" or "Supervised Medication Agreement" and have the patient sign and date. One copy should be given to the patient and another copy sent to scan.

Urine Drug Testing
A UDS should be performed at the initiation of a SMA; at a minimum of every 3 months for the first year; at least every 6 months thereafter; with closer monitoring as circumstances warrant. A UDS may be performed randomly by asking patient to come to office and give urine for specimen in order to get a prescription at the discretion of the provider. The UDS test is expensive and not covered by all insurers so judicious ordering is recommended and it should not be ordered on every patient visit unless there is concern for aberrant behavior/misuse. It is recommended that controlled substances **not** be prescribed or continued for a new patient until appropriate UDS results are obtained. UDS obtained external to our practices (including the Emergency Departments) should not necessarily be considered a disqualifier as the rate of false positives and negatives of those screens is high unless a confirmatory test is performed.

Ordering
1) **EPIC ordering** – The most recent available drug test "with confirmation" is recommended. As of the update of this policy, this was the **"Prescription Abuse Monitoring 15 Panel" (A23015)** under order entry. (Date of policy 11/2017)

2) **Documenting time of last dose** – Providers or clinical staff nurses MUST document date, time, and amount of last dose in order to allow for proper interpretation of the UDS. This should include all controlled substances that the patient is taking.

3) **If checking for benzodiazepines such as clonazepam (Klonopin) or alprazolam (Xanax)** – List the drugs that should be present in the screen in the comments section of the order.
4) **Clonazepam (Klonopin)** – should be ordered separately due to its decreased sensitivity in being picked up on the UDS.
5) Identify patient using 2 identifiers and assist patient in collecting at least 40ml of fresh urine in a sterile urine container.
6) Label the container in the presence of the patient with first and last name and DOB.
7) **Interpreting**

    a. **Urine Creatinine** – a specimen consistent with normal human urine usually has a creatinine concentration greater than 20mg/dL. A concentration of less than 20mg/dL is considered abnormally dilute and less than 5mg/dL is not consistent with human urine.

    b. **Confirmatory Testing** – all positive tests on the UDS 15 are automatically confirmed by follow-up gas chromatography or mass spectrometry testing.

    c. **Illicit drug detection** – detection of illegal drugs (cocaine, marijuana, cannabinoids, etc.) or controlled medications that are not prescribed is considered a violation of the SMA.

    d. **True Negative Urine Results** (binging vs. diversion) – the lack of prescribed controlled medication in a UDS when the last dose was documented within the window of detection is considered a violation of the CSA/SMA. Of note, due to its rapid metabolism, clonazepam could be taken appropriately and fail to be demonstrated in a UDS.
    e. For assistance in interpreting results, call 1.877.40.RXTOX (1.877.407.9869) for the next available toxicology specialist at Quest.

Pill Counting

Clinical staff is expected to participate in pill counting with patient as directed by provider. A second staff to observe during the pill count is recommended, but not required.

Respectful Communication

a. Clinical staff is expected to engage in respectful and compassionate communication with patients and staff. The challenging communications around chronic pain and controlled substances are supported by participation in the Cornerstone on Demand course **Non-Violent Awareness** Education **(SRI231A).**

b. Clinical staff is expected to escalate any staff or patient concerns related to pain medications, the process, including addiction, diversion, violating the CSA, or any individual is at risk. Talk with your providers if you have concerns that a patient is breaking their CSA or at risk in anyway.

Updated
1/2018

Always go to the online version "Inside Carilion Page Center X Reports" for most recent policy version!

CARILIONCLINIC
FAMILY AND COMMUNITY MEDICINE

POLICY / PROCEDURE
FCM USE OF OPIOID MEDICATIONS FOR CHRONIC NON-MALIGNANT PAIN

KEY TERMS
Controlled medications, chronic pain, controlled substances agreement, supervised medication agreement, prescribing, risk management, opioid, narcotic.

PURPOSE
The goal of pain treatment is to decrease pain and improve function while monitoring for any adverse side-effects. Controlled Medications are one modality for the treatment of chronic pain. The safe use of these modalities in the context of a comprehensive plan to manage chronic pain is important for the long-term health of our patients.

DEFINITIONS
Controlled Medication Review A scheduled medicine (I – V) as defined by the Controlled Substance Act of 1970.

1. **Schedule I** drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Providers are unable to write prescriptions for this class though they are sometimes available for research only.
2. **Schedule II** drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. No Refills; these can only be faxed if patient is in Hospice or long-term medical facility. Prescription is limited to 30 days' worth of doses, although exceptions are made for cancer patients, burn victims, etc. and oral prescriptions for schedule II drugs must be confirmed in writing within 3 days.
    a. **Oxycodone, Hydromorphone, Hydrocodone, Fentanyl, Methadone, Meperidine, Morphine**
    b. Amphetamines/dextroamphetamines/Methylphenidate
3. **Schedule III** V drugs, substances, or chemicals with a moderate to low potential for physical and psychological dependence. May prescribe up to 5 months of refills if non-opioid. **May prescribe maximum of 2 refills if opioid.** Currently, may print/sign or phone in but not electronically transmit by EMR.
    a. Schedule III Butalbital (specifically Fiorinal, **Fiorinal with Codeine**, and **Fioricet with Codeine**)
    b. Schedule IV Benzodiazepines, Butorphanol, Phenobarbitol, Zolpidem (Ambien), Eszopiclone (Lunesta), Zaleplon (Sonata), **Tramadol (Ultram)**
    c. Schedule V **Codeine**, Lomotil, Lyrica

Policy Definitions

1. SMA - Supervised Medication Agreement
2. CSA - Controlled Substance Agreement
3. PMP - Prescription Monitoring Program; State Database of Controlled Substance prescriptions that a patient has obtained from state pharmacies
4. UDS - Urine Drug Screen

5. MME - Morphine Milligram Equivalent dose
6. PCP - Primary Care Provider
7. ED - Emergency Department
8. Opioids - Substances that act on opioid receptors. These include, but are not limited to, the schedule II, III, IV and V drugs noted in bold face type above. Because **Lomotil** is not considered a pain medication, it is **not subject to the VA DHP regulations or FCM policy**, though should be prescribed carefully and monitored for abuse.
9. FCM – Department of Family and Community Medicine

SCOPE

This policy applies to all providers who see patients at any of the Department of Family and Community Medicine (FCM) clinical sites.

PROCEDURE

Prescribing Guidelines

1. The prescribed use of opioid/narcotic medications for short courses to manage **acute pain (less than 3 months)** is at the discretion of the health care provider. "Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months. A SMA should be considered if risk factors exist or if prescribing more than 2-3 days of medication. Initiation of opioid treatment for all patients shall include the following:
    a. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days. Treat with the lowest possible dose (department goal not to exceed 50 MME, which places the patient at significant increased risk for complication or death).
    b. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint and conduct an assessment of the patient's history and risk of substance abuse/misuse.
    c. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. **A PMP database query is required for any opioid prescription longer than 7 days duration.**
    d. The practitioner shall carefully consider and document in the medical record when there are reasons to exceed 50 MME/day.
    e. Prior to exceeding 90 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist. The preferred practice is to taper down and off rather than to escalate doses when pain is not managed effectively with lower doses.
    f. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 90 MME/day, or concomitant benzodiazepine is present.

g. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.
h. Medical records for acute pain The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

2. As of November of 2016, the Carilion Clinic Supervised Medication Agreement (SMA) will supersede all previous agreements, and should be initiated if one has not already been reviewed and signed.
3. **The following guidelines are for the use of Schedule II - V opioid medications for the management of non-malignant pain longer than 3 months. Following this guideline should be considered for any patient prescribed opioid medications for longer than 1 week or at any time based on provider discretion**.
    a. **Risk Evaluation Should be Performed**
        i. Review of personal and family history of alcohol or drug abuse/misuse, psychiatric conditions, and emotional or sexual abuse should be obtained and documented. Patients who are positive for these have a higher risk of controlled substance abuse and misuse potential.
        ii. Review present medication lists, with particular attention to active prescriptions for other controlled medications Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.
        iii. Review hepatic and renal function.
        iv. Patients who are age > 65 face increased risk.
        v. Patients who have obstructive sleep apnea (OSA) are at higher risk.
        vi. EKG should be performed if patient is on methadone (risk of QT prolongation).
        vii. History of dismissal from another provider for an opioid agreement violation.
        viii. **Use of the Opioid Risk Tool (ORT) screening tool is encouraged before initiating pain treatment with opioids beyond 7 days**.
        ix. Consider mood or depression screening tools such as PHQ-2, PHQ-9, GAD-7 or others where appropriate.
    b. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including
        i. The nature and intensity of the pain;
        ii. Current and past treatments for pain;
        iii. Underlying or coexisting diseases or conditions;
        iv. The effect of the pain on physical and psychological function, quality of life and activities of daily living;

v. A request for prior applicable records.

c. **SMA should be reviewed and signed and UDS obtained** (see "q" for UDS information) – In EPIC, order as "Supervised Medication Agreement" or "Controlled Substance Agreement" with the associated diagnosis of "Supervised Medication Agreement Signed" which should be added to the problem list. The SMA must be printed; initialed by the patient in all appropriate lines upon review by the patient; reviewed, discussed and signed by both the patient and prescribing clinician; then scanned into chart with copy given to patient. It is required to hold a risk, benefit and alternative approach discussion with the patient, obtain informed consent and include these discussions in the EHR. This discussion should include a discussion of the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs and also address the parameters of treatment, including those behaviors which will result in referral to a higher level of care, cessation of treatment, or dismissal from care. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective. The FCM EPIC Smartphrase .PAINPLAN can also help document these required steps.

d. **Add the Reason for the Chronic Prescription on the Problem List** – need specific diagnoses necessitating chronic pain treatment. "Chronic Pain" is not sufficient. In the Problem List Overview section of the pain Diagnosis, consider listing the date the SMA was signed as well as dates for most recent PMP and UDS check.

e. **PMP Database Search** – To be initiated at time of CSA/SMA.
   i. By Virginia law, PMP searches must be performed at the initiation of any opioid prescription that will last more than 7 days.
   ii. A PMP search at least every 3 months is required. Additional periodic requests should be made as clinically indicated.

f. **Treatment of Chronic Pain with Opioids**.
   i. Non-pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.
   ii. In initiating and treating with an opioid, the practitioner shall
      1. **Treat with the lowest possible dose (department goal not to exceed 50 MME**, which places the patient at significant increased risk for complication or death).
      2. If treatment exceeds 50 MME/day, carefully consider and document in the medical record the reasons.
      3. Prior to exceeding 90 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist. The **goal is to taper these patients to <50 MME/day.**
      4. **Prescribe naloxone for any patient when risk factors of prior overdose, substance abuse, doses in excess of 90 MME/day, or concomitant benzodiazepine or high-risk drug is present.**
      5. Document the rationale to continue opioid therapy every three months.
      6. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative

hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

g. **Functional Goals and Treatment Plan** Should be documented in progress note.
   i. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function, quality of life, and daily activities.
   ii. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
   iii. The prescriber shall document in the medical records the presence or absence of any indicators for medication misuse, abuse or diversion and shall take appropriate action.
   iv. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.
   v. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.
   vi. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.
   vii. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

h. The practitioner shall **regularly evaluate for opioid use disorder** and shall initiate specific treatment for opioid use disorder, consult with an appropriate healthcare provider, or refer the patient for evaluation for treatment if indicated.

i. **Medical records for chronic pain** the prescriber shall keep current, accurate and complete records in an accessible manner readily available for review to include:
   i. The medical history and physical examination;
   ii. Past medical history;
   iii. Applicable records from prior treatment providers and/or any documentation of attempts to obtain;
   iv. Diagnostic, therapeutic and laboratory results;
   v. Evaluations and consultations;
   vi. Treatment goals;
   vii. Discussion of risks and benefits;
   viii. Informed consent and agreement for treatment;
   ix. Treatments;
   x. Medications (including date, type, dosage and quantity prescribed and refills).

xi. Patient instructions; and
xii. Periodic reviews.

j. **Treatment**
   i. When initiating opioid therapy, short-acting opioids should be prescribed rather than long-acting formulations (LA/ER).
   ii. Long-acting medication for maintenance of pain relief and short-acting medication for breakthrough symptoms is recommended when needed. The breakthrough medication should not be prescribed or used as a standing dose.
   iii. Providers should not co-prescribe an opioid with the following medications (per VA Board Regulations in bold and Federation of State Medical Boards model policy). If there are extenuating circumstances, a provider may co-prescribe an opioid, but is required to document a tapering plan to achieve the lowest possible effective dose
      1. **all benzodiazepines (particularly alprazolam/Xanax)**
      2. **zolpidem (Ambien) and sedative hypnotics**
      3. promethazine (Phenergan)
      4. **carisoprodol (SOMA)**
      5. barbiturates (Fiorinal, Fioricet)
      6. quetiapine (Seroquel) (can potentiate opioid effect)
      7. **tramadol (which is also considered an opioid under the VA DHP regulations).**

k. **Refills**
   i. PCP – refills of controlled medications should be completed by the assigned PCP unless he/she is unavailable for more than 2 business days
   ii. Early refills – not authorized
   iii. One designated pharmacy – in the CSA/SMA, patient agrees to obtain controlled medications from one pharmacy only. If this pharmacy is changed, the change should be documented by an update of the CSA/SMA.
   iv. Patients may identify one designee to pick up prescriptions for them in the circumstance when they are unable to do so.
   v. A minor may not pick up a prescription for opioid medications for themselves or a parent.

l. **Lost or Stolen Prescriptions** – will NOT be refilled early as stated in the CSA/SMA.

m. **Compliance with other Treatment Modalities** – Continued controlled medication therapy requires the patient comply with and participate in all therapies and referrals the provider recommends. Provider should consider individual patient and regional health care circumstances such as lack of insurance, inability to afford therapies, lack of available local pain management resources, etc. when placing these expectations on the patient.

n. **Informing the Practice of other Controlled Medication Prescriptions** – Patients are required to inform the practice within the next 2 business days when other facilities (including the ED) prescribe them narcotic/opioid medications. Filling such medications may be in violation of the CSA/SMA.

o. **New Patients on Chronic Controlled Medications**

i. Patients seen for a new visit who are on controlled medications will need to be evaluated as to the appropriateness of this treatment plan. This should include review of records from the previous provider as well as relevant laboratory and/or radiology reports and consultant reports. A provider is under no obligation to prescribe controlled substances at a new patient appointment or on follow-up visits.
ii. A **PMP database check** is **required initially and at least every 3 months thereafter**. A **UDS** or similar is **required initially, every 3 months for the first year of treatment and at least every 6 months thereafter.** There must be documented informed consent, alternative treatments and a signed CSA/SMA. If the last prescription was filled by a pharmacy of a state not participating in a shared agreement with Virginia, the medication should be confirmed by a call to the last filling pharmacy.
iii. If a patient has previously been dismissed or left a Carilion practice due to a SMA or CSA violation, controlled medications should not be prescribed.
iv. Practices will see new patients who require pain management as part of their overall health care. However, our practices are not Pain Management Centers and will not continue to follow new patients who only desire pain management.

p. **Follow up**
   i. **At least every 3 months** – It is required that patients on chronic opioids have a CSA/SMA and are seen and have their pain addressed at least every 3 months by their assigned provider or delegate. The patient should be seen more frequently if the provider deems significant risk or concern.
      1. At least every 3 months, it is recommended that risk, abuse, aberrant behavior tools [such as the FCM Department EPIC Smartphrases (.PAINHPI and .PAINPLAN) or the Current Opioid Misuse Measure (COMM) screening tool] be utilized and reviewed by the provider. A positive screen should be addressed with the patient and documented in the EMR. Strong consideration should be made for the ongoing safety of continued prescription.
      2. Functional goals should be reviewed. One structure for doing so is by using 5 "A"s– Analgesia, Activity, Adverse Effects, Aberrant Substance-Related Behaviors and Affect. It is recommended that the tenets of the FCM pain follow-up template or Smartphrase .PAINHPI be used.
      3. PMP search is required at least every 3 months.
      4. These visits can be combined with other chronic diseases at the discretion of the provider.
   ii. **Annually** – It is recommended that patients on controlled substances for chronic pain management have an annual visit appointment where only the chronic pain issues are discussed and addressed. Annually, an in depth pain visit is required where the Supervised Medication Agreement must be reviewed and this review documented; a PMP search must be obtained; Current Opioid Misuse Measure (COMM) screening tool should be considered, though the FCM Department EPIC Smartphrases. PAINHPI and PAINPLAN can substitute.

q. **UDS** – should be performed at the initiation of a SMA; at a minimum of every 3 months for the first year; at least every 6 months thereafter; with closer monitoring as circumstances warrant. A UDS may be performed randomly by asking patient to come to office and give urine for specimen in order to get a prescription at the discretion of the provider. The UDS test is expensive and not covered by all insurers so judicious ordering is recommended and it should not be ordered on every patient visit unless there is concern for aberrant behavior/misuse. It is recommended that controlled substances **not** be prescribed or continued for a new patient until appropriate UDS results are obtained. UDS obtained external to our practices (including the Emergency Departments) should not necessarily be considered a disqualifier as the rate of false positives and negatives of those screens is high unless a confirmatory test is performed.
r. **Pill Counts** – Random calls for pill counts may be used, and are recommended for patients for whom there is a concern for diversion.
s. **Contract Violations** –See below
t. **No Mailing** – Prescriptions for opioid/narcotic medications should NOT be mailed.
u. **Printing Prescriptions** – It is expected that all prescriptions for controlled substances provided to the patient will be printed electronically on safety paper. In the rare event that the EPIC system is down and a handwritten prescription is given, it is expected that this will be documented in the patient record. Schedule III, IV and V medications must be issued electronically. These may be printed on safety paper, print/faxed on plain paper or called in by the nurse with appropriate documentation in the EHR.
    i. Pain Management Consultations – Consultation and possible co-management with a Pain Management specialist is recommended for patients on a MME dosage of > 50 and strongly recommended where reasonably available for patients on a MME dosage of > 90. Providers are strongly encouraged to titrate <90, especially where pain referral and co-management is not available.

URINE DRUG TESTING

1. Ordering
    a. **EPIC ordering** – The most recent available drug test "with confirmation" is recommended. As of the update of this policy, this was the **"Prescription Abuse Monitoring 15 Panel" (A23015)** under order entry.
    b. **Documenting time of last dose** – Providers or nurses MUST document date, time, and amount of last dose in order to allow for proper interpretation of the UDS. This should include all controlled substances that the patient is taking.
    c. **If checking for benzodiazepines such as clonazepam (Klonopin) or alprazolam (Xanax)** – List the drugs that should be present in the screen in the comments section of the order.
    d. **Clonazepam (Klonopin)** – should be ordered separately due to its decreased sensitivity in being picked up on the UDS.
2. Collecting
    a. Collect at least 40ml of fresh urine in a sterile urine container.
    b. Label the container in the presence of the patient with first and last name and DOB.
3. Interpreting

a. **Urine Creatinine** – a specimen consistent with normal human urine usually has a creatinine concentration greater than 20mg/dL. A concentration of less than 20mg/dL is considered abnormally dilute and less than 5mg/dL is not consistent with human urine.
b. **Confirmatory Testing** – all positive tests on the UDS 15 are automatically confirmed by follow-up gas chromatography or mass spectrometry testing.
c. **Illicit drug detection** – detection of illegal drugs (cocaine, marijuana, cannabinoids, etc.) or controlled medications that are not prescribed is considered a violation of the SMA.
d. **True Negative Urine Results** (binging vs. diversion) – the lack of prescribed controlled medication in a UDS when the last dose was documented within the window of detection is considered a violation of the CSA/SMA. Of note, due to its rapid metabolism, clonazepam could be taken appropriately and fail to be demonstrated in a UDS.
e. For assistance in interpreting results, call 1.877.40.RXTOX (1.877.407.9869) for the next available toxicology specialist at Quest.

VIOLATIONS OF CSA/SMA

1. Violations of the CSA/SMA include but are not limited to not giving a UDS sample when requested; UDS samples containing illegal substances, not containing prescribed substances or being too dilute; frequent calls for early refills; repetitive lost/stolen medication or prescription.
2. Patients who violate CSA/SMA will not be automatically dismissed from the practice but will be informed in writing that the practice will no longer be prescribing controlled medications to them. This will be documented in the problem list and FYI section of EPIC. Providers are encouraged to continue to provide medical care to these patients without the prescription or continuation of controlled medications. In extreme circumstances, if the provider believes that the patient needs to be dismissed from the practice, they should contact our Patient Liaison at 540-981-7798 or the Regional Medical Director.
3. Patients who violate a CSA/SMA will be educated about addiction and given information and resources to obtain addiction and substance abuse treatment and counseling. Resources can include **Substance Abuse and Mental Health Services Administration** 1-800-662-HELP at findtreatment.samhsa.gov and National Institute on Drug Abuse (NIDA) at drugabuse.gov.

OTHER ISSUES / CONCERNS

Separate documents will be created as "Guidelines" to provide tools to assist with the management of patients who are being treated for chronic non-malignant pain.

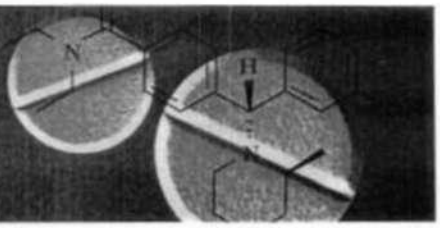
Approvals

Name	Title	Dept./Committee	Date
Michael Jeremiah, MD	Chair	Family and Community Medicine	
Kim Roe	VP	Family and Community Medicine	

Updated
1/2018

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW



Prescription opioids can be used to help relieve moderate-to-severe pain and are often prescribed following a surgery or injury, or for certain health conditions. These medications can be an important part of treatment but also come with serious risks. It is important to work with your health care provider to make sure you are getting the safest, most effective care.

WHAT ARE THE RISKS AND SIDE EFFECTS OF OPIOID USE?

Prescription opioids carry serious risks of addiction and overdose, especially with prolonged use. An opioid overdose, often marked by slowed breathing, can cause sudden death. The use of prescription opioids can have a number of side effects as well, even when taken as directed:

- Tolerance—meaning you might need to take more of a medication for the same pain relief
- Physical dependence—meaning you have symptoms of withdrawal when a medication is stopped
- Increased sensitivity to pain
- Constipation
- Nausea, vomiting, and dry mouth
- Sleepiness and dizziness
- Confusion
- Depression
- Low levels of testosterone that can result in lower sex drive, energy, and strength
- Itching and sweating

receiving prescription opioids long term in a primary care setting struggles with addiction.

* Findings from one study

RISKS ARE GREATER WITH:

- History of drug misuse, substance use disorder, or overdose
- Mental health conditions (such as depression or anxiety)
- Sleep apnea
- Older age (65 years or older)
- Pregnancy

Avoid alcohol while taking prescription opioids. Also, unless specifically advised by your health care provider, medications to avoid include:

- Benzodiazepines (such as Xanax or Valium)
- Muscle relaxants (such as Soma or Flexeril)
- Hypnotics (such as Ambien or Lunesta)
- Other prescription opioids

CDC U.S. Department of Health and Human Services Centers for Disease Control and Prevention

American Hospital Association

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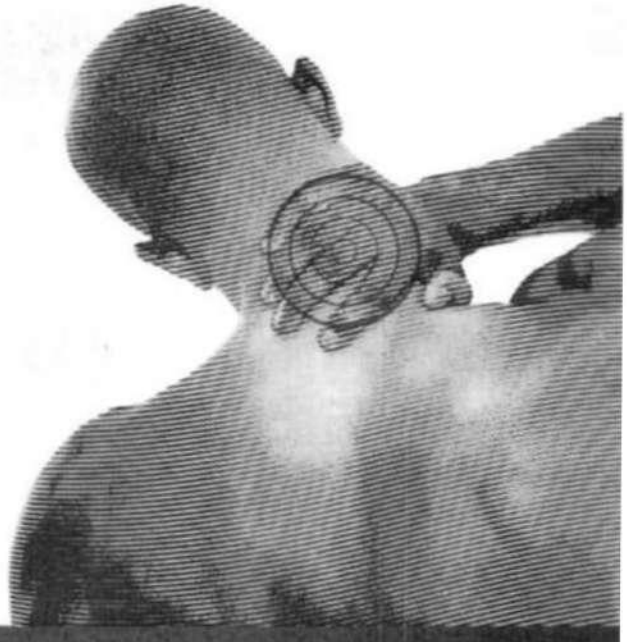
KNOW YOUR OPTIONS

Talk to your health care provider about ways to manage your pain that don't involve prescription opioids. Some of these options **may actually work better** and have fewer risks and side effects. Options may include:

- ☐ Pain relievers such as acetaminophen, ibuprofen, and naproxen
- ☐ Some medications that are also used for depression or seizures
- ☐ Physical therapy and exercise
- ☐ Cognitive behavioral therapy, a psychological, goal-directed approach, in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress.

Be Informed!

Make sure you know the name of your medication, how much and how often to take it, and its potential risks & side effects.



IF YOU ARE PRESCRIBED OPIOIDS FOR PAIN:

- ☐ Never take opioids in greater amounts or more often than prescribed.
- ☐ Follow up with your primary health care provider within ___ days.
  - – Work together to create a plan on how to manage your pain.
  - – Talk about ways to help manage your pain that don't involve prescription opioids.
  - – Talk about any and all concerns and side effects.
- ☐ Help prevent misuse and abuse.
  - – Never sell or share prescription opioids.
  - – Never use another person's prescription opioids.
- ☐ Store prescription opioids in a secure place and out of reach of others (this may include visitors, children, friends, and family).
- ☐ Safely dispose of unused prescription opioids: Find your community drug take-back program or your pharmacy mail-back program, or flush them down the toilet, following guidance from the Food and Drug Administration (www.fda.gov/Drugs/ResourcesForYou).
- ☐ Visit www.cdc.gov/drugoverdose to learn about the risks of opioid abuse and overdose.
- ☐ If you believe you may be struggling with addiction, tell your health care provider and ask for guidance or call SAMHSA's National Helpline at 1-800-662-HELP.

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

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FAMILY AND COMMUNITY MEDICINE

Dear @NAME@,

I want to notify you regarding strict new laws the Virginia Board of Medicine enacted on March 15, 2017, which affect the prescribing of opioid (narcotic) medications for pain. This law was enacted due to concerns regarding a statewide increase in opioid addiction, abuse, overdoses and opioid related deaths. This new law requires a change in my practice as well as all medical practices in our state. The following changes will be made immediately in accordance to this new law

- A Supervised/Controlled Substance Agreement and its requirements will need to be read, understood and signed.
- Office visits for pain management will need to occur at least every 3 months. Refills for opiates will not be provided for tardy visits until an office visit has been completed.
- For patients on higher dosages of opiates, I may require office visits every month. The new policies and regulations require that I taper doses below strict levels and to the lowest possible dose. Additionally, for some patients, I am required to make a referral to a pain management specialist.
- Due to the strict new laws, it is important to adhere to changes in your medication refill process. Please discuss this with your provider.
- A urine drug screen is now required at least every 3-6 months.
- Because of the increased risk of accidental overdose, if you are on the following medications (in addition to your pain medicines), I will need to taper you off these medications benzodiazepines (Xanax, Klonopin, Ativan, Valium, Restoril, etc), sedative hypnotic sleeping pills (Ambien, Sonata, Lunesta) and certain muscle relaxers (Soma/Carisoprodol).

Given the new law, I ask that you please schedule an office visit so that we can review our goals for your pain management.

In closing, I apologize for any inconveniences that this new law presents. However, I am obligated to adhere to laws passed by Virginia legislature and overseen by the Virginia Board of Medicine. With that said, I remain committed to providing optimal and safe medical care, which includes your pain management.

Sincerely,

@ME@

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

Opioid and Buprenorphine Prescriber Regulations Guide

MSV℠
MEDICAL SOCIETY OF VIRGINIA

Updated
1/2018

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

The Virginia Board of Medicine has adopted emergency regulations 18 VAC 85-21-10 et seq. that establish new rules regarding the prescribing of opioids for pain treatment and buprenorphine for addiction treatment. The regulations became effective March 15, 2017 and reflect updates released on August 24, 2017. We have published an abbreviated summary of the new regulations for your reference. To view a full copy of the regulations, please visit the Virginia Board of Medicine website.

New Requirements for Treating Acute Pain
(Pain lasting less than 3 months)

Step 1
Before prescribing an opioid for acute pain, consider the following:

- Consider non-pharmacologic and non-opioid treatments. If an opioid is necessary for acute pain treatment, prescribe short-acting opioids at the lowest effective dose and frequency

Step 2
Query the Prescription Monitoring Program (PMP) in accordance with Virginia Code § 54.1-2522.1.

- Query the PMP for opioid prescriptions longer than 7 days and longer than 14 days following surgery or invasive procedures, unless exempted.
  - Effective upon Governor's signature (Spring 2017)
  - Current law and exceptions can be found here.
- Assign delegate to query the PMP on your behalf.

Step 3
Follow these guidelines when choosing the strength, length, and pill supply:

- Limits to the number of days in a supply:
  - Acute: 7 days*
  - Emergency department discharge: 7 days*
  - Post-surgical: 14 days*
- Limits to the number of pills in a supply:
  - Follow manufacturer's directions for use*
- Limits to the prescribed strength:
  - > 50 MME, document reasons in the medical record
  - > 120 MME, document reasonable justification or refer to or consult with a pain management specialist

**May prescribe longer and/or exceed the manufacturer's directions for use if extenuating circumstances are clearly documented in the medical record.*

Special Considerations

Do co-prescribe naloxone when the following risk factors exist:

- Prior overdose
- Substance misuse
- Doses in excess of 120 MME/day
- Concomitant benzodiazepine is present

Don't co-prescribe an opioid if these medications are currently prescribed:*

- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

**If there is an extenuating circumstance, a prescriber may co-prescribe an opioid. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.*

Buprenorphine is not indicated for acute pain in outpatient setting, except when a waivered buprenorphine prescriber is treating pain in a patient whose primary diagnosis is the disease of addiction.

Step 4
Include the following required documentation in the medical record:

- Description of the pain
- Presumptive diagnosis for the pain origin
- Examination appropriate to the complaint
- Treatment plan
- The medication prescribed or administered and include the date, type, dosage, and quantity

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New Requirements for Treating Chronic Pain
(Pain lasting more than 3 months)

Step 1
Before prescribing an opioid for chronic pain, complete the following:

- Consider non-pharmacologic and non-opioid treatment for pain
- Perform a medical history, physical examination, including a urine drug screen or serum medication level, and mental status examination and document in the medical record
- Discuss with the patient:
  - The known risks and benefits of opioid therapy
  - The responsibilities of the patient during treatment, including secure storage and proper disposal
  - An exit strategy for the discontinuation of opioids if not effective

Step 2
Query the Prescription Monitoring Program (PMP) in accordance with § 54.1-2522.1 of the Virginia Code.

- Query the PMP for opioid prescriptions longer than 7 days and longer than 14 days following surgery or invasive procedures, unless exempted.
  - Effective upon Governor's signature (Spring 2017)
  - Current law and exceptions can be found here.
- May assign a delegate to query the PMP on your behalf.

Step 3
When choosing the strength of an opioid prescription, follow these guidelines:

- Limits to the prescribed strength:
  - > 50 MME/day, document reasons in the medical record
  - > 120 MME/day, document reasonable justification in the medical record and refer to or consult with a pain management specialist

Special Considerations

Do co-prescribe naloxone when the following risk factors exist:

- Prior overdose
- Substance misuse
- Doses in excess of 120 MME/day
- Concomitant benzodiazepine is present

Do regularly evaluate for opioid use disorder and initiate treatment, consult with an appropriate healthcare provider, or refer for evaluation for treatment if indicated

Don't co-prescribe an opioid if the patient is already taking these medications*

- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

**If there is an extenuating circumstance, a prescriber may co-prescribe an opioid. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.*

Don't prescribe buprenorphine mono-product in the tablet form for chronic pain.

Step 4

Establish a treatment plan that includes:

- Measures to determine progress in treatment
  - Pain relief and improved physical and psychosocial function
  - Quality of life
  - Daily activities
- Further diagnostic evaluations and the extent to which the pain is associated with physical and psychosocial impairment
- The presence or absence of any indicators for medication misuse or diversion and take appropriate action

Step 5

Include informed consent in the medical record:

- Risks
- Benefits
- Alternative approaches

Step 6

Include a written treatment agreement in the medical record that includes:

- Parameters of treatment
- Permission for the practitioner to obtain urine drug screens or serum medication levels, query and receive reports from the PMP, and consult with other prescribers or pharmacists
- Expected outcomes of treatment
- Limitations and side effects
- Patient signature

Step 7

During the course of treatment, complete the following every 3 months:

- Review the course of treatment
- Document the rationale to continue opioid therapy
- Check the Prescription Monitoring Program
- Order and review a urine drug screen or serum medication levels at least every 3 months for the first year of treatment and at least every 6 months thereafter
- If continuing opioid treatment, document the continued benefit in the medical record. If a patient's progress is unsatisfactory, consider other treatment options

Step 8

Perform additional consultations if needed

- When necessary to achieve treatment goals, refer the patient for additional evaluation and treatment
- When a prescriber makes the diagnosis of opioid use disorder, the prescriber shall:
  - Initiate treatment for opioid use disorder OR
  - Refer the patient for evaluation and treatment

Step 9

Keep detailed medical records that include:

- Medical history and physical examination
- Past medical history
- Applicable records from prior treatment providers and/or any documentation of attempts to obtain
- Diagnostic, therapeutic and laboratory results
- Evaluations and consultations
- Treatment goals
- Discussion of risks and benefits
- Informed consent and agreement for treatment
- Treatments
- Medications (including date, type, dosage, and quantity prescribed and refills)
- Patient instructions
- Periodic reviews

Updated
1/2018

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

MEDICAL SOCIETY OF VIRGINIA MSV

New Requirements for Prescribing of Buprenorphine for Addiction Treatment

Step 1

All prescribers must be waivered by the Substance Abuse Mental Health Services Administration (SAMHSA), registered with the Drug Enforcement Administration (DEA), and follow all state and federal laws governing buprenorphine prescribing.

- **Nurse Practitioners and Physician Assistants must be waivered and have a practice agreement with a waivered physician**

Step 2

Before prescribing buprenorphine to treat opioid use disorder, perform and document a patient assessment that includes:

- **Comprehensive medical and psychiatric history**
- **Substance misuse history**
- **Family history and psychosocial supports**
- **Appropriate physical examination**
- **Urine drug screen**
- **Pregnancy test for women of childbearing age and ability**
- **Infectious disease testing for HIV, Hepatitis B, Hepatitis C and TB, when clinically indicated**

Step 3

Query the Prescription Monitoring Program (PMP) before initiating and during treatment

- **May assign a delegate to query the PMP on your behalf.**

Step 4

Establish a treatment plan that includes:

- **The practitioner's rationale for selecting medication assisted treatment**
- **Patient education**
- **Written informed consent**
- **How counseling will be accomplished**
- **A signed treatment agreement that outlines the responsibilities of the patient and the prescriber**

Special Considerations

Do refer the patient to a mental health service provider, as defined by § 54.1-2400.1 of the Virginia Code, for counseling or provide counseling within the practice and document in the medical record

Don't co-prescribe buprenorphine if the patient is already taking these medications*

- Benzodiazepines
- Sedative hypnotics
- Carisoprodol
- Tramadol

**If there is an extenuating circumstance, a prescriber may co-prescribe buprenorphine. In this case, the prescriber is required to document a tapering plan to achieve the lowest possible effective dose.*

Step 5

During the induction phase, follow these guidelines:

- **Initiate treatment with no more than 8 mg. buprenorphine, except for medically indicated circumstances as documented in the medical record**
- **The prescriber shall see the patient at least once a week**

Step 6

During the stabilization phase, follow these guidelines:

- **Increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving**

Step 7

During the course of treatment:

- Ensure counseling for the patient (see special considerations for details)
- Limits to strength of prescription:
  - Document in the medical record rationale for prescribed doses exceeding 16 mg. of buprenorphine per day
  - Do not exceed 24 mg. of buprenorphine per day
- Require urine drug screens or serum medication levels at least every 3 months for the first year of treatment and at least every 6 months thereafter
- Take steps to reduce the chances of buprenorphine diversion by:
  - Using the lowest effective dose
  - Appropriate frequency of office visits
  - Pill counts
  - Checks of the Prescription Monitoring Program (PMP)
- Incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined by § 54.1-2400.1 of the Virginia Code

Step 8

Include the following required documentation in the medical record

- Records shall be timely, accurate, legible, complete and readily accessible for review
- Treatment agreement and informed consent
- Confidentiality requirements of 42 CFR Part 2
- Compliance with Board of Medicine Regulations 18VAC85-20-27

Prescribing Limits of Buprenorphine Mono-products:

- Do not prescribe buprenorphine without naloxone (buprenorphine mono-product) unless:
  - The patient is pregnant
  - Converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed 7 days
  - Prescribing in formulations other than tablet form for indications approved by the FDA
  - Prescribing for patients who have demonstrated intolerance to naloxone. Such prescriptions shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber and the exception shall be clearly documented in the patient's medical record.
- Buprenorphine mono-tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs), but, with the exception of those conditions listed above, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite from the program
- Document in the medical record evidence for the decision to use buprenorphine mono-product

Special Populations in Addiction Treatment:

- Pregnant women
  - May be treated with buprenorphine mono-product, usually 16 mg. per day or less
- Patients under 16 years
  - Do not prescribe buprenorphine for addiction treatment unless such treatment is approved by the FDA
- Patients with chronic pain
  - Assess the progress of patients with chronic pain by reduction of pain and functional objectives which can be identified, quantified and independently verified
- Patients with medical comorbidities:
  - Evaluate by history, physical exam, appropriate laboratory studies, and be aware of interactions of buprenorphine with other prescribed medications
- Patients with psychiatric comorbidities and that are not stable
  - Do not undertake buprenorphine treatment
  - Refer the patient for psychiatric evaluation and treatment prior to initiating medication-assisted treatment

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

MEDICAL SOCIETY OF VIRGINIA MSV

Contact Information

Virginia Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463
Telephone: 804-367-4600
medbd@dhp.virginia.gov

Virginia Prescription Monitoring Program
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
Telephone: 804-367-4514 or 804-367-4409
Fax: 804-527-4470
pmp@dhp.virginia.gov

Medical Society of Virginia
2924 Emerywood Pkwy Ste 300
Richmond, VA 23294-3746
804-377-1033
healthpolicy@msv.org

TABLE 2. MORPHINE MILLIGRAM EQUIVALENT (MME) DOSES FOR COMMONLY PRESCRIBED OPIOIDS

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf).

Updated
1/2018

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FAMILY AND COMMUNITY MEDICINE

PRESCRIBE TO SAVE LIVES!

Increasing access to naloxone for at-risk individuals and their families is supported by the American Medical Association, American Pharmacists Association, American Society of Addiction Medicine, the World Health Organization and the Office for National Drug Control Policy.[3-7] Also see: **www.prescribetoprevent.org**




	INTRA-NASAL	INTRA-NASAL RELEASED IN 2016	IM	AUTO-IM
STRENGTH	Naloxone 1mg/1mL	Naloxone 4mg/0.1mL	Naloxone 0.4mg/1mL	Naloxone 0.4mg/1mL
QUANTITY	Two 2 mL prefilled Luer-Jet™ Luer-Lock needleless syringe PLUS 2 mucosal atomizer devices (MAD-300)	#1 two pack	Two single-use 1 mL vials	#1 two pack
SIG *for suspected opioid overdose*	Spray 1 mL (half of the syringe) into each nostril. Repeat after 2-3 minutes if no or minimal response.	Spray full dose into one nostril. Repeat into other nostril after 2-3 minutes if no or minimal response.	Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.	Use as directed by voice-prompt. Press black side firmly on outer thigh. Repeat after 2-3 minutes if no or minimal response.
REFILLS	Two	Two	Two	Two

OFFER BUPRENORPHINE TREATMENT

- Highly effective in reducing illicit opioid use[8,9]
- Associated with reduced overdose death rates[10]
- Very low risk for overdose
- Decreased risk of abuse
- Available in ambulatory care settings

BUPRENORPHINE TRAINING & CERTIFICATION

- eTraining and Practice Tools **www.buppractice.com**
- Buprenorphine Physician Training Events **www.buprenorphine.samhsa.gov/training.html**
- Providers Clinical Support System for Medication Assisted Treatment (PCSS-MAT) **www.pcssmat.org**

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4. *APhA Policy: Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents.* (apha 54(4) July/August 2014)(reviewed 2015). www.pharmacist.com
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6. *Opioid Overdose: preventing and reducing opioid overdose mortality.* Discussion paper UNODC/WHO 2013. www.unodc.org
7. *Fact Sheet: Preventing, Treating, and Surviving Overdose.* Office of National Drug Control Policy, Office of Public Affairs. August 28, 2013. www.whitehouse.gov
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9. Heer YI, Evans E, Huang D, Weiss R, Saxon A, Carroll KM, Woody G, Liu D, Wakim P, Matthews AG, Hatch-Maillette M, Jolstrom E, Wiest K, McLaughlin P, Ling W. Long-term outcomes after randomization to buprenorphine/naloxone versus methadone in a multi-site trial. Addiction 2015 Nov 24.
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PRESCRIBE
T:: Save Lives

Tapering

A gradual reduction of benzodiazepines and barbiturates is slower than opiates. For benzodiazepines the dose should be reduced by less than 10% every 3 days. Opioids can be tapered at a higher percentage of 20% every other day. 1 week for opiates and up to 8 weeks for benzodiazepines. If the reduction of more than one medication is indicated and contacts with the patient are limited, it is probably wisest to decrease only one at a time. Provide the patient with a daily taper schedule and ask the patient to call periodically with an update.

Pain Clinical Manual Second edition Margo McCaffery, RN, MS, FAAN, Chris Pasero RN,

MSNc, mosby 1999.

INTERPRETATION OF OPIATE URINE DRUG SCREENS

Health Partners Evidence-based Summary

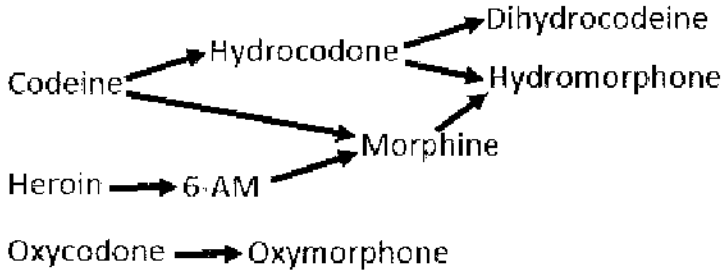
Urine drug testing is highly reliable, but false positives can rarely occur for some drugs. As always, clinical judgment is necessary when interpreting test results. The length of time a drug can be detected in the urine varies due to several factors, including hydration, dosing, metabolism, body mass, urine pH, duration of use, and a drug's particular pharmacokinetics. (See table below for some "average" times for different drugs.)

Length of Time Drugs of Abuse Can Be Detected in UrineDrug	**Time**
Alcohol	7-12 h
Amphetamine	48 h
Methamphetamine	48 h
Barbiturate	
Short-acting (eg, pentobarbital)	24 h
Long-acting (eg, phenobarbitol)	3 wk
Benzodiazepine	
Short-acting (eg, lorazepam)	3 d
Long-acting (eg, diazepam)	30 d
Cocaine metabolites	2-4 d
Marijuana	
Single use	3 d
Moderate use (4 times/wk)	5-7 d
Daily use	10-15 d
Long-term heavy smoker	30 d
Opioids	
Codeine	48 h
Heroin (detected as morphine)	48 h
Hydromorphone	2-4 d
Methadone	3 d
Morphine	48-72 h
Oxycodone	2-4 d
Propoxyphene	6-48 h
Phencyclidine	
	8 d

-- Mayo Clinic Proc. 2008; 83(1)66-76

Sometimes the specific drug ingested is not detected, but instead one of its metabolites is found.

Opiate/Opioid Metabolism



Two types of urine drug tests are used for HealthPartners patients – immunoassay and gas chromatography-mass spectrometry (GC/MS). The first test done is the immunoassay. This can be susceptible to false positives, so when a positive result is obtained it is confirmed by GC/MS.or the pain management urine drug screen,/MS is done for these drugs regardless of the immunoassay screen result morphine, codeine, oxycodone, oxymorphone, hydrocodone, hydromorphone. The GC/MS confirmation assays are highly reliable and specific tests with very rare interferences. Fentanyl (Duragesic) is not easily detected in either urine or serum. Our current system does not allow accurate determination of the presence of this drug. HealthPartners may purchase new equipment that will make this possible within the next year. Until that happens, you will not be able to tell whether a patient is using fentanyl (Duragesic patches) based on the results of the urine drug screen.

Discussion

Current urine drug testing methods were designed to identify illicit use of drugs in the forensic or occupational setting. In this setting, high specificity was needed to avoid a false positive result and this was carried out by using a relatively high cutoff concentration needed to trigger a positive result. In the setting of pain management compliance testing, both drug pharmacokinetics (how the body acts on a drug) and testing limitations that affect the results of urine testing must be understood for proper interpretation.

Although the name "opiate" is often used to describe any member of the class of drugs that acts on opioid receptors, the term "opiate" properly refers to the natural alkaloids found in opium poppy resin (Papaver somniferum), which include morphine, codeine and thebaine. The term "opioid" refers to the synthetic and semi-synthetic opioid receptor drugs, including heroin, hydromorphone, hydrocodone, oxycodone, oxymorphone, buprenorphine, fentanyl, and methadone.

Drug	Half-life (hr)	Metabolites	Concentrations above the cutoff will screen positive for
morphine	1.5 - 6.5	normorphine, **hydromorphone (<2.5%)**	Opiates
codeine	1 - 4	**morphine, hydrocodone (<11%)**, norcodeine	Opiates
oxycodone	4 - 12	**oxymorphone**, noroxycodone	Oxycodone
oxymorphone	3 - 6	6-hydroxy-oxymorphone	Oxycodone
hydrocodone	3.5 - 9	**hydromorphone**, norhydrocodone, **dihydrocodeine**	Opiates
hydromorphone	3 - 9	hydromorphol	Opiates

* **bolded** metabolites are identical to pharmaceutically available drugs

Assay Technologies The pain management urine drug screen offered within the HealthPartners Family of Care consists of two steps. First, a qualitative (positive/negative) immunoassay screen is completed, including tests for opiates (300 ng/mL cutoff), oxycodone (100 ng/mL cutoff), amphetamine, barbiturate, benzodiazepines, cocaine, methadone, PCP, propoxyphene, and THC. These drugs are reported as positive if they are present at a concentration above the designated cutoff (see Regions Hospital Laboratory Toxicology website on myPartner for specific cutoffs and drugs detected) and confirmed as positive by GC/MS. For the pain management panel only, regardless of the screen results, GC/MS confirmation for the following drugs are completed and reported individually as positive/negative with a detection limit of 100 ng/mL morphine, codeine, oxycodone, oxymorphone, hydrocodone, hydromorphone. This allows for higher sensitivity and specificity along with offering results for each drug individually.

In general, immunoassay technologies are susceptible to interfering substances (false positives) and cross-reactivity (true positives for non-target drugs, due to structural similarity) to varying degrees. Accordingly, each result needs to be interpreted in the context of the clinical picture and in conjunction with our confirmatory method of gas chromatography/mass spectrometry (GC/MS). The immunoassay for opiates is primarily targeted to detecting morphine, hydrocodone, dihydrocodeine, codeine, 6-acetylmorphine (metabolite of heroin), and hydromorphone. Due to that assay's insensitivity for oxycodone, the oxycodone assay is utilized to detect oxycodone and oxymorphone. The GC/MS confirmation assays are highly reliable and specific tests with very rare interferences.

Detection Windows

The window to detect the presence of a particular drug in a person's urine is highly dependent on multiple factors, such as Hydration - More dilute urine from high fluid intake may cause dilution of drug and therefore a negative result due to levels present but below the cutoff. Conversely, a patient may greatly reduce fluid intake in order to concentrate their urine when trying to mask inappropriate reduced intake of their prescribed drug.

Dosing - If a patient is on a low dose or has a long interval between doses, the level of drug in their urine may be too low to be detected by the immunoassay or confirmation assay, i.e. below the cutoff. Similarly, the time between the last dose of a drug taken and the collection of the urine specimen may affect if the drug is present at concentrations adequate to produce a positive result.

Metabolism - Metabolism is unique to each individual, determined by genetic and environmental factors. Genetic polymorphisms of the CYP450 2D6 enzyme can cause individuals to be poor or rapid metabolizers of opioids and other drugs metabolized by those enzymes1. Additionally, environmental influences further complicate metabolism. For example, co-administered drugs that are also metabolized by CYP450 enzymes used by the opioids or that inhibit CYP450 2D6 cause decreased metabolism, see Table below. Conversely, rifampin and dexamethasone are known to induce CYP450 2D6, causing increased metabolism of opioids with a resulting shortened detection window. Other factors affecting metabolism include age, sex, ethnicity, and renal or liver impairment.

TABLE 3. Cytochrome P450 2D6 Substrates, Inhibitors, and Inducers

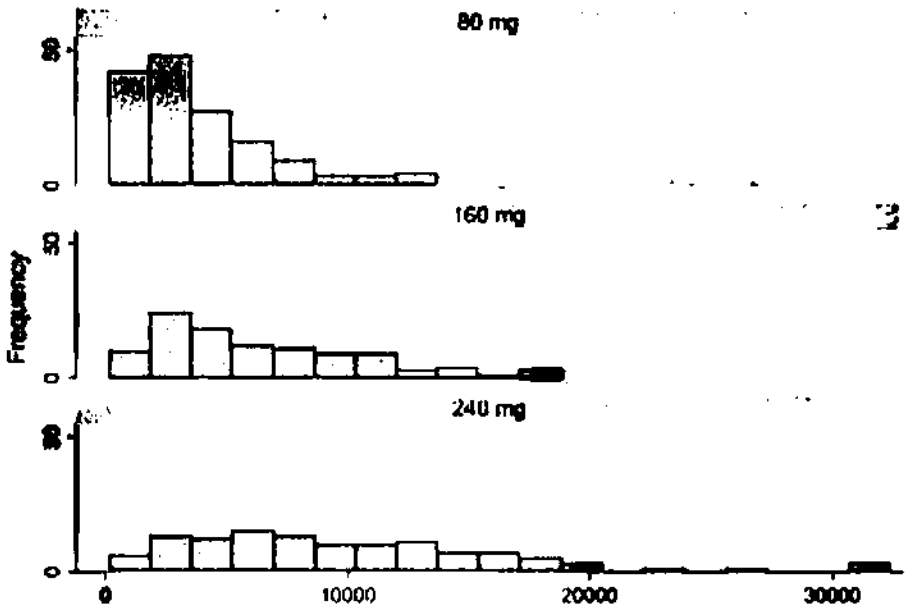
Substrates		Inhibitors		Inducers
Antiarrhythmic agents	*SSRIs*	*Antidepressants*	*Antihistamines*	*Antibiotic*
Encainide	Fluoxetine	[illegible]	Chlorpheniramine	Rifampin
Flecainide	Fluvoxamine	Quinidine	*Histamine H_2 receptor antagonists*	*Glucocorticoid*
Lidocaine	Paroxetine	*Antipsychotic agents*	Cimetidine	Dexamethasone
Mexiletine	*Tricyclics*	Chlorpromazine	Ranitidine	
Propafenone	Amitriptyline	[illegible]peridol	*Other drugs*	
Sparteine	Amoxapine	[illegible]mine	Celecoxib	
β-Blockers	Clomipramine	*SNRI*	Doxorubicin	
Alprenolol	Desipramine	Duloxetine	Ritonavir	
Carvedilol	Doxepin	*SSRIs*	Terbinafine	
Metoprolol	Imipramine	Citalopram		
Propranolol	Nortriptyline	Escitalopram		
Timolol	*Other drugs*	Fluoxetine		
Antipsychotic agents	Amphetamine	Paroxetine		
Aripiprazole	Chlorpheniramine	Sertraline		
Haloperidol	Debrisoquine	*Tricyclic*		
Perphenazine	Dextromethorphan	Clomipramine		
Risperidone	*Histamine H_1 receptor antagonists*	*Other antidepressant/ antiemetic/antibiotic agents*		
Thioridazine	Metoclopramide	Bupropion		
Zuclopenthixol	Phenformin	Moclobemide		
SNRIs	Tamoxifen			
Duloxetine				
Venlafaxine				

SNRI = serotonin norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor.
From Indiana University School of Medicine,[2] with permission.

Other Factors

The detection window of a drug is also affected by duration of use, body mass, urine pH and a drug's particular chemistry, i.e. half-life and volume of distribution. If a negative result is obtained for a drug prescribed to the patient, the entire clinical picture must be taken into consideration to determine if the patient was 1) not taking the drug, 2) taking a lower dose than instructed, or 3) taking the drug properly but the results were negative due to one of above factors. Similarly, if a positive result is obtained for a drug not prescribed to the patient, the entire clinical picture must be taken into consideration to determine if the patient was taking the non-prescribed drug, has a false positive result (applies to immunoassay only) or if the drug is simply a metabolite of a prescribed drug (as applicable).

The following figure exemplifies the amount of variation possible in the concentration of drug present in individuals taking the same dose of a drug2. In this example, 36 healthy participants that had taken no drugs in the previous 30 days were given one of 3 doses (n=12 per dose) of OxyContin®. The following shows the combined distribution of multiple urine specimens taken from each individual days 3 and 4 after dosing began



Raw LC-MS-MS Distribution by Dose Level

Interpretation Cautions

- Interferents, sensitivity and cutoffs vary by immunoassay, see Reference 3 for a review of immunoassay types and interferents; EMIT assays are used by Regions Hospital's Toxicology lab, which serves the entire HP Family of Care.
- Hydromorphone has been shown to be a minor metabolite in chronic pain patients receiving high amounts of morphine.4,5
- Hydrocodone has been shown to be a minor metabolite detectable in patients on high amounts of codeine6; as the metabolite of hydrocodone, hydromorphone may also be detectable in these cases.
- A small amount of codeine may be evident with morphine administration due to manufacturing impurities (up to 0.04% of parent dose); high amounts of morphine should be present in these cases.7
- A small amount of hydrocodone may be evident with oxycodone administration due to manufacturing impurities; high amounts of oxycodone should be present in these cases8
- Ingestion of poppy seeds or herbal teas containing Papaveris fructus may cause a true positive opiate (morphine, codeine) results.9,10
- Oxymorphone has a longer half-life than oxycodone; a patient prescribed oxycodone may only have oxymorphone detected in urine.
- Heroin is metabolized to morphine, which may be detectable after its use.

- The dose taken cannot be extrapolated from drug screen results, even if a quantitative result is obtained.

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11. Moeller K, Lee K, Kissack J. Urine Drug Screening Practical Guide for Clinicians. Mayo Clinic Proc. 2008; 83 66-76.

Questions

Please reply to this e-mail, and your questions(s) will be directed to the author of this Pearl, Kalen Olson, PhD, Clinical Laboratory Director.

Pearl Archive HUhttp//www.imehealthpartners.comU
All Pearl recommendations are consistent with professional society guidelines,
and reviewed by HealthPartners Physician Leadership.

POLICY / PROCEDURE TERMINATION OF PHYSICIAN – PATIENT RELATIONSHIPS CARILION CLINIC PRACTICES

Key Terms
Dismissal, Termination, Abandonment, Supervised Medication Agreement, No Show, Verbal Abuse)

I. PURPOSE
The Physician-Patient relationship is built on mutual trust, respect and a shared responsibility that has therapeutic implications for patients. This policy outlines criteria and obligations that should be met to terminate a physician-patient relationship, mitigate risk to the physician, staff and Carilion Clinic, and comply with regulatory and legal requirements.

Ii. Scope
The scope of this policy applies to all patients receiving care from a Carilion Clinic practice, and all staff working for Carilion Clinic practices.

Iii. Definitions
- Electronic Medical Record (EMR) Computerized charting system containing patient information.
- Abandonment The state of casting away, leaving or deserting a patient with an acute problem or in a medical crisis.
- Termination The ending of a relationship with a specific physician.
- Dismissal Written notification of discharge from the care of a specific physician or physicians.
- No Show Failure to keep a scheduled appointment in one practice within the calendar year without contacting the physician practice in advance to notify of cancellation. Safe Watch Carilion's event reporting system
- Verbal Abuse use of words to cause harm to the person being spoken to through insults, intimidation, threatening, shaming, demeaning or otherwise derogatory communication.

Iv. Procedure
The following criteria may be considered for dismissal / termination:

1. Verbal abuse, threats of physical harm, stalking or sexual advances towards any Carilion Clinic physician, staff or other patients may result in immediate termination and dismissal from a Carilion Clinic practice. Behaviors and dismissal need to be documented in the patient's medical record.
2. Repeated failure to keep 3 consecutive, scheduled appointments in the same practice in a 12-month period without contacting the physician practice may be considered for dismissal. Consideration should be made to allow a patient to utilize same day open appointments for medical needs when available prior to dismissal. In the event the No Show is for a referral appointment, the referral may be discontinued, requiring a new referral to be made. Appointments may be scheduled as available.

Process for Physician-Patient Termination and Dismissal
It's important to ensure that supportive documentation is placed in the EMR in the event a decision is made to terminate a provider / patient relationship or a dismissal. Contact with Clinical Risk

Management is required prior to termination / dismissal. Documentation reflects interventions that have been attempted, patient response, and helps diminish risk to the organization.

1. A Verbal Discussion
   - A discussion with the patient is an important first step to investigate reasons and solutions for termination / dismissal consideration, and to set expectations for the patient, allowing for changes in behaviors. A behavioral contract can be utilized.

   - The Site Manager, Provider or Designee that wishes to terminate the relationship or dismiss the patient is required to contact Clinical Risk Management at 540-981-7798 to examine the reasons for termination / dismissal, and ensure that the following elements are documented in the patient's EMR
     - Documentation of the reasons / behaviors for termination / dismissal consideration in the EMR, and/or warning letter with clear explanation of expectations. All letters must be scanned into the EMR.
     - Any interventions that have been taken/attempted to understand and resolve root causes of the issue, including a behavioral contract.
     - The patient's failure to keep 3 consecutive scheduled appointments in the same practice in a 12-month period, and interventions taken to understand reasons/barriers to being able to keep appointments.

2. A written notice sent to the patient indicating the intent to terminate the physician-patient relationship is the second step after a verbal discussion. The letter must contain the following information:
   - The reason for the termination.
   - The date the termination will be effective (must be a minimum of 30 days from the date of the letter). Statement addressing the importance of continuing medical care.
   - Notification that continuing care for non-emergent conditions requiring timely care should be sought at a local Urgent Care in the event another physician has not been selected within 30 days. All emergent conditions requiring immediate interventions need to be evaluated in an Emergency Department.
   - A referral resource the patient may use to locate another physician, and/or provide alternate provider names and contact information. Notification that they may also contact their insurance company for a list of approved providers.
   - An offer to send the patient's medicals records to a new provider upon receipt of a properly completed medical record release authorization form. The release form is to be sent along with the dismissal letter.

3. Patients who exhibit verbal abuse, threaten physical harm, stalking or sexual advances, or otherwise creates a threatening environment for physicians, staff or other patients may be terminated immediately with a verbal discussion, but must have a written letter sent after the verbal termination with elements outlined under written notice. This event and letter needs to be documented and scanned into the patient's EMR.

4. Physicians need to prescribe medications for 30 days for patients with high risk and severe chronic conditions. Details of the prescribed medications need to be provided in the termination/dismissal letter.

Patients with emergent or psychiatric needs may need to seek services through an Emergency Department or local community services.

5. To facilitate the sharing of medical information with the patient's chosen provider, a Carilion Clinic Authorization to Release Protected Health Information form will be sent with the written notice by both regular, and certified mail, to the patient's last known address. Copies of the written notice, authorization form and certified letter form will be scanned into the EMR. Returned, unopened letters or certified mail, and any correspondence with the patient and/or family after termination or dismissal will also be scanned into and/ or documented in the EMR.

6. Patient's with an emergent medical condition, including a psychiatric crisis, and patients who are greater than 20 weeks pregnant with potential signs of labor, shall have these conditions resolved or stabilized prior to the termination. Urgent or time sensitive medical and psychiatric needs should be resolved or addressed prior to termination.

7. Patients have the right to receive considerate, respectful, compassionate and appropriate clinical care in a safe setting regardless of age, gender, race, color, national origin, religion, language, culture, sexual orientation, gender identity and/or expression, marital or parental status, pregnancy, disabilities, veteran's status, citizenship or source of payment. Accordingly, dismissal processes shall be consistently applied.

8. In the event a workable solution is unable to be achieved, or there is continued disagreement between Risk Management and the provider/practice, a review will be escalated to the Department Chair and/ or designee for a decision.

9. In the event there is a request made to dismiss the patient from the organization for extenuating circumstances, contact Risk Management to discuss the situation prior to dismissing the patient. If it's determined there is a valid reason to continue this process, the situation will be escalated to Carilion Police and the Legal Department for further investigation and recommendations.

V. OTHER ISSUES / CONCERNS

Please refer to the Supervised Medication Agreement for patient's being considered for termination / dismissal for violation of the Supervised Medication Agreement

Approvals

Name	Title	Dept./Committee	Date
Kim Roe	VP	Family Community Medicine	5/23/2017
Vicki Clevenger	VP, Chief Compliance Officer	Organizational Integrity & Compliance	5/19/2017
Kathleen Baudreau	VP	Clinical Advancement – Quality / Patient Safety	5/22/2017
John Gleason	VP	Clinical Advancement- Quality / Patient Safety	5/22/2017
Patrice Weiss	Executive VP	Administration	5/23/2017
Steve Arner	Executive VP	Administration	5/23/2017

Updated
1/2018

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

Questionnaire developed by Lynn R. Webster, MD to asses risk of opioid addiction.

Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk too. Pain Med. 2005; 6 (6) : 432

CURRENT OPIOID MISUSE MEASURE (COMM)™

The Current Opioid Misuse Measure (COMM)™ is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM™ was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors: - Signs & Symptoms of Intoxication - Emotional Volatility - Evidence of Poor Response to Medications - Addiction - Healthcare Use Patterns - Problematic Medication Behavior

The COMM™ will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM™ examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM™ is:

• A quick and easy to administer patient-self assessment

• 17 items

• Simple to score

• Completed in less than 10 minutes

• Validated with a group of approximately 500 chronic pain patients on opioid therapy

• Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.

• The COMM™ is for clinician use only. The tool is not meant for commercial distribution.

• The COMM™ is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM™ scores to decide if and when modifications to particular patient's treatment plan is needed.

• It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

Please answer each question as honestly as possible. Keep in mind that we are only asking about the past 30 days. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

CARILION CLINIC
FAMILY AND COMMUNITY MEDICINE

Please answer the questions using the following scale:	Never 0	Seldom 1	Sometimes 2	Often 3	Very Often 4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

Scoring Instructions for the COMM™

To score the COMM™, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM™ was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM™ will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM™ is at different cutoff values. These values suggest that the COMM™ is a sensitive test. This confirms that the COMM™ is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM™ are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM™ score (at a cutoff of 9) is nearly 3 times (3.48 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one

should remember that a low COMM™ score suggests the patient is really at low-risk, while a high COMM™ score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM™ Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	3.48	.08

 The COMM™ was developed with a grant from the National Institutes of Health and an educational grant from Endo Pharmaceuticals.

The Patient Health Questionnaire-2 (PHQ-2) - Overview

The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the past two weeks. The PHQ-2 includes the first two items of the PHQ-9.

- The purpose of the PHQ-2 is not to establish final a diagnosis or to monitor depression severity, but rather to screen for depression in a "first step" approach.
- Patients who screen positive should be further evaluated with the PHQ-9 to determine whether they meet criteria for a depressive disorder.

Clinical Utility

Reducing depression evaluation to two screening questions enhances routine inquiry about the most prevalent and treatable mental disorder in primary care.

Scoring

A PHQ-2 score ranges from 0-6. The authors[1] identified a PHQ-2 cutoff score of 3 as the optimal cut point for screening purposes and stated that a cut point of 2 would enhance sensitivity, whereas a cut point of 4 would improve specificity.

Psychometric Properties[1]

Major Depressive Disorder (7% prevalence)				Any Depressive Disorder (18% prevalence)			
PHQ-2 Score	Sensitivity	Specificity	Positive Predictive Value (PPV*)	PHQ-2 Score	Sensitivity	Specificity	Positive Predictive Value (PPV*)
[redacted]	97.6	59.2	15.4	[redacted]	90.6	65.4	36.9
2	92.7	73.7	21.1	2	82.1	80.4	48.3
[redacted]							
4	73.2	93.3	45.5	4	50.9	97.9	81.2
[redacted]	53.7	96.8	56.4	[redacted]			
6	26.8	99.4	78.6	6	12.3	99.8	92.9

** Because the PPV varies with the prevalence of depression, the PPV will be higher in settings with a higher prevalence of depression and lower in settings with a lower prevalence.*

1. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: Validity of a Two-Item Depression Screener. Medical Care 2003, (41) 1284-1294

Updated
1/2018

CARILION CLINIC
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The Patient Health Questionnaire-2 (PHQ-2)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

The Patient Health Questionnaire (PHQ-9) - Overview

The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression:

- The PHQ-9 incorporates DSM-IV depression diagnostic criteria with other leading major depressive symptoms into a brief self-report tool.
- The tool rates the frequency of the symptoms which factors into the scoring severity index.
- Question 9 on the PHQ-9 screens for the presence and duration of suicide ideation.
- A follow up, non-scored question on the PHQ-9 screens and assigns weight to the degree to which depressive problems have affected the patient's level of function.

Clinical Utility

The PHQ-9 is brief and useful in clinical practice. The PHQ-9 is completed by the patient in minutes and is rapidly scored by the clinician. The PHQ-9 can also be administered repeatedly, which can reflect improvement or worsening of depression in response to treatment.

Scoring

See PHQ-9 Scoring on next page.

Psychometric Properties

- The diagnostic validity of the PHQ-9 was established in studies involving 8 primary care and 7 obstetrical clinics.
- PHQ scores ≥ 10 had a sensitivity of 88% and a specificity of 88% for major depression.
- PHQ-9 scores of 5, 10, 15, and 20 represents mild, moderate, moderately severe and severe depression.[1]

1. *Kroenke K, Spitzer R, Williams W. The PHQ-9: Validity of a brief depression severity measure. JGIM, 2001, 16:606-616*

The Patient Health Questionnaire (PHQ-9) Scoring

Use of the PHQ-9 to Make a Tentative Depression Diagnosis:
The clinician should rule out physical causes of depression, normal bereavement and a history of a manic/hypomanic episode

Step 1: Questions 1 and 2
Need one or both of the first two questions endorsed as a "2" or a "3"
(2 = "More than half the days" or 3 = "Nearly every day")

Step 2: Questions 1 through 9
Need a total of five or more boxes endorsed within the shaded area of the form to arrive at the total symptom count. (Questions 1-8 must be endorsed as a "2" or a "3"; Question 9 must be endorsed as "1" a "2' or a "3")

Step 3: Question 10
This question must be endorsed as "Somewhat difficult" or "Very difficult" or "Extremely difficult"

Use of the PHQ-9 for Treatment Selection and Monitoring
Step 1
A depression diagnosis that warrants treatment or a treatment change, needs at least one of the first two questions endorsed as positive ("more than half the days" or "nearly every day") in the past two weeks. In addition, the tenth question, about difficulty at work or home or getting along with others should be answered at least "somewhat difficult"

Step 2
Add the total points for each of the columns 2-4 separately
(Column 1 = Several days; Column 2 = More than half the days; Column 3 = Nearly every day. Add the totals for each of the three columns together. This is the Total Score
The Total Score = the Severity Score

Step 3
Review the Severity Score using the following TABLE.

PHQ-9 Score	Provisional Diagnosis	Treatment Recommendation *Patient Preferences should be considered*
5-9	Minimal Symptoms*	Support, educate to call if worse, return in one month
10-14	Minor depression ++ Dysthymia* Major Depression, mild	Support, watchful waiting Antidepressant or psychotherapy Antidepressant or psychotherapy
15-19	Major depression, moderately severe	Antidepressant or psychotherapy
>20	Major Depression, severe	Antidepressant and psychotherapy (especially if not improved on monotherapy)

** If symptoms present ≥ two years, then probable chronic depression which warrants antidepressants or psychotherapy (ask "In the past 2 years have you felt depressed or sad most days, even if you felt okay sometimes?")*

++ If symptoms present ≥ one month or severe functional impairment, consider active treatment

Updated
1/2018

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FAMILY AND COMMUNITY MEDICINE

The Patient Health Questionnaire (PHQ-9)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Column Totals		_____ +	_____ +	_____
Add Totals Together			_____	

10. If you checked off any problems, how difficult have those problems made it for you to Do your work, take care of things at home, or get along with other people?

☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult