

SELF-MEDICATION PROGRAMS (SMP)

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Handbook provides guidance for the management of Self-Medication Programs (SMP) designed to monitor patient progress towards the understanding and independent administration of medications.

2. SUMMARY OF MAJOR CHANGES. This VHA Handbook incorporates the tools necessary to assess a patient for participation in an SMP and to define education, monitoring and documentation of progress towards independent medication administration. The use of self-medication has been incorporated into many Department of Veterans Affairs (VA) treatment programs and may be considered a viable program for all official VA bed sections. The most significant change from the former policy is the reduction in levels of dependence from five to three. This Handbook adjusts the complexity of the program to enable more widespread usage of this dispensing format. In addition, storage requirements for non-controlled substances and controlled substances are defined in this Handbook.

3. RELATED DIRECTIVE. VHA Directive 1108.3; March 15, 2005.

4. RESPONSIBLE OFFICE. The Chief Consultant, Pharmacy Benefits Management Services (119) is responsible for the contents of this Handbook. Questions may be addressed to (202) 461-7362.

5. RESCISSIONS. This VHA Handbook rescinds VHA Handbook 1108.3, dated March 15, 2005.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of February 2015.

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DISTRIBUTION: E-mailed to the VHA Publication Distribution List 2/12/10

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SELF-MEDICATION PROGRAM (SMP)

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides new procedures for the operation of Self-Medication Programs (SMP).

2. BACKGROUND

In 1993, VHA SMP policy was delineated in M-2, Part VII, Chapter 11, and rescinded by VHA Handbook 1108.3 “Self-Medication Program,” March 15, 2005. Since 1993, VHA has increasingly shifted health care delivery from traditional inpatient hospital-based approaches to a range of residential and community-based delivery systems. This shift has fostered a greater emphasis on rehabilitative approaches that promote patient education and skill development designed for improved self-care. With these newer approaches to health care, patients are able to learn and practice self-care skills, including the self-management of their medication regimens.

3. DEFINITION OF TERMS

a. **Level of Independence.** Each patient accepted into the SMP must be categorized as either “dependent” (Level I), “semi-independent” (Level II) or “independent” (Level III) with regard to medication administration.

(1) **Dependent Patient (Level I).** Dependent patient (Level I) refers to the patient who requires additional education and varying levels of medication monitoring with the direct involvement of nursing for dispensing, observing and documenting each self-administered medication.

(2) **Semi-independent Patient (Level II).** Semi-independent patient (Level II) refers to the patient who requires periodic reviews and documentation by professional staff of the patient’s self-medication practices, visual counts of the patient’s medications, and clinical observations of patient responses.

(3) **Independent Patient (Level III).** Independent patient (Level III) refers to the patients who understand medication therapy management, potential side effects and are capable of assuming complete responsibility for the storage, security, and self-administration of their medications.

b. **Multi-dose Prescription Vial.** The multi-dose prescription vial is the standard vial used to dispense and store tablets or capsules of prescription drugs.

4. SCOPE

a. SMP are structured programs for patients to learn and practice skills for the self-management of their prescribed medications. *NOTE: SMP may be practiced on all official Department of Veterans Affairs (VA) bed sections with the exception of those units designated as*

Mental Health Residential Rehabilitation Treatment Program (MH RRTP) units (see VHA Handbook 1162.02) and in accordance with local medical center policy. The self-management of medications includes:

(1) Methods that permit selected patients to self-administer medications authorized by their health care provider, and

(2) Instructions for teaching patients to assume responsibility for their medication storage.

b. VHA policy establishes programs that maximize patient functioning and independence for self-medication and identifies patients who are appropriate for such programs. Knowledge of one's medication regimen, the ability to self-administer and demonstrated compliance with a medication regimen are considered important aspects of self-care. The SMP is designed to teach and monitor self-medication administration, storage and compliance. Therefore, this process may be more labor intensive than routine inpatient medication dispensing formats and is not intended to be used to solve staffing or other workforce-related issues.

c. This Handbook is designed to assist in the development of local policies that foster maximum opportunity for patients to improve and utilize self-care skills prior to discharge (or transfer) to less supervised or structured levels of care.

5. RESPONSIBILITY OF THE MEDICAL CENTER DIRECTOR

The Medical Center Director is responsible for ensuring a written SMP policy that covers all participating wards, units or programs. SMP policies must include guidance for:

- a. Assessing patients' suitability for the SMP;
- b. Patient education and compliance;
- c. Administration, safekeeping and storage of medication;
- d. Monitoring clinical responses to medications; and
- e. Reporting adverse drug events.

6. PATIENT SELECTION CRITERIA AND ASSESSMENT

a. Prior to each patient's entry into the SMP, a provider or other qualified staff, must assess patients in VA bed sections who may benefit from participating in a SMP. **NOTE:** Qualified staff is to be defined in local medical center policy. A progress note, with a provider's order, must document that the patient has been assessed and is eligible for the SMP. This assessment must include the patient's degree of knowledge and understanding of the following:

(1) Assessment of Medication Therapy Management (MTM)

(a) The name of each medication;

(b) How to administer each medication (such as appropriate frequency, routes of administration, dose, etc.);

(c) Storage requirements;

(d) Reason for taking each medication; and

(e) Common side effects of the medication.

(2) Physical and /or Cognizant assessment as it relates to SMP

(a) Integration of medications into the patient's lifestyle;

(b) Possible barriers to compliance;

(c) Possible barriers to learning; and

(d) Procedures for requesting a change in medication regimen.

b. Before discharge from the SMP, the provider must document in the patient's electronic medical record the outcome of the patient's ability to self-medicate.

7. VARIOUS LEVELS OF PATIENT INDEPENDENCE IN SELF-MEDICATION

Based on the results of the patient assessment, each patient must be categorized as either a "dependent", "semi-independent" or "independent" participant in the SMP. *NOTE: Appendix A, entitled "Description of Key Functions for Levels of Self-Medication Program" provides guidance for medication dispensing, administration, monitoring, education, and storage for each level.*

a. Patients' self-medication status can change throughout their treatment as they develop the skills necessary to manage their own medications or when closer supervision is warranted.

b. Key functions involved in all levels of self-medication programming include the following:

(1) **Periodic Assessment of Patient Medication Management.** Assessment of patient medication knowledge is a process by which a patient's ability to accurately and safely self-manage their own medication regimen is determined. This assessment must take place at least weekly and all findings documented in the patient's medical record (e.g., to ensure understanding when a self-medication patient is treated by a Dentist who dispenses an antibiotic directly to the patient).

(2) **Pharmacy Method of Dispensing.** All VA and non-VA medication will be labeled in accordance with current VA policy. The VA pharmacy is required to check prescription and non-prescription over the counter (OTC) medication and herbal products not dispensed by the

VA Pharmacy, when they are approved by the VA provider for self-medication (e.g., in a Blind Rehabilitation SMP). *NOTE: Local medical center policy can be more restrictive.*

(3) **Type of Medication Administration.** Patients with “semi-independent level” status may regress or progress towards increasing independence based on the staff’s assessment of the patient’s ability (see Appendix A). When independent, self-medication status is indicated, the patient may receive up to a 30-day supply of medication. In this instance, medications may be dispensed directly to the patient from the outpatient pharmacy section if stated in local medical center policy. Outpatient dispensing to the patient may take place for all medications prescribed with the exception of controlled substances. *NOTE: For patients with “independent level” status, controlled substances may be dispensed in accordance with paragraph 9.b.(2).*

(4) **Compliance Monitoring and Documentation of Medication Administration.** Staff responsibility for monitoring patient compliance with self-medication may range from direct observance and documentation of each dose to only clinical monitoring and documentation of the patient’s response to medication. Each facility must define the responsibilities for documentation in their local self-medication policy. *NOTE: Intermediate levels of monitoring patient compliance may include observation of a patient filling a daily pillbox, periodic staff review, or counting the medication in the patient’s possession.*

(5) **Patient Education.** A thorough understanding of patient’s medications is vital to achieving success with self-medication. Following an initial assessment of the patient’s knowledge of their medication regimen, education must be provided by clinical personnel for each medication, regardless of the patient’s level of independence. *NOTE: The use of learning aids may be beneficial for increased comprehension and are encouraged. Examples could include: a demonstration of proper metered dose inhaler technique, daily flow sheets of medications and administration times; posters; and the use of a pill box.* The education provided needs to be documented in the patient’s clinical record. This documentation is to include the:

- (a) Name of person providing education;
- (b) Education provided;
- (c) Level of understanding demonstrated and/or verbalized by the patient; and
- (d) Assessment of a patient’s learning needs (e.g. barriers, preferred methods of learning, etc.)

(6) **Responsibility for Medication Storage.** Responsibility for medication storage may range from unit dose storage of all medications by designated staff to patient storing their own medications. In all cases, medications (including controlled substances) must be stored in locked locations, accessible only to appropriate clinical staff and the “independent level” patient for whom the medications are prescribed.

8. CLINICAL MONITORING

Clinical monitoring of the patient's response to medications must be recorded in the patient's progress notes as needed but at least weekly. This is in addition to the compliance monitoring described in subparagraph 7b(5). Examples of clinical monitoring include:

- a. Identification of target symptoms;
- b. Medication efficacy assessment for target symptoms and adverse events (including the patient's own perception about efficacy and side effects);
- c. Reviewing relevant laboratory results; and
- d. Assessment of educational needs and barriers.

9. MEDICATION SELECTION CRITERIA

a. Medication for use in the SMP requires a licensed health care provider to review and assess the patient's medication regimen and to document, in the electronic medical record, that portion of the regimen approved for self-medication. Intravenous or injection therapy will not be permitted in the SMP; the exception being insulin. Any additional injectable must be approved in local medical center policy.

b. If the VA facility determines that controlled substances are to be included in their self-medication program, the facility must adhere to standards in the VHA Handbook 1108.1 and 1108.2 on the handling, storage and inspection of controlled substances. In addition, they must adhere to the following:

(1) Controlled Substances that are administered intravenously, or by injection, are not permitted in the SMP;

(2) Controlled Substances used in the SMP will be administered to the patient on a dose by dose basis by designated staff; *NOTE: Patients with "independent level status," in later stages of evaluation for transition to the community, may need to be assessed for proper management of prescribed controlled substances. If the patient is deemed appropriate, controlled substances may be dispensed for self-medication in 7 day quantities, or less.*

(3) Controlled Substances administered to patients by licensed independent practitioners will be managed in accordance with local medical center policy and Handbook 1108.1, "Controlled Substances Pharmacy Stock;" and

(4) Storage for controlled substances administered by the patient must have a secure locked system (e.g. cabinet, locker, wall mounted box, etc.).

c. OTC medications and herbal products are permitted in the SMP only after a licensed health care provider has evaluated the patient's medical history and current medication regimen,

and given approval for the products use. **NOTE:** *If a medical center elects to allow the patient to bring OTCs or medications prescribed by outside providers, then it must be defined in local medical center policy.*

d. The following methods must be used to obtain the correct medication packaging for a SMP patient:

(1) The Outpatient Pharmacy Software Package must be used for ordering self-medication in patients requiring multi-dose prescription vials use.

(2) The Inpatient Software Package must be used for ordering medication for patients requiring unit-dose format. This package allows a Medication Administration Record (MAR) to be printed if desired. **NOTE:** *Medication may be monitored and documented by staff using this software package.*

10. MEDICATION SECURITY CRITERIA

a. All medications (including controlled substances) must be stored on the unit in accordance with VHA Handbook 1108.1, “Controlled Substances (Pharmacy Stock)” and VHA Handbook 1108.6, “Inpatient Pharmacy Services.”

b. Medications for patients with “semi-independent” and “independent level” status must be kept in a locked cabinet or locker accessible only to the patient’s provider or designated ward staff and the patient. **NOTE:** *Keys must be unique and not usable in other patient cabinets or lockers. Facilities may consider the utilization of keyless entry security systems.*

c. Exceptions to security requirements are made for self-medication that must be stored under refrigerated conditions. **NOTE:** *Patients must agree, in writing, to comply with all security requirements in order to participate in the SMP. This agreement must include a statement that the patient is responsible for the security of self-medication(s) and lock-box key or security code issued to them.*

APPENDIX A

**DESCRIPTION OF KEY FUNCTIONS FOR LEVELS
OF SELF-MEDICATION PROGRAM**

Key Functions	Level I "DEPENDENT"	Level II "SEMI-INDEPENDENT"	Level III "INDEPENDENT"
Assessment of patient medication knowledge.	Not demonstrated for self-medication at higher level.	Demonstrated for Level II self-administration.	Demonstrated for Level III self-administration.
Pharmacy method of dispensing.	Unit dose.	Multi-dose prescription vial.	Multi-dose prescription vial.
Means of medication receipt.	Unit nurse to administer all medication dosing.	Patient receives a 7-day supply of approved medications.*	Patient receives a 7 to 30-day supply of approved medications.
Monitoring of medication education, management, and documentation of administration.	Nurse observes and documents patient self-administration. Performed daily.	Patient documents daily self-administration of medication. Nurse verifies compliance and documents on Mondays and Thursdays.**	Clinical monitoring and documentation of patient's response to medications. Random spot check of medication is conducted at least weekly.
Patient Education.	Nurse provides education at each dispensing of medications.	Nursing provides education at time of dispensing. (including pillbox use)	Appropriately credentialed staff provides education (including pillbox use) at time of dispensing.
Responsibility for medication storage.	Nurse stores all medications in locked location.	Patient stores own medications in a locked location.	Patient stores own medications in a locked location.

* Controlled substances will be unit doses by nursing staff.

** Nurse observes filling of pillbox, if used.