

SELF-MEDICATION PROGRAMS (SMP)

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

2. SUMMARY OF MAJOR CHANGES: Over 10 years ago, an inter-disciplinary group formed to develop a handbook that would standardize how self-medication was being taught and assessed in a variety of VA health care settings. This VHA Directive incorporates the tools necessary to assess a Veteran for participation in an SMP and to define education, monitoring and documentation of progress towards fully independent or supervised 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 including residents in VA Community Living Centers (CLC). The most significant change from the former policy is the reduction in levels of independence from five to three and specific references to Veterans in the CLC. This Directive 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 Directive.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management Services (10P4P) is responsible for the contents of this Directive. Questions may be addressed to (202) 461-7362.

5. RESCISSIONS: VHA Handbook 1108.3, dated February 3, 2010.

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of November 30, 2021. This VHA Directive will continue to serve as national VHA policy until it is recertified or rescinded.

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VHA DIRECTIVE 1108.03

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SELF-MEDICATION PROGRAM (SMP)

1. PURPOSE

This Veterans Health Administration (VHA) Directive provides new procedures for the operation of Self-Medication Programs (SMP). **AUTHORITY:** 38 U.S.C. 501, 1712(d), 1745(b), 7301(b).

2. BACKGROUND

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 including VA Community Living Centers (CLC). This shift has emphasized rehabilitative approaches that promote Veteran education and skill development designed for improved self-care. With these approaches to health care, Veterans are able to learn and practice self-care skills, including the self-management of their medication regimens. This national policy sets basic guidelines to standardize how Veterans are assessed and educated toward the end goal of self-medication. Local sites may opt to have a more stringent self-medication policy dependent upon the site and the needs of the Veterans.

a. SMPs are established to enable Veterans to learn and practice skills for the self-management of their prescribed medications. The self-management of medications include:

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

(2) Instructions for teaching Veterans or their designated care givers to assume responsibility for prescribed and over the counter (OTC) medication storage.

NOTE: *Self-medication may be practiced on all official Department of Veterans Affairs (VA) bed sections, including CLCs, 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 facility policy.*

b. VHA policy establishes programs that maximize Veteran function and independence for self-medication and identifies Veterans who are appropriate for such programs. The self-medication program is an important therapeutic aspect of patient-centered care, taking into consideration the Veteran's ability and goals of care. 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. These are important elements in reducing post-discharge medication errors and readmission due to adverse medication events.

c. The SMP is designed to teach and monitor self-medication administration, storage, and compliance. Therefore, this process may be more labor intensive than traditional inpatient medication dispensing formats and is not intended to be used to solve staffing or other workforce-related issues. When a Veteran is expected to be

discharged from any VA medical facility to home or a community-based setting, they are identified early in the admission as Level I, Level II or Level III for medication administration in the plan of care. The plan of care should address the approaches to maximize the Veteran's medication knowledge and administration ability and set an expected goal for the Level of Independence at discharge or the transfer to another level of care.

3. DEFINITIONS

a. **Comprehensive Medication Management.** Comprehensive medication management is the standard of care that ensures each patient's medications (VA dispensed, non-VA dispensed, herbal, alternative, and over the counter (OTC) medications) are individualized and optimized for the patient based on the patient's medical conditions; comorbidities; individualized patient parameters, such as age-related changes in pharmacokinetics and pharmacodynamics of medications; and patient-centered care factors. It includes the management of chronic diseases, the acute manifestations of those diseases, and management of adverse events or reactions to medications. Comprehensive medication management includes components of medication therapy management, but it is a broader term that encompasses a larger spectrum of services that is provided by clinical pharmacists with a scope of practice. It takes into account drug-food interactions, drug-drug interactions and drug disease interactions. It includes a patient-specific therapeutic plan, goals and monitoring to ensure the best possible outcomes. In addition, the patient understands, agrees with, and is an active partner in the plan development and the patient's clinical outcomes.

b. **Designated Caregiver.** A designated caregiver oversees and facilitates safe administration of the patient's medication. The designated caregiver may be the Veteran's spouse, significant other, friend, or whomever the Veteran identifies as the designated caregiver, subject to approval by the primary care physician or responsible team member identified in local policy. In the CLC, a designated caregiver is the person who would assume responsibility for the Veteran's care in a home or community-based setting and designated to oversee and facilitate safe medication administration.

c. **Level of Independence.** "Level of independence" refers to the degree to which each Veteran SMP participant is assessed as being capable of safely administering their own medication by VA health care providers. There are three different levels: Level I- Dependent, Level II- Semi-independent, or Level III- Independent. (See Appendix A).

(1) **Level I- Dependent.** Dependent refers to a Veteran who requires: additional education and varying levels of medication monitoring; the direct involvement of nursing personnel or a designated caregiver for dispensing; and the observance and documentation of each self-administered medication by either nursing staff or a designated caregiver.

(2) **Level II- Semi-Independent.** Semi-Independent refers to a Veteran who requires periodic reviews and documentation by a professional staff member or a designated caregiver regarding their self-medication practices; including visual counts of the Veteran's medications and clinical observations of Veteran responses.

(3) **Level III- Independent.** Independent refers to a Veteran who understands: medication therapy management and the potential for drug side effects, and who is capable of assuming complete responsibility for the storage, security and self-administration of their medications.

d. **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. POLICY

It is VHA policy that all VA medical facilities will develop local policies that foster maximum opportunity for the Veteran to improve and utilize self-care skills prior to discharge, or transfer to less supervised or structured levels of care.

5. RESPONSIBILITIES OF THE VA MEDICAL FACILITY DIRECTOR

The VA medical facility director is responsible for ensuring that the facility has a written SMP policy that covers all participating wards, units, CLC households or programs. SMP policies must include requirements for:

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

6. VETERAN SELECTION CRITERIA AND ASSESSMENT

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

- (1) Comprehensive medication management (see paragraph 3.a.);
 - (a) The name of each medication;

(b) How to administer each medication (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 cognitive assessment as it relates to SMP;

(a) The integration of medications into the Veteran's lifestyle;

(b) Possible barriers to safe medication management and administration;

(c) Possible barriers to learning; and

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

b. Before discharge from SMP, the provider must document, in the Veteran's electronic medical record, either the outcome of the individual's ability to self-medicate or the established support systems that are in place to assure safe medication administration.

7. VARIOUS LEVELS OF VETERAN INDEPENDENCE IN SELF-MEDICATION

Based on the results of the assessment, each Veteran must be categorized as a Level I, Level II, or Level III ("independent") participant in SMP. **NOTE:** *Appendix A provides guidance for medication dispensing, administration, monitoring, education and storage for each level.*

a. A Veteran's 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 Medication Management.** Assessment of medication knowledge is an important part of the process by which a Veteran'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 Veteran's medical record (e.g., to ensure provider understanding of a Veteran's ability to self-medicate when a Veteran is treated by a dentist who dispenses an antibiotic directly to the Veteran).

(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 verify

any prescription drug, OTC medication and herbal product that is not dispensed by the VA medical facility pharmacy, if prescribed by a VA provider for self-medication (e.g., in a Blind Rehabilitation SMP). **NOTE:** *Local VA medical facility policy can be more restrictive.*

(3) Type of Medication Administration. Veterans with “semi-independent” (Level II) status may progress (or regress) towards increasing (or decreasing) independence based on a staff member’s assessment of the Veteran’s ability (see Appendix A). When independent, self-medication status is indicated, the Veteran may receive up to a 30-day supply of medication. In this instance, medications may be dispensed directly to the Veteran from the outpatient pharmacy section if allowed by local VA medical facility policy. Outpatient dispensing to the Veteran 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 member responsibility for monitoring the Veteran’s ability to self-medicate may range from direct observation and documentation of each dose to only clinical monitoring and documentation of the Veteran’s response to medication (see Appendix A). Each VA medical facility must define the responsibilities for documentation in their local self-medication policy. **NOTE:** *Intermediate levels of monitoring the Veteran’s ability to self-medicate may include observation of a Veteran filling a daily pillbox, periodic staff member review, or a physical count of the medication in the Veteran’s possession.*

(5) Veteran and Caregiver Education. Both the Veteran and their designated caregiver must understand the Veteran’s medication regimen. Following an initial assessment of the Veteran’s knowledge of their medication regimen, education by clinical personnel must be provided to the Veteran and/or caregiver for each medication regardless of the Veteran’s level of independence. The education provided must be documented in the Veteran’s medical record. This documentation is to include the:

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

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.*

(6) **Responsibility for Medication Storage.** Responsibility for medication storage may range from unit dose storage of all medications by designated staff members to the Veteran storing their own medications. In the CLC, a designated lockable storage area or compartment, specific to each individual, must be provided. In all cases, medications (including controlled substances) must be stored in locked locations, accessible only to appropriate clinical staff members and the “independent level” Veteran for whom the medications are prescribed.

8. CLINICAL MONITORING

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

- a. Identification of target symptoms;
- b. Medication efficacy assessment for target symptoms and adverse events (including the Veteran’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. A licensed health care provider must review and assess the Veteran’s medication regimen and document in the electronic medical record that portion of the regimen approved for self-medication. Except for insulin, intravenous or injection therapy will not be permitted in SMP. Any additional injectable must be approved by the local VA medical facility policy.

b. If the VA medical facility, including the CLC, determines that controlled substances are to be included in their SMP, the VA medical facility must adhere to standards in VHA Handbook 1108.01, “Controlled Substances (Pharmacy Stock),” and 1108.02, “Inspection of Controlled Substances,” 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 SMP will be administered to the Veteran on a dose-by-dose basis by designated staff members. **NOTE:** *Veterans 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 Veteran is deemed qualified, controlled substances may be dispensed for self-medication in 7 day quantities, or less.*

(3) Controlled substances administered to Veterans by licensed independent practitioners will be managed in accordance with local VA medical facility policy and Handbook 1108.01 and

(4) Storage for controlled substances administered by the Veteran and or designated care giver must have a secure locked system (e.g. cabinet, locker, wall mounted box, etc.).

c. OTC medications and herbal products are permitted in SMP only when an approved VA provider has authorized the product's use after careful evaluation of the agent's appropriateness based on the Veteran's medical history and current medication regimen. **NOTE:** *The local VA medical facility may permit the Veteran to bring OTCs or medications prescribed by outside providers if permitted by facility policy.*

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

(1) The Outpatient Pharmacy Software Package must be used for ordering self-medication for Veterans requiring a multi-dose prescription vial.

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

10. MEDICATION SECURITY CRITERIA

a. All medications (including controlled substances) must be stored on the unit or CLC household in accordance with VHA Handbook 1108.01 and VHA Handbook 1108.06, Inpatient Pharmacy Services.

b. Medications for Veterans with "semi-independent" and "independent" status must be kept in a locked cabinet or locker accessible only to the Veteran's provider, designated staff members and the Veteran or their designated care giver. **NOTE:** *Keys must be unique and not usable in other Veteran's cabinets or lockers. VA medical facilities, including CLCs may consider the utilization of keyless entry security systems.*

c. Exception to security requirements are to be made for self-medication that must be stored under refrigerated conditions. However, Veterans and their designated caregivers must agree in writing to comply with all applicable security requirements in order to participate in SMP. This agreement must include a statement that the Veteran or designated care giver 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	Level II	Level III
	"DEPENDENT"	"SEMI- INDEPENDENT"	"INDEPENDENT"
Assessment of 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, pill box or blister pack or other aide	Multi-dose prescription vial	Multi-dose prescription vial
Means of medication receipt.	Nurse to administer or prepare 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 self-administration (Performed daily).	Veteran documents daily self-administration of medication. Nurse verifies and documents on Mondays and Thursdays. **	A clinical monitoring and documentation of Veteran's response to medications. Random spot check of medication is conducted at least weekly.
Education of Veteran and or designated care giver	Nurse to provide education at each administration of medications.	Nurse to provide education at time of administration (including pillbox use).	Appropriately credentialed staff provides education (including pillbox use) at time of administration.
Responsibility for medication storage	Nurse stores all medications in locked location.	Veteran stores own medications in a locked location.	Veteran stores own medications in a locked location.

*Controlled substances will be unit-doses by nursing staff members.

** Nurse observes filling of pillbox, if used.

***Veterans may be transitioned from one level to another.