Risk Evaluation & Mitigation Tool-Kit: Strategies to Promote the Safe Use of Opioids
# RISK EVALUATION & MITIGATION (REM) TOOL-KIT: STRATEGIES TO PROMOTE SAFE USE OF OPIOIDS

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INTRODUCTION

On behalf of the Virginia Association for Hospice and Palliative Care, we are pleased to offer this toolkit, "Risk Evaluation & Mitigation (REM): Strategies to Promote the Safe Use of Opioids". This toolkit represents one year of work by VAHPC members across the state, all of whom are committed to excellence in hospice care and responsible use of medications for our hospice patients.

Opioids and other controlled substances are invaluable tools used by hospices to promote comfort. Without these medications, many of our patients would suffer needlessly at the end of life, unable to focus on what is truly important at this special time, and causing incalculable suffering not only to the patient but to their family and loved ones as well. Inappropriate use of opioids, both unintentional and intentional, is a public health safety risk. We as hospice providers must commit to partnering with our patients and families to assure to the best of our ability that the medications prescribed for our patients are used in a safe and effective manner.

This toolkit takes a proactive, "partnering" approach to opioid safety and assumes that patients and families want to assure that medications are used safely. It includes sample assessment tools, agreements, policies, and forms that each hospice may adapt to their own unique needs and the needs of their patients. This project is a "work in progress", and we expect to be updating it as more information and better tools become available.

We are especially grateful to Dr. Leslie Blackhall, Associate Professor of Medicine; Medical Director, Palliative Care Outpatient Services University of Virginia School of Medicine who has stirred our consciences about the role hospices should play in promoting opioid safety. Through her involvement on this committee, she has shared her wealth of knowledge and experience and provided much of the information included in this toolkit.

We invite your feedback about any of the tools we have included, and we also welcome your submissions of tools and information that you find helpful in your hospice work. Thank you for joining our efforts to promote the safe use of opioids for the sake of our patients, families, and the communities in which we work and live.

Sue Ranson RN. MSN
Chair, Public Policy Committee
Virginia Association for Hospices and Palliative Care
The purpose of this toolkit to help those who work with hospice patients and their family members address the issue of substance abuse and diversion.

Cancer-related pain is a source of severe suffering for our patients, and opioid pain medications have been shown, in multiple studies, to be safe and effective for treating this type of pain. As hospice providers, we must work diligently to relieve pain, and this will usually mean using appropriate doses of both opioid and non-opioid pain medications.

The treatment of cancer pain does not cause addiction to opioids. However, patients with substance abuse disorders get cancer and other terminal illnesses. Furthermore, the family members who care for our patients may have these problems. Substance abuse and diversion is a serious medical problem, and a source of significant suffering for patients and family members.

The purpose of this toolkit is to help hospice providers identify patients and family members at risk for misuse of opioid pain medications, and to make plans for the safe use of these medications.

This toolkit is based on the following principles:

1. Substance abuse, when untreated and uncontrolled is a source of suffering for the abuser and all those around him or her.
2. Patients with substance misuse disorders may also have severe and uncontrolled pain, and treatment of both of these conditions respectfully and safely should be our goal.
3. Assessment, evaluation and treatment of this problem in an inter-professional and non-judgmental way can improve the care of our patients and reduce the stress these situations place on the hospice team.

We look forward to your feedback about the use of this toolkit.

Leslie J Blackhall MD MTS
Associate Professor of Medicine
Medical Director, Palliative Care Outpatient Services University of Virginia School of Medicine
**Risk Evaluation and Mitigation (REM): Strategies to Promote the Safe Use of Opioids**

### All Patients Receiving Opioids
1. Conduct Opioid Risk Assessment
2. Identify who will control medication administration
3. Opioid Safety Education
   - Side Effects
   - Use as prescribed
   - One prescriber only
   - Secure storage
   - Driving and other limitations
   - Who to call with questions
   - Safe disposal
4. Safety Plan Agreement Signed

### Moderate & High Risk
- Reconcile opioids every visit
- Up to 2 weeks maximum supply
- Avoid benzodiazepines, consider alternatives such as antidepressants, anxiolytics
- Treat associated mental health issues
- For Patients
  - Ask: How recent is the substance abuse? Which substance(s) are being abused? How significant is the abuse?
  - Action:
    - Reconcile opioids every visit
    - Up to 2 weeks maximum supply
    - Avoid benzodiazepines, consider alternatives such as antidepressants, anxiolytics
    - Treat associated mental health issues

### Additional Step for High Risk
1. Emphasize safety
2. Express concerns explicitly
3. Limit supply to 1 week or less
4. Frequent evaluations
5. Identify family member to control opioid administration
6. Consider the use of:
   - Prescription Monitoring Program (PMP)
   - Urine drug-screen
   - Long-acting opioids without short-acting breakthrough opioids

### Low Risk
1. Continue Monitoring safe use of Opioids
   - Reconcile opioids every RN visit
   - Safe storage
   - Review safety plan PRN

### Highest Risk
**Defined as currently abusing or noncompliant with established opioid safety plan.**
1. Inform the patient & family that the plan has been violated and that the hospice must evaluate its options
2. Immediate IDT review
3. New Plan
   - Identify safety issue, consider family meeting
   - Identify reasons for ongoing opioid use
   - Safety Plan Options
     - Prevent abuser’s access to opioids
     - Admit patient to controlled environment
     - Reduce limited supply further
     - Single reliable person to administer opioids
4. Additional Considerations
   - Ethics consult
   - Hospice will no longer manage/supply opioids
   - Hospice will discharge patient
   - Contact law enforcement and/or adult or child protective services

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Developed by the Public Policy Committee of the Virginia Association for Hospices & Palliative Care
<Hospice Name>

**POLICY: Medication Management and Control**

To provide a framework for interventions for managing and controlling medications in the home care environment.

**PROCEDURE:**

The hospice nurse will reconcile medications during every visit. This may include counting controlled substances to ensure that the proper quantities are available and are taken as prescribed by the physician.

Upon admission into the hospice program the patient/caregiver agree to be responsible for the proper storage, administration and documentation of medications.

The patient/caregiver agree to administer medications according to the prescribed doses and ranges as authorized by a physician. Medication changes will be implemented by the hospice nurse in collaboration with a physician.

If there is a concern that medications are missing, the hospice team will assist the patient/caregiver in trying to locate the medications or identify the amount of medication missing and where/when the loss may have occurred.

If there is a concern of possible drug diversion the patient’s home/facility, the following steps should be taken:

1. Report the loss to the Clinical Manager including the following information, if available:
   - a. The name of the patient and their location;
   - b. The medication involved and the quantity;
   - c. How the suspected diversion was discovered;
   - d. Any patient outcomes related to the suspected diversion
   - e. The name of the person(s) suspected of diversion;

2. The Vice President of Clinical Services, Vice President of Patient and Family Support Services, Hospice Medical Director or designee, dispensing physician and dispensing Pharmacy should be notified.

3. The primary nurse and/or designee will implement the following corrective actions:
   - a. Inventory all controlled substances in the home/facility.
   - b. Implement steps to safeguard the medications:
     1. Initiate the controlled substance agreement
     2. Place a lockbox in the home
     3. Limit the quantity dispensed
     4. Alter medications routes as appropriate i.e.: patch/pump
     5. Consider alternate locations for safe storage
     6. Increase visit frequency
     7. Implement mandatory controlled substance counts and document them at every visit to ensure that medication administration is no more than the prescribed dosage

Reprinted with Permission: Blue Ridge Hospice, Winchester, VA.
8. Initiate a medication administration record to be used by the patient/caregiver to document all doses and times that controlled substances are administered.

9. If the above interventions are not effective in controlling the medications, additional interventions may be implemented to include:
   
i. Notification of local authorities
   ii. Discussing alternate placement of the patient
   iii. Refer the patient to the pain clinic
   iv. Discuss potential discharge from hospice services with patient/caregiver

   d. If the patient resides in a facility, the nurse will collaborate with the facility staff to help to identify the source of the loss and actions to prevent reoccurrence.
<Hospice Name>

POLICY: Drug Diversion

PURPOSE: To define a process for handling situations where drug diversion is strongly suspected or confirmed. (See Toolkit algorithm handout “Risk Evaluation & Mitigation: Strategies to Promote Safe Use of Opioids”)

GUIDELINES: The Federal Controlled Substance Act requires that the pharmacist affix a label on all controlled medications that states: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it is prescribed.”

PROCEDURE:

1. Any hospice staff member, including volunteers, suspecting that drugs are being diverted from a patient’s residence must inform their supervisor as soon as possible.

2. Accurately as possible whether or not drug diversion is taking place. Staff participating in the mini-team may include, but are not limited to:
   a. Medical Director
   b. RN case manager
   c. SW
   d. Staff member/volunteer raising the issue
   e. Clinical administrative staff
   f. Compliance Director

3. If more information is needed to discern if drug diversion is taking place, or if a high probability of drug diversion appears to be occurring, a plan to obtain more information and/or to clarify the issues and expectations concerning drug diversion will be put in place. The plan may include:
   a. Notifying the attending physician of the possible drug diversion
   b. Holding a family meeting for the purpose of:
      i. Reviewing with the patient/family, the following information:
         1. Patient Rights—Patients have the right to:
            a. Have property and person treated with courtesy, consideration & respect;
            b. Receive effective pain management & symptom control from hospice;
            c. Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including misappropriation or exploitation of property;
         2. Disposal of Prescription Drugs, which includes information about hospice’s policy on the management of medications, including the statement, “Inappropriate use of medication is a serious issue. If the nurse or any member of the hospice team has a concern about the illegal/inappropriate use of medications, especially Schedule II through V drugs, Good Samaritan Hospice may contact the appropriate authorities about this concern.”
      ii. Obtaining a written agreement, signed by the patient and/or appropriate caregivers, that includes specific expectations of the patient/family as well as possible consequences if the conditions of the agreement are not met. The nurse and SW will both sign the agreement. The original signed agreement will be kept in the patient’s medical record. A copy will be given to the patient/appropriate caregiver, and the attending physician.
c. A lock box may be necessary to protect medications. The patient and/or appropriate caregiver(s) should be part of the plan to utilize a lock box, including who will have the key, how medications will be received, etc.

4. Reasonable expectations on the part of hospice may include, but are not limited to:
   a. Documentation of medication given, including the name, dose, time of administration and person administering the medication
   b. Careful review of medications in the home by the hospice RN, including documenting quantities.

5. If there is sufficient evidence that the team believes drug diversion continues to occur in spite of hospice interventions, (see strategies outlined in Toolkit algorithm handout “Risk Evaluation & Mitigation: Strategies to Promote Safe Use of Opioids”):
   a. A mini-team will be called by the patient’s hospice team
   b. The attending physician and APS will be notified. (Drug diversion is considered “exploitation” and therefore a mandatory condition for an APS report.)
   c. Local police may be notified.
   d. The patient may no longer receive pain management services through hospice.
   e. The patient may be discharged from hospice services.

6. Careful documentation in the patient’s medical record of all conversations with the patient, caregivers, and other hospice team members, including the attending physician is essential.
<Your Hospice Name>

POLICY: DISPOSAL AND MANAGEMENT OF PRESCRIPTION/CONTROLLED DRUGS (391-190C7; 418.106(2i))

POLICY STATEMENT: Hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient’s home.

RATIONALE: The Federal Controlled Substance Act requires that the pharmacist affix a label on all controlled medications that states: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it is prescribed.” In addition, Section 54.1-3400 of the Code of Virginia states that all prescription drugs not included in Schedules II through V of the Federal Controlled Substance Act are placed in Schedule VI in Virginia and are also referred to as “controlled” drugs or substances. The FDA has distributed guidelines regarding the destruction of unused, unneeded, or expired prescription drugs (attached).

GSH POLICY:
1. At the same time when controlled drugs are first ordered, the hospice must:
   a. Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family.
   b. Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs.
   c. Document in the patient’s clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.
2. Medications are to be taken exactly as prescribed, including by the person for whom they are prescribed, and in the dose and frequency in which they are prescribed.
3. Hospice nurses shall encourage disposal of unused/discontinued medications at the time of the patient’s death or discharge/revocation from hospice according to federal guidelines. NO STAFF (INCLUDING VOLUNTEERS) shall transport any patient’s medications after a patient’s death. On request of the patient or family, staff or volunteers may pick up medications from a pharmacy and deliver to the patient in extenuating circumstances or when convenient. This is not to be done on a regular basis.

PROCEDURE:
(1) On admission, the admitting nurse will review the information with the patient/caregiver(s) regarding controlled drugs. Thereafter, the nurse case manager will review this information as frequently as necessary to ensure that the patient or representative understands the proper use of medications. These conversations will be recorded in the medical record by the nurse(s).

(2) At the time of death, the nurse making the visit shall inquire if prescription medications for the deceased patient are in the home.

(3) The nurse will inform the family/patient representative (who must be age 18 or older) of the prescription medication should be taken only by the person for whom it is prescribed.
(4) The nurse shall ask if the family/patient representative would like her to assist with the destruction of the medications.

(5) On request/approval of the family/patient representative, the nurse will assist with the destruction of all prescription medications of the deceased patient with family members as witnesses. Method of disposal shall be in accordance with federal guidelines.

(6) The “Drug Disposal Record” will be completed by the nurse with the appropriate information and signatures and filed in the patient’s medical record. Drug disposal information will also be recorded on the electronic record.

(7) If unused medications are brought to the Hospice office by families or inadvertently by staff, said medication will be destroyed at that time by a licensed nurse and witness according to federal guidelines, who will both sign the “Drug Disposal Record” to be filed in the patient’s medical record.

(8) If a patient dies in a hospital or is moved to a facility and medications are left in the home, the primary nurse or the nurse documenting the death is responsible for calling the caregiver/POA, explaining Hospice’s policy on disposal of drugs, and asking that these medications be destroyed. The nurse should visit the home and assist with destruction of the medications per policy if the caregiver prefers and can be present to witness the destruction of the medications. The nurse will document this conversation and/or visit on the “Drug Disposal Record” and in the electronic record.

(9) If a patient is discharged or revokes the hospice benefit and does not plan to return to hospice care in the near future, the nurse notifies the caregiver/POA to destroy any unused/discontinued meds (such as a comfort kit) that are still in the home. The nurse should visit the home and assist with the destruction of the medications per policy if the caregiver prefers and can be present to witness the destruction of the medications. The conversation is documented in the patient record.

(10) If the nurse has concern about the illegal/inappropriate use of medications, especially Schedule II through V, the nurse should emphasize the Federal Controlled Substance Act to the family/caregiver and advise that Hospice may be contacting the appropriate authorities about this concern. Other Hospice staff members, as well as the nurse, who have concerns about the use of patient medications should discuss their concerns with their supervisor. The conversation(s) and any action take are documented in the patient record.

I have read and fully understand the Hospice policy on “Disposal of Controlled Drugs”.

________________________________________  _______________________
Staff Signature  Date
MONITORING AND DISPOSAL OF SCHEDULE II MEDICATIONS – INPATIENT CARE CENTER

POLICY:
Monitoring and disposal of Schedule II medications are completed in accordance with the Blue Ridge Hospice’s established procedures.

PURPOSE:
To ensure the safe control and accountability of Schedule II medications

RESPONSIBLE PARTY:
Registered nurses and Licensed Practical Nurses

PROCEDURE:

Monitoring

1. All Schedule II medications are kept in a locked cabinet in the medication room and/or in the refrigerator in the medication room.
   A. The key to the medication room and the narcotic cabinet is held, at all times, by a nurse who is currently on duty.
   B. The medication room is kept locked at all times. The door shall not be propped open for any reason.
   C. The narcotic cabinet is kept locked at all times.
2. All Schedule II medications delivered by the contract pharmacy are verified by the receiving nurse who then signs the receipt.
   A. A nurse must verify the drug and quantity, complete the Narcotic Record Sheet for each controlled substance drug and place it in the Narcotic Notebook.
3. Each dose of a Schedule II medication is recorded on the Narcotic Record Sheet as well as on the Medication Administration Record by the nurse administering the drug.
   A. When the record is complete, it is kept on file for 5 years.
4. At the start and end of each shift, two nurses conduct a “narcotic count”.
   A. One person must be from the off-going shift, and one from the oncoming shift.
   B. Prior to initiating the narcotic count, the narcotic keys must be collected by a nurse from the off-going shift.
   C. Each Schedule II medication in the medication room is counted.
   D. The incoming nurse counts the number of pills or other units of measurement for each narcotic.
   E. The other nurse visually confirms the counts and verifies the count according to the Narcotic Record Sheet.
   F. If the count is accurate, each person signs in the designated space on the narcotic count sheet.
   G. If the count is not accurate, the Clinical Manager or designee is informed and
      i. No staff may leave until the discrepancy is resolved.
      ii. If unable to resolve the discrepancy, the Manager or designee may release staff members to go home while the investigation continues.
      iii. Staff members on duty during the time period of the discrepancy may be requested to participate in a drug toxicity screening.
      iv. Each patient’s medication administration record is reviewed and cross-referenced to the narcotic control sheet.
      v. All staff who administered any medications during the off-going shift will be verbally queried regarding medication usage.
      vi. If the count is not accurate on a liquid medication, steps one and two should still be followed.
   H. If the discrepancy is not found, the actual discrepancy will be recorded on the narcotic count sheet and signed by both nurses.
i. A medication occurrence report will be completed and forwarded to the Vice President of Clinical Services.

I. Once the count has been validated the nurse from the oncoming shift is given the narcotic keys.

J. Only nurses who are on duty and Clinical Manager/Vice President of Clinical Services may have access to the medication room at any time. Any other staff member who needs access to the medication room such as Housekeeping, Maintenance, etc. must have a nurse present at all times.

K. No nurse or other staff member is to keep personal belongings such as their purse or bag in the medication room. Storage spaces are provided for this purpose in the nurses’ station.

L. If a nurse on duty leaves the premises for any reason the narcotic keys may not be taken. The keys must be given to another nurse or Clinical Manager.

M. If a nurse inadvertently leaves the premises with the narcotic keys, they must return them immediately.

Disposal

1. Any medication brought in with the patient should be returned to the patient upon discharge from the Inpatient Care Center unless permission is given to destroy medications no longer prescribed. If medications are taken home, they must be bagged and labeled. Schedule II medications must remain in the narcotic cabinet and recounted immediately prior to returning to the patient. The following must be documented on the “Schedule II continual Inventory Form for Individual Patients”:
   A. Amount remaining
   B. Disposition: sent home with patient
   C. Nurses’ signature

2. Any Schedule II medications will be processed for destruction when no longer needed or when expired.
   A. The medications will be maintained in the locked narcotic cabinet and counted each shift until destroyed.
   B. Medications to be destroyed will be placed in a sharps container that is designated for disposal of medications (see separate procedure for disposing medications) and is filled with a combination of kitty litter and water.
   C. Two licensed nurses will confirm the count, and waste the medications by placing them in the designated sharps container. Liquid medications will be poured into the container and all pills and suppositories will be removed from the original container and poured into the sharps container with the witness of the nurse on duty. The amount destroyed will be documented on the Narcotic Record Sheet and witnessed by the nurse.

3. Any Schedule II medications that require disposal as a result of partial dose order or administration will be destroyed as noted above, and documented by two nurses on the Narcotic Record Sheet.
Date:__________________________
Patient Name:__________________________

**OPIOID RISK TOOL**

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<th>Item Score</th>
<th>Item Score</th>
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<tbody>
<tr>
<td>Mark each box that applies</td>
<td>if female</td>
</tr>
</tbody>
</table>

1. **Family History of Substance Abuse**
   - Alcohol [ ] 1 3
   - Illegal Drugs [ ] 2 3
   - Prescription Drugs [ ] 4 4

2. **Personal History of Drug Abuse**
   - Alcohol [ ] 1 3
   - Illegal Drugs [ ] 2 3
   - Prescription Drugs [ ] 4 4

3. **Age (mark box if 16-45)** [ ] 1 1

4. **History of Preadolescent Sexual Abuse** [ ] 3 0

5. **Psychological Disease**
   - Attention Deficit Disorder [ ] 1 1
   - Obsessive Compulsive Disorder
   - Bipolar
   - Schizophrenia
   - Depression [ ] 1 1

**Total:** __________  __________

**Total Score Risk Category**
- Low Risk: 0-3
- Moderate Risk: 4-7
- High Risk: 8 or more
The Controlled Substances Agreement

The purpose of this agreement is to protect you and your caregiver(s) responsibility in managing controlled substances prescribed to you while under the care of Blue Ridge Hospice.

Because these drugs have the potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from your primary physician, or during his or her absence, by the covering physician, unless specific authorization is obtained for an exception.

2. You are expected to inform our office of any new medications or medical conditions and of any adverse effects you experience from any of the medications you take.

3. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability.

4. You may not share, sell, or otherwise permit others to have access to these medications.

5. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.

6. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medications and prescriptions. They should not be left where others might see or otherwise have access to them.

7. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of the reach of such people.

8. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.

9. Early refills will generally not be given.

10. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.
11. If the responsible legal authorities have questions concerning your treatment, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to records of controlled substances administration.

12. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribed by this physician or referral for further specialty assessment.

13. Renewals are contingent on keeping an ongoing, accurate record of administration as ordered by a physician.

14. It should be understood that any medical treatment is initially a trial and that continued prescription is contingent on evidence of benefit.

15. Any unused medications will be disposed of by a Blue Ridge Hospice RN.

16. The risks and potential benefits of these therapies have been explained and you acknowledge that you have received such explanation.

17. You affirm that you have full right and power to sign and be bound by this agreement; and that you have read, understand, and accept all of its terms.

Hospice Physician Name (Printed)  
Hospice Physician Signature  Date

Patient Name and P# (Printed)  
Patient Signature  Date

Caregiver Name (Printed)  
Caregiver Signature  Date
RISK EVALUATION AND MITIGATION (REM): STRATEGIES TO PROMOTE THE SAFE USE OF OPIOIDS

HOSPICE PAIN MEDICATION SAFETY PLAN & AGREEMENT

As your hospice team, our goal is to help you control your pain, and avoid serious side effects of medications.

- If the pain medications you are prescribed are not working, call your hospice nurse. Do not adjust your dose on your own as this may increase the risk of side effects.
- The benefits of opioid pain medications include improvement in pain control, level of functioning, sleep and energy. Adverse effects include constipation, nausea, sedation, impaired respiration and even death, so it is important to only use these medications as directed by your physician and hospice team.
- We advise you not to drive or operate machinery while taking opioid medications or other medications that can slow your reflex time or cause sleepiness, unless directed by your physician.
- Only the patient and a family member who has been instructed to help with medications should have access to your pain medications. Other people could be harmed if they take medications prescribed for you, so it is important that you keep your prescriptions and medications secure and under your control. We will help dispose of unused or discontinued medications.
- We may contact the Virginia Prescription Monitoring Program for prescription review.
- When used appropriately for pain control, addiction is rare. We will work with you to avoid this problem.

Your pain control is very important to us! We are dedicated to helping you improved your quality of life.

Please call with questions or concerns. (___) ___ ____ (insert numbers here)

I acknowledge and understand the above plan

Signature __________________________ Date _________________

Reviewed by __________________________ Date _________________

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## Implementing Hospice Pain Medication Safety Plan

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Only one physician (or his/her partners) should write prescriptions for pain medications. This physician will be working closely with the hospice team to keep your pain under control. It is important to avoid getting pain medications from other providers in order to avoid dangerous drug interactions! The physician prescribing your medications is ______________________________.</td>
<td>Which MD’s normally write pain and nerve prescriptions for you?</td>
</tr>
<tr>
<td>If the pain medications you are prescribed are not working, call our hospice nurse. Do not adjust your dose on your own, as this may increase risk of side effects.</td>
<td>What do you do when your pain and nerve medications don’t work?</td>
</tr>
<tr>
<td>The benefits of opioid pain medications include improvement in pain control, level of functioning, sleep and energy. Adverse effects include constipation, nausea, sedation, impaired respiration and even death, so it is important to only use these medications as directed by your physician and hospice team.</td>
<td>Are you having any side effects and if so, how do you manage them?</td>
</tr>
<tr>
<td>We advise you not to drive or operate machinery while taking opioid medications or other medications that can slow your reflex time or cause sleepiness, unless directed by your physician.</td>
<td>Do you drive and do your medications affect your driving?</td>
</tr>
<tr>
<td>Only the patient and a family member who has been instructed to help with medications should have access to your pain medications. Other people could be harmed if they take medications prescribed for you, so it is important that you keep your prescription medications under your control. We will help dispose of unused or discontinued medications.</td>
<td>Can you think of anyone who comes into your home, including family and friends that might try to take your medications?</td>
</tr>
<tr>
<td>We may contact the Virginia Prescription Monitoring Program for prescription review.</td>
<td>Have you ever heard of the Virginia Prescription Monitoring Program (PMP)</td>
</tr>
<tr>
<td>When used appropriately for pain control, addiction is rare. We will work with you to avoid this problem.</td>
<td>Are you concerned about addiction for you or any of your family members?</td>
</tr>
</tbody>
</table>

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<Hospice Name>

**DRUG DISPOSAL FORM**

PATIENT'S NAME_________________________________________ ID# ______________________

The following drug(s) has/have been disposed of in my presence:

<table>
<thead>
<tr>
<th>Drug:</th>
<th>Amount:</th>
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</tbody>
</table>

The drug(s) was/were disposed of by: ____________________________________________

Witness__________________________________________

Date__________________________________________

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<Hospice Name>

Drug Disposal Record

Patient Name: ________________________________________________ ID # _______________  
☐ Active Patient  ☐ Deceased/discharged Patient

Family/Patient Representative Section:
I understand that Federal and State laws prohibit transfer, use, or further distribution of any controlled drug, including all prescription medications, to anyone other than the patient for whom they are prescribed. I ☐ request ☐ do not request that the nurse assist with the disposal of the medications prescribed for the above patient.

____________________________________________________________  
____________________________________________________________  
____________________________________________________________  
____________________________________________________________  

Signature  Relationship to Patient

Family/Patient Representative Section:

RN Signature  Witness Signature

Date  Date
Virginia’s Prescription Monitoring Program (PMP)

The Virginia Prescription Monitoring Program (PMP) was created in 2003 as a response to concerns about the prescription drug abuse epidemic primarily located in Southwest Virginia. In 2006 the PMP went statewide. The PMP Mission is “to promote the appropriate use of controlled substances for legitimate medical purposes while deterring the misuse, abuse, and diversion of controlled substances.”

The PMP is a centralized data base maintained by the Virginia Department of Health Professions with information about Schedule II-IV drugs prescribed to patients in Virginia. The purpose of the database is to assist prescribers and in making more informed treatment and dispensing decisions and to help authorized law enforcement and regulatory personnel conduct investigations related to prescription drug abuse and diversion.

Only prescribers and pharmacists for their patients, investigators for licensing boards and certain law enforcement agents may access the database. After registering on the PMP WebCenter site (https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx), practitioners may access the database to see a patient’s prescribing history 24/7. Patients may request their own prescription history if they are over 18 and provide a notarized request by mail or in person.

In April 2012 Virginia became one of 13 states to join the fight against drug diversion and illegal use of prescription pain medication through increased online technology. This approach is the result of a cooperative agreement between the Department of Health Professions Prescription Monitoring Program and the National Association of the Boards of Pharmacy, PMP InterConnect Project (PMPi). PMPi gives practitioners and pharmacists access to a state by state data sharing hub. Currently the only participating state which borders Virginia is West Virginia.

**PMP Links**

PMP home page:

http://www.dhp.virginia.gov/dhp_programs/pmp/

Laws governing the PMP:


Regulations governing the PMP:

RISK EVALUATION AND MITIGATION STRATEGIES TO PROMOTE THE SAFE USE OF OPIOIDS

Helpful Online Resources

DISPOSAL GUIDELINES

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm

DISPOSAL OF UNUSED MEDICINES: WHAT YOU SHOULD KNOW

This FDA document lists medications, including Fentanyl, that may best be disposed of by flushing down the sink or toilet.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseOfMedicine/SafeDisposalofMedicines/ucm186187.htm#MEDICINES

VIRGINIA ASSOCIATION FOR HOSPICES & PALLIATIVE CARE

www.virginiahospices.org

VIRGINIA PRESCRIPTION MONITORING PROGRAM

http://www.dhp.virginia.gov/dhp_programs/pmp/
Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A few drugs should be flushed down the toilet. And a growing number of community-based “take-back” programs offer another safe disposal alternative.

Guidelines for Drug Disposal
FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs. Issued by ONDCP in February 2007 and updated in October 2009, the federal guidelines are summarized here:

• Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
• Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Call your city or county government’s household trash and recycling service (see blue pages in phone book) to see if a take-back program is available in your community. The Drug Enforcement Administration, working with state and local law enforcement agencies, is sponsoring National Prescription Drug Take Back Days (www.deadiversion.usdoj.gov) throughout the United States.
• If no instructions are given on the drug label and no

Take drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds ...
take-back program is available in your area, throw the drugs in the household trash, but first:

° Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.
° Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.

FDA’s Deputy Director of the Office of Compliance Ilisa Bernstein, Pharm.D., J.D., offers some additional tips:

• Before throwing out a medicine container, scratch out all identifying information on the prescription label to make it unreadable. This will help protect your identity and the privacy of your personal health information.
• Do not give medications to friends. Doctors prescribe drugs based on a person’s specific symptoms and medical history. A drug that works for you could be dangerous for someone else.
• When in doubt about proper disposal, talk to your pharmacist.

Bernstein says the same disposal methods for prescription drugs could apply to over-the-counter drugs as well.

Why the Precautions?
Disposal instructions on the label are part of FDA’s “risk mitigation” strategy, says Capt. Jim Hunter, R.Ph., M.P.H., senior program manager on FDA’s Controlled Substance Staff. When a drug contains instructions to flush it down the toilet, he says, it’s because FDA, working with the manufacturer, has determined this method to be the most appropriate route of disposal that presents the least risk to safety.

Drugs such as powerful narcotic pain relievers and other controlled substances carry instructions for flushing to reduce the danger of unintentional use or overdose and illegal abuse.

For example, the fentanyl patch, an adhesive patch that delivers a potent pain medicine through the skin, comes with instructions to flush used or leftover patches. Too much fentanyl can cause severe breathing problems and lead to death in babies, children, pets, and even adults, especially those who have not been prescribed the drug. “Even after a patch is used, a lot of the drug remains in the patch,” says Hunter, “so you wouldn’t want to throw something in the trash that contains a powerful and potentially dangerous narcotic that could harm others.”

Environmental Concerns
Despite the safety reasons for flushing drugs, some people are questioning the practice because of concerns about trace levels of drug residues found in surface water, such as rivers and lakes, and in some community drinking water supplies. However, the main way drug residues enter water systems is by people taking medications and then naturally passing them through their bodies, says Raanan Bloom, Ph.D., an environmental assessment expert in FDA’s Center for Drug Evaluation and Research. “Most drugs are not completely absorbed or metabolized by the body, and enter the environment after passing through waste water treatment plants.”

A company that wants FDA to approve its drug must submit an application package to the agency. FDA requires, as part of the application package, an assessment of how the drug’s use would affect the environment. Some drug applications are excluded from the assessment requirement, says Bloom, based on previous agency actions.

“For those drugs for which environmental assessments have been required, there has been no indication of environmental effects due to flushing,” says Bloom. In addition, according to the Environmental Protection Agency, scientists to date have found no evidence of adverse human health effects from pharmaceutical residues in the environment.

Nonetheless, FDA does not want to add drug residues into water systems unnecessarily, says Hunter. The agency reviewed its drug labels to identify products with disposal directions recommending flushing or disposal down the sink. This continuously revised listing can be found at FDA’s Web page on Disposal of Unused Medicines (www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm).

Another environmental concern lies with inhalers used by people who have asthma or other breathing problems, such as chronic obstructive pulmonary disease. Traditionally, many inhalers have contained chlorofluorocarbons (CFCs), a propellant that damages the protective ozone layer. The CFC inhalers are being phased out and replaced with more environmentally friendly inhalers.

Depending on the type of product and where you live, inhalers and aerosol products may be thrown into household trash or recyclables, or may be considered hazardous waste and require special handling. Read the handling instructions on the label, as some inhalers should not be punctured or thrown into a fire or incinerator. To ensure safe disposal, contact your local trash and recycling facility.
Responsible Medication Disposal Saves Lives and Protects the Environment

Follow your medication prescriber’s instructions and use all medications as instructed. If you do not use all of your prescribed or over-the-counter medication, you can take a few small steps to make a huge impact in safeguarding lives and protecting the environment by disposing of unused medications properly.
Disposal of Home Pharmaceuticals

**Step 1:** Remove the medications from their bottles and place them in a container with a lid or into a sealable baggie. Tip: Try not to touch the medications. If the tablets are solid, crush them or add water to dissolve them.

**Step 2:** Mix in an ingredient, such as kitty litter, coffee grounds, sawdust, etc. to make the medications “undesirable” to pets and children. If a sealable baggie was used, place the baggie into another sealable container.

**Step 3:** Remove and destroy all identifying personal information on the pill bottle (prescription label) before discarding.

**Step 4:** Throw in trash.

**REMEMBER:**
DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain or in the toilet unless the label or patient information leaflet specifically tells you to do so!

**OTHER OPTIONS TO DISPOSE OF MEDICATIONS:**
Drop your pharmaceutical medications off at a local take-back event. A take-back event is sponsored by the Federal Drug Enforcement Agency that provides a venue for people to want to dispose of unused or unwanted prescription or over-the-counter medications. For more information about local venues and dates, visit www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html.

Go to www.disposemymeds.org to find a pharmacy that will take back medications or provide information on how to do so.

**CONSULT YOUR PHARMACIST**
If you have any additional questions regarding disposal options or visit the Virginia Department of Environmental Quality at www.deq.state.va.us.
OPIOID SAFETY TASK FORCE: 2012

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