

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1108.13(1)
Transmittal Sheet
February 6, 2019

PROVISION AND USE OF NURSING MEDICATION MANAGEMENT PROTOCOLS IN OUTPATIENT TEAM-BASED PRACTICE SETTINGS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy and requirements for the development and utilization of medication management protocols for select high volume medications by nursing staff in team-based, outpatient practice settings within VHA.

2. SUMMARY OF CONTENT:

a. Amendment dated March 13, 2019, updates the responsibilities for the Associate Director for Patient Care Services/Nurse Executive, specifically, 5.e.(5); and the VA Medical Facility, Pharmacy and Therapeutics Committee, specifically 5.g.(4).

b. The italicized text preceding the note in paragraphs (1) and (2) below have been amended:

(1) Paragraph 5.e.(5): All nursing medication management protocols utilized have a specific quality monitoring program developed with delineated responsibility to a specific service chief for completion and reported no less than *twice a year* to the VA medical facility P&T Committee and the appropriate VA medical facility-based authorizing body. **NOTE:** *Twice a year replaced annually.*

(2) Paragraph 5.g.(4): Tracking and trending of medication errors, adverse drug reactions, and allergies is performed for patients treated by a nursing medication management protocol and reported to the P&T Committee at a minimum of *twice a year*. **NOTE:** *Twice a year replaced semi-annually.*

c. This is a new directive that:

(1) Establishes the policy and procedures for VA medical facilities that make the decision to utilize national nursing medication management protocols in team-based, outpatient practice settings and requires VA medical facilities using these protocols to comply with all elements stated in this directive.

(2) Requires that nursing medication management protocols only be utilized by Registered Nurses (RNs) whose State licenses and State Board of Nursing statutes and regulations allow them to perform medication adjustments delegated by providers in the form of protocol. **NOTE:** *All legend drugs, over-the-counter medications, and herbal or alternative medications are classified as medication. For purposes of this directive, the term medication excludes influenza and pneumococcal vaccines, which may be administered in accordance with VHA Directive 1013(1), Prevention and Control of Seasonal Influenza with Vaccines, dated February 5, 2015, and VHA Directive 2013-*

006, The Use of Unlicensed Assistive Personnel in Administering Medication, dated March 27, 2013, without requiring an individual patient order.

(3) Requires that VA medical facilities only use national nursing medication management protocols developed and approved by Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), and Veterans Integrated Service Network (VISN) Formulary Committees, when appropriate.

(4) Requires that VA medical facilities review the approved national nursing medication management protocols prior to use and implementation, through the facility's Pharmacy and Therapeutics (P&T) Committee, Executive Committee of the Medical Staff (ECMS), and other appropriate governing committee, to determine the practice setting and nursing staff that will utilize these protocols.

(5) Requires that any nursing medication management protocol in place at a VA medical facility prior to the implementation of this directive be transitioned to national protocols expeditiously as stated in this directive.

(6) Requires the signature of a VA prescriber for all medication orders, including all medication adjustment actions contained within the protocol, prior to release of the order.

(7) Requires that medication management actions are delegated solely to RN staff and not to adjunct staff.

(8) Requires that the staff responsibilities established by the VA medical facility with regards to nursing medication management protocols are consistent with the facility's medical bylaws, the facility's credentialing and privileging requirements, and within the nursing staff's State Board of Nursing statutes and regulations and scope of practice.

3. RELATED ISSUES: VHA Handbook 1108.05, Outpatient Pharmacy Services, dated June 16, 2016; VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016; VHA Handbook 1108.11(1), Clinical Pharmacy Services, dated July 1, 2015; and VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT), dated February 5, 2014.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Services (10P4P) in the Office of Patient Care Services (10P4) is responsible for the content of this directive. Questions may be addressed to (202) 461-7326.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of February 2024. This VHA directive will continue to service as national VHA policy until it is recertified or rescinded.

February 6, 2019

VHA DIRECTIVE 1108.13(1)

CERTIFIED BY:

**BY THE DIRECTION OF THE UNDER
SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for
Health for Policy and Services

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for
Health for Policy and Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List February 8, 2019.

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PROVISION AND USE OF NURSING MEDICATION MANAGEMENT PROTOCOLS IN OUTPATIENT TEAM-BASED PRACTICE SETTINGS

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy and requirements for the utilization of medication management protocols for select high volume medications by nursing staff in team-based, outpatient practice settings within VHA. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. VHA is committed to safe decision making in the delivery of health care. This directive focuses on the provision and use of nursing medication management protocols in outpatient team-based setting, which include, but are not limited to, Patient Aligned Care Teams (PACTs), special population PACTs, Home Telehealth and medicine and surgical specialty team settings as described in VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014. This policy was created in conjunction with the Office of Nursing Service (ONS), Patient Care Services, and other key stakeholders with primary responsibility assigned to Pharmacy Benefits Management (PBM) Services (10P4P) and focuses on improving access to care while ensuring the safe delivery of that care to our Veterans. A nursing medication management protocol describes the conditions, roles, responsibilities, and a series of actions that includes the authorization of Registered Nurses (RNs) to review and recommend adjustment or titration of certain specifically identified medications for final signature by an authorized prescriber. In VHA, prescriptive authority is authorized for physicians, Physician Assistants, Advanced Practice Registered Nurses (APRNs), and Clinical Pharmacists among others, as outlined in their locally defined clinical privileges and/or scopes of practice. VHA RNs are dependent practitioners who practice under a collaborative relationship with other healthcare professionals, but do not have prescriptive authority (e.g., ability to independently initiate or adjust medications) outlined in their scope of practice. **NOTE:** *This directive pertains to protocols involving the initiation or adjustment of medications or “drugs.”*

b. Team-based care is a core concept of VHA and roles and responsibilities, including specific actions designated to be performed by each team member, should be delineated for all appropriate team members to promote efficiency and effectiveness with everyone working at the top of their education and training. VA medical facilities are encouraged to examine their team-based setting resources and facility care delivery systems to determine how to best meet the medication management needs of the Veteran population. Clinical Pharmacists and Clinical Pharmacy Specialists (CPS) provide medication management services across the Department of Veterans Affairs (VA); however, due to the burden of co-morbidities, there is an increasing need to have other team members participate in medication management for chronic disease management.

c. Currently VHA does not have a policy authorizing nursing practice through protocols and has an obligation to ensure that patient care is appropriate and safe and its health care practitioners meet generally accepted professional standards of care. The authority to allow nursing staff to perform tasks delegated by providers in the form of protocol is outlined in State Board of Nursing statutes and regulations. These State acts and regulations differ regarding the ability for nursing professionals to perform medication management actions (e.g., medication adjustment) under a protocol or standing order. Therefore, before implementing use of nursing medication management protocols, it is imperative that VA medical facilities review the individual RN's State license and corresponding State Board of Nursing statutes and regulations to ensure it allows the use of such protocols. The Joint Commission and Centers for Medicare and Medicaid Services (CMS) provide definitions of standing orders. The Joint Commission outlines requirements for standing orders in its Medication Management Standards stating that hospitals must have a written policy for the utilization of standing orders when they are utilized. Guidance for the development and use of non-medication nursing protocols for the ambulatory care setting has been developed by the Office of Nursing Services and the Assistant Deputy Under Secretary for Health for Patient Care Services, and can be found at:

http://vaww.va.gov/nursing/docs/7477114doc215434Guide_Develop_Nsg_ProtocolsNo_Medications.pdf. **NOTE:** *This is an internal VA Web site that is not available to the public.* Many protocols or standing orders may have both medication and non-medication actions; therefore, it is important to note that this directive does not apply to the ability of VA medical facilities to utilize non-medication protocols (e.g., clinical reminders, laboratory orders, etc.) but rather outlines policy requirements for facilities that opt to use nationally approved nursing medication management protocols.

3. DEFINITIONS

For purposes of this directive, the following definitions apply:

a. **Adjunct Staff.** Adjunct staff include all non-prescriber and non-RN staff designated to provide support to a panel or a cohort of patients and includes the Licensed Practical Nurse (LPN) or Licensed Vocational Nurse (LVN), Unlicensed Assistive Personnel (UAP), and Administrative Associate among others.

b. **Home Telehealth.** Home Telehealth is a program where care and case management principles are used to coordinate care using health informatics, disease management, and telehealth technologies to facilitate access to care and to improve the health of Veterans participating in VHA's Home Telehealth program. The goal of Home Telehealth is to improve clinical outcomes and access to care while reducing complications, hospitalizations, and clinic or emergency room visits for Veterans in post-acute care settings and high-risk patients with chronic disease. (See <http://vaww.telehealth.va.gov>. **NOTE:** *This is an internal VA Web site that is not available to the public.*)

c. **Licensed Practical/Vocational Nurse.** A Licensed Practical/Vocational Nurse (LPN/LVN) is a professional who has received training resulting in a postsecondary non-

degree award from a school of nursing National League for Nursing Accrediting Commission (NLNAC) or the Commission on Collegiate Nursing Education (CCNE), successfully passed a national licensure examination, and is registered to practice in a State by the State authority. A LPN/LVN works under the direction of a RN or other VA provider. A LPN/LVN may only assume non-medication actions outlined in nursing medication management protocols and may not be delegated medication management actions.

d. **Medication.** Medications are any item that is defined as a drug per 21 U.S.C. 321(g)(1). **NOTE:** *All legend drugs, over-the-counter medications, and herbal or alternative medications are classified as medication. For purposes of this directive, the term medication excludes influenza and pneumococcal vaccines, which may be administered in accordance with VHA Directive 1013, Prevention and Control of Seasonal Influenza with Vaccines, dated February 5, 2015, without requiring an individual patient order.*

e. **Non-Medication Actions.** Non-medication actions are discreet steps and processes, performed by various team members, that augment the specific medication protocol actions that are necessary to provide comprehensive care delivery associated with the condition identified by the specific nursing medication management protocol. Examples of team delineation of duties within a Nursing Medication Protocol may be found in Appendix C.

f. **Nursing Medication Management Protocol.** The term nursing medication management protocol refers to a standardized care process for select high volume medications which outlines written document of steps or actions that contains nursing actions, team actions, and provider-specific orders. These protocols include 1) medication adjustments by the RN and 2) non-medication actions by adjunct staff such as a LPN/LVN, UAP, and Administrative Associates as outlined in the protocol and in accordance with individual functional statements and position descriptions. They also may contain independent nursing actions such as coaching and teaching and will often include interdependent nursing actions. Interdependent nursing actions are appropriate when they are evidence-based, support population health, and are utilized in a team-based setting in which nurses have adequate support to ensure patient safety. Additional team responsibilities must be described for each adjunct staff role. A protocol may also contain standing orders as appropriate. **NOTE:** *Nursing medication management protocols may only be utilized by RNs whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols.*

g. **Prescriber.** A prescriber is a VA authorized provider with medication prescriptive authority outlined in their clinical privileges or scope of practice. In VHA, prescriptive authority is only authorized for physicians, physician assistants, APRNs, and clinical pharmacists, as stated in their locally defined clinical privileges and/or scopes of practice.

h. **Standing Order.** A standing order is a written document of orders that clearly delineates the circumstances under which personnel can be delegated to initiate orders.

They describe the specific type of practice to be delegated when predetermined conditions have been met, the specific health care clinician class, delineate the procedures that personnel must follow, identify the patient population that may be served, specify the level of provider supervision required, and govern the locations where the services may occur. **NOTE:** For additional information related to non-medication protocols, please see:

http://vaww.va.gov/nursing/docs/7477114doc215434Guide_Develop_Nsg_ProtocolsNo_Medication.pdf. This is an internal VA Web site that is not available to the public.

i. **Team.** A team consists of a group of health care professionals that collectively accepts responsibility for the care of a patient or group of patients. The team includes, but is not limited to, a Prescriber, RN, LPN/LVN, unlicensed assistive personnel, administrative associate, clinical pharmacist, and registered dietitian nutritionist.

j. **Outpatient Team-Based Settings.** Outpatient team-based settings refer to areas where the RN works collaboratively with a team of health care professionals to provide comprehensive care in partnership with the patient (and the patient's personal support person(s)), which may include primary care (e.g., PACT, including special population PACTs) and medicine and surgical specialty team settings. In outpatient team-based practice settings, team members should have access to readily available communication processes to address any urgent situations that may arise and require intervention (e.g., clarification of orders, critical laboratory results). Nursing medication management protocols may not include settings such as telephone triage locations, centralized call centers, or other areas where the RN does not have a team-based relationship with the patient and the VA prescriber.

k. **Registered Nurse.** An RN is a nursing professional who has graduated from a school of nursing accredited by the NLNAC or the CCNE, successfully passed a national licensure examination, and is registered to practice in a State by the State authority. Nursing medication management protocols may only be utilized by RNs whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols and they meet all required education and training requirements to use such protocols. In addition, only RNs may be delegated medication management actions.

4. POLICY

It is VHA policy that VA medical facilities utilizing nursing medication management protocols will meet all elements identified in this directive. Nursing medication management protocols are only utilized by a RN whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols. This directive does not mandate the use of nursing medication management protocols, although it does require when they are utilized that any such protocols must be developed and approved by the Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), Veterans Integrated Service Network (VISN) Pharmacist Executive (VPE) and VISN Formulary Committees in addition to the VA medical facility, as outlined in this directive.

5. RESPONSIBILITIES

a. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant PBM, is responsible for ensuring that:

(1) National nursing medication management protocols for select high volume medications are developed and approved by the PBM, MAP, VPE, and VISN Formulary Committees and in accordance with VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016. Protocols written for RNs working in a specialty care setting may involve specialty high volume medications not appropriate to alternate outpatient settings.

(2) Approved national nursing medication management protocols are distributed to VA medical facilities as appropriate. National nursing medication management protocols are located at

<https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>.

NOTE: This is an internal VA Web site that is not available to the public.

(3) An annual review of medications recommended for inclusion in nationally developed nursing medication management protocols is performed. This review will occur in an equal partnership collaboration with the Office of Nursing Services (ONS) and in collaboration with other internal key stakeholders.

(4) An annual assessment and review of national nursing medication management protocols is performed based on current evidence, PBM, MAP, VPE, and VISN Formulary Committee guidance, national formulary changes, or medication safety concerns.

(5) The PBM, MAP, VPE, and VISN Formulary Committees respond in a timely manner, but no later than 60 days of the date an issue arises related to national nursing medication management protocols (e.g., changes to PBM, MAP, VPE, and VISN Formulary Committee guidance, VA National Formulary changes, or medication safety concerns).

b. **Chief Nursing Officer, Office of Nursing Services.** The Chief Nursing Officer for ONS is responsible for ensuring that:

(1) An annual review of medications to be considered for the development of national nursing medication management protocols is performed in partnership with PBM.

(2) Guidance on non-medication actions for approved national nursing medication management protocols is provided to PBM.

(3) Medication requests by ONS that meet the elements in this directive are reviewed and forwarded to the PBM for national nursing medication management protocol consideration by the MAP, VPE, and VISN Formulary committees.

(4) National and VA medical facility consultation for nursing practice elements is provided related to nursing medication management protocols.

(5) Providing guidance for recommended training and assessment of competence is provided related to nursing medication management protocols.

(6) Guidance is provided to VA medical facilities when questions arise related to RN State licensure and State Board of Nursing statutes and regulations regarding the utilization of nursing medication management protocols.

c. **VA Medical Facility Director.** The VA medical facility Director is responsible for ensuring that:

(1) If the VA medical facility decides to utilize national nursing medication management protocols, that the facility ensures they meet all elements outlined in this directive to ensure the structure, accountability and oversight for the effective, safe, and efficient implementation of such protocols.

(2) Nursing medication management protocols are only utilized by RNs whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols. Medication management actions may be delegated to RN staff only.

(3) Nursing medication management protocols are used only for patients in outpatient, team-based practice settings and meet the standards identified in this directive.

(4) The VA medical facility utilizes only nursing medication management protocols developed and approved by PBM, MAP, VPE and VISN Formulary Committees. National nursing medication management protocols are found on the following SharePoint site:

<https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx> .

NOTE: *This is an internal VA Web site that is not available to the public.*

(5) Any nursing medication management protocol in place at the VA medical facility prior to the implementation of this directive may be continued for a maximum of 180 calendar days to avoid disruption in patient care. However, these protocols must be reviewed expeditiously and discontinued or transitioned to nationally approved nursing medication management protocols, as appropriate.

(6) The VA medical facility ensures nursing medication management protocols are reviewed by the facility Pharmacy and Therapeutics (P&T) Committee and Executive Committee of the Medical Staff (ECMS) and the local nursing practice council prior to implementation and use. This reviewing process must be interprofessional and at a minimum include medicine, nursing, pharmacy, and other key stakeholders with responsibilities outlined in the protocol.

(7) Nursing medication management protocols utilized are delineated by the practice setting and standardized across similar outpatient team-based practice areas or clinics

to ensure all elements are consistently and safely addressed, e.g., all PACT clinics, all Cardiology clinics, and between parent facility and Community Based Outpatient Clinics (CBOCs).

(8) Adequate resources are available when nursing medication management protocols are utilized.

(9) Need of a VA medical facility for nursing medication management protocols is in accordance with the mission of the facility where the nursing staff is employed and the available resources to provide health care.

(10) Verification of the credentials of the RN and other requirements as stated in paragraph 5.e. of this section.

(11) Approval by the appropriate VA medical facility authorizing body that indicates that the RN, LPN/LVN has demonstrated the clinical experience, knowledge, and skills necessary to perform the tasks stated in the protocol.

(12) Nursing medication management protocols include the delineation of responsibilities for medication management actions to the prescriber and RN, and for adjunct staff, including LPN/LVN, UAP, and administrative associates for non-medication actions. Delegation to adjunct staff for non-medication actions must be in accordance with individual functional statements or position descriptions.

(13) All medication orders, including all medication adjustment actions, contained within the protocol are signed by a VA prescriber prior to release of the order. The RN will place the medication order with "hold for signature" for the VA prescriber to review and approve.

(14) An infrastructure exists for submitting medications for consideration in national nursing medication management protocols. This consideration process includes:

(a) The VA medical facility must ensure the recommendation meets all criteria and standards in this directive and Appendix A; and

(b) The medication request for national nursing medication management protocol consideration is forwarded through the VA medical facility P&T Committee and the nursing practice council to the PBM, MAP, VPE and VISN Formulary Committees for review and final approval. **NOTE:** *Requests for medications for national nursing medication management protocol consideration are done via VA Form 10-10159, Form for Facility Recommendation of a Medication (To Be Considered) For Inclusion in a National Nursing Medication Management Protocol(s) (For Use in Outpatient Team-Based Practice Settings), available at: <https://vawww.va.gov/vaforms/medical/pdf/10-10159.pdf>. This is an internal VA Web site that is not available to the public.*

NOTE: *It is important that the request addresses all elements contained in this directive and that all parties involved with the delivery of care via the protocol, to include at a minimum, medical, nursing and pharmacy subject matter experts, are in agreement.*

d. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (COS) is responsible for ensuring that:

(1) Any patient receiving care under a nursing medication management protocol has a valid patient-specific order from a VA prescriber.

(2) Nursing medication management protocols used at the VA medical facility are reviewed and approved prior to implementation through the VA medical facility P&T Committee, ECMS, and appropriate VA medical facility governing bodies.

(3) Nursing medication management protocols are implemented in areas where the RN has a relationship with a patient, there is effective communication and team cohesiveness, and practice is coordinated with the VA prescriber to ensure protocols are safely and effectively used. These areas do not include settings such as telephone triage locations, centralized call centers, or other areas where the RN does not have a direct relationship with the patient and the VA Prescriber.

(4) The VA medical facility does not modify nursing actions within the protocol that involve medication management actions. Modifications may be approved to accommodate individual clinic workflow and operational needs; however, modification to medication actions may not be approved for individual VA prescriber or clinic use, e.g., drug dosages, less stringent monitoring, etc.

(5) VA prescribers who utilize nursing medication management protocols have a clear understanding of protocol elements and are prepared to assume full accountability for the provision of safe care, although the RN remains fully accountable and liable for their practice.

(6) There is an effective contingency plan in place to assure VA prescribers and RNs are able to address any urgent situations that may arise and require intervention, e.g., adverse drug reactions, critical laboratory results, etc.

(7) All VA prescribers utilizing nursing medication management protocols receive training regarding the protocol elements, as appropriate.

e. **Associate Director for Patient Care Services/Nurse Executive.** The Associate Director for Patient Care Services (DCPS)/Nurse Executive is responsible for ensuring that:

(1) Nursing medication management protocols are only utilized by RNs whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols. Medication management actions may be delegated to RN staff only.

(2) Nursing protocols are in compliance with accreditation bodies.

(3) Nursing protocols have actions consistent with nursing scope of practice policy as defined by the State and the local facility.

(4) All RNs and adjunct staff with responsibilities delineated in nursing medication management protocols have received all required training and have competency assessments performed initially, and at a minimum of annually as appropriate. Results of the competency assessments are reported to the ECMS and any appropriate VA medical facility-based authorizing body, as applicable.

(5) All nursing medication management protocols utilized have a specific quality monitoring program developed with delineated responsibility to a specific service chief for completion and reported no less than twice a year to the VA medical facility P&T Committee and the appropriate VA medical facility-based authorizing body. The program should include:

(a) The evaluation of fidelity to the performed elements in the nursing medication management protocol for all involved clinical staff utilizing these protocols. Include verification that specific actions outlined in the protocol are carried out correctly for the right patient by appropriate roles within correct time frames);

(b) The evaluation of safety and quality, including patient outcomes; development of measures; mechanisms for data capture; and frequency and oversight accountability;

(c) The evaluation of protocol documentation including follow-up of patient encounters in the electronic medical record. A standardized template containing protocol elements is encouraged for nursing medication management protocol; and

(d) Analysis and ongoing tracking and trending of quality monitoring elements over time to evaluate opportunities for improvement and appropriateness of continued use.

f. **VA Medical Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy is responsible for ensuring that:

(1) VA prescription database information is provided, as appropriate, for the quality monitoring program to the appropriate individuals (or P&T Committee) at the VA medical facility level to evaluate that all medication orders originated from nursing medication management protocols are signed by the VA authorized prescriber prior to implementation.

(2) All medication requests for the development of national nursing medication management protocols are reviewed prior to being submitted to the VA medical facility P&T Committee to ensure adherence to all requirements of this directive as outlined in Appendix B. **NOTE:** *Requests for medications for national nursing medication management protocol consideration are done via VA Form 10-10159, Form for Facility Recommendation of a Medication (To Be Considered) For Inclusion in a National Nursing Medication Management Protocol(s) (For Use in Outpatient Team-Based Practice Settings), available at: <https://vaww.va.gov/vaforms/medical/pdf/10-10159.pdf>. This is an internal VA Web site that is not available to the public.*

g. **VA Medical Facility, Pharmacy and Therapeutics Committee.** The VA medical facility P&T Committee is responsible for ensuring that:

(1) Only PBM, MAP, VPE and VISN Formulary Committee nationally approved nursing medication management protocols are utilized at the VA medical facility. These protocols are reviewed and approved for use at the VA medical facility prior to implementation, and meet all elements outlined in this directive. National nursing medication management protocols are found on the following SharePoint site: <https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>.

NOTE: *This is an internal VA Web site that is not available to the public.*

(2) An infrastructure exists for the VA medical facility to respond, no later than 60 calendar days after issues related to national nursing medication management protocols arise based upon PBM, MAP, VPE, and VISN Formulary Committee guidance, VA National Formulary changes, or medication safety concerns.

(3) A quality monitoring program is developed and reported to the P&T Committee no less than twice a year for each nursing medication management protocol used at the VA medical facility; these reports should be analyzed, tracked and trended over time to evaluate the appropriateness of continued use of the protocol.

(4) Tracking and trending of medication errors, adverse drug reactions, and allergies is performed for patients treated by a nursing medication management protocol and reported to the P&T Committee at a minimum of twice a year.

(3) A process exists for submitting medications for consideration as nationally approved nursing medication management protocols. **NOTE:** *Requests for medications for national nursing medication management protocol consideration are done via VA Form 10-10159, Form for Facility Recommendation of a Medication (To Be Considered) For Inclusion in a National Nursing Medication Management Protocol(s) (For Use in Outpatient Team-Based Practice Settings), available at:*

<https://vaww.va.gov/vaforms/medical/pdf/10-10159.pdf>. *This is an internal VA Web site that is not available to the public.*

h. **VA Medical Facility Team.** All VA medical facility team members that utilize nursing medication management protocols are responsible for ensuring that:

(1) Only national nursing medication management protocols developed and approved by PBM, MAP, VPE and VISN Formulary Committees are utilized in outpatient, team-based settings when appropriate. National nursing medication management protocols are found on the following SharePoint site: <https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>.

NOTE: *This is an internal VA Web site that is not available to the public.*

(2) All nursing medication management protocols are initiated by an order signed by a VA prescriber. Once a signed protocol is in place, each medication order, including all medication adjustment actions, must be signed by a VA prescriber prior to release of the order and delegated solely to RN staff. The RN will place the medication order with “hold for signature” for the VA prescriber to review and approve.

(3) National nursing medication management protocols elements are not altered in any way. Team members are responsible for following all procedures and processes outlined in the national nursing medication management protocol for identified patients and may not modify nursing actions within the protocol that involve medication management actions. Modifications may be approved to accommodate individual clinic workflow and operational needs; however, modification to medication actions may not be approved for individual VA prescriber or clinic use, e.g. drug dosages, less stringent monitoring, etc.

(4) Upon initiation of a nursing medication management protocol, the VA prescriber will document the individualized patient treatment goal(s) that were developed through ongoing shared decision-making with the patient and the team as appropriate. Any changes to the treatment goal after the initiation of the protocol must be documented by the prescriber and communicated to the RN and other team members as appropriate.

(5) Appropriate contingency plans and procedures exist to ensure the timely responsiveness for covering prescribers and RNs to address any urgent situations that may arise and require intervention, e.g., adverse drug reactions, critical laboratory results, etc.

(6) The responsibilities outlined in the nursing medication management protocols and performed by the team member are in accordance with their individual functional statements, functional statements, position descriptions, applicable State and Federal regulations, and meet all elements outlined in VHA policy.

(7) Care delivery is appropriately documented in the electronic health record, including, but not limited to, addressing urgencies, patient response, and patient and caregiver education.

(8) VA prescribers, RNs, and adjunct staff with protocol responsibilities complete any required training and formally demonstrate the competency to safely use the protocol, as appropriate.

(9) Adverse events involving medication errors, adverse drug reactions, and allergies are disclosed to the patient in accordance with VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012, and medical facility policy.

6. TRAINING REQUIREMENTS

There are no training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If

you have any questions regarding any aspect of records management, you should contact your facility Records Manager or your Records Liaison.

8. REFERENCES

a. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Title 42 Code of Federal Regulations (CFR), Parts 482 & 485.

b. VA Handbook 5005/27, Part II, Appendix G-6, Qualification Standard, dated March 17, 2009.

c. VHA Directive 1013, Prevention and Control of Seasonal Influenza with Vaccines, dated February 5, 2015.

d. VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016.

e. VHA Directive 2007-033, Telephone Service for Clinical Care, dated October 11, 2007.

f. VHA Directive 2013-006, The Use of Unlicensed Assistive Personnel in Administering Medication, dated March 5, 2013.

g. VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.

h. VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT), dated February 5, 2014.

i. VHA Handbook 1108.05, Outpatient Pharmacy Services, dated June 16, 2016.

j. VHA Handbook 1108.11(1), Clinical Pharmacy Services, dated July 1, 2015.

k. VHA Handbook 1907.01, Health Information Management and Health Records, dated March 19, 2015.

l. VA Form 10-10159, Form for Facility Recommendation of a Medication (To Be Considered) For Inclusion in a National Nursing Medication Management Protocol(s) (For Use in Outpatient Team-Based Practice Settings), available at: <https://vaww.va.gov/vaforms/medical/pdf/10-10159.pdf>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

m. Office of Nursing Services (ONS), Guidance for the Development of Nursing Protocols without Medication Management for the Patient Aligned Care Team Setting, available at: http://vaww.va.gov/nursing/docs/7477114doc215434Guide_Develop_Nsg_ProtocolsNo_Medications.pdf. **NOTE:** *This is an internal VA Web site that is not available to the public.*

February 6, 2019

VHA DIRECTIVE 1108.13(1)

n. Nursing: Scope and Standards of Practice, 3rd edition, 2015, American Nursing Association (ANA).

REQUIRED ELEMENTS OF NURSING MEDICATION MANAGEMENT PROTOCOLS

a. Nursing medication management protocols utilize a standardized approach and includes all elements defined in this directive and listed below. The use of nursing medication management protocols is not mandated and is at the discretion of the Department of Veterans Affairs (VA) medical facility and its governing bodies. However, when nursing medication management protocols are adopted, the protocols must meet the following criteria:

(1) Is limited to a single medication;

(2) Focused on medications that can be effectively and safely prescribed and titrated under a nursing medication management protocol for high volume disease states within outpatient, team-based practice settings;

(3) Inclusive of VA National Formulary for medications that are in compliance with Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), and Veterans Integrated Service Network (VISN) Formulary Committee criteria for use, guidance and medication safety recommendations;

(4) Provide clear and standardized medication doses (including maximum doses) and adjustment schedules supported by evidence and within Food and Drug Administration (FDA) approved dosing limits;

(5) All medication orders, including all medication adjustment actions contained within the protocol, require signature by a VA prescriber prior to release of the order and delegated solely to Registered Nurse (RN) staff. The RN will place the medication order with "hold for signature" for the VA prescriber to review and approve. Non-medication actions, such as obtaining a laboratory test, may not require an additional provider signature. **NOTE:** *Nursing medication management protocols may only be utilized only by RNs whose State licenses and State Board of Nursing statutes and regulations allow the use of such protocols.*

(6) Ensure a patient specific order is signed by a VA prescriber to initiate the protocol. In addition, the VA prescriber documents the individualized patient treatment goal as appropriate. Any changes to the treatment goal after the initiation of the protocol must be documented by the prescriber and communicated to the RN; and

(7) Address all the following elements:

(a) Patient inclusion and exclusion criteria;

(b) Mechanism or procedure for initiating the protocol order;

(c) Medications utilized to include dosages and titration schedule;

(d) Appropriate treatment goals for patients participating in the protocol in accordance with VA/Department of Defense (DoD) guidance, PBM, MAP and VISN Formulary Committee criteria for use, or other applicable evidence;

(e) Monitoring parameters for medications utilized and the intervals at which monitoring is required;

(f) Management of adverse drug events and allergic reactions;

(g) Parameters by which the patient would be referred to the referring provider, urgent care, or emergency care;

(h) Provisions for non-medication actions delineated for each adjunct staff role;

(i) Progress note documentation requirements and how the VA prescriber will be notified of changes and actions;

(j) Patient and the patient's personal support person education to be performed to include non-pharmacological management of diet and exercise as well as counseling on medication adherence;

(k) Quality monitoring program and oversight of the protocol; and

(l) Provision for training, education, and competency assessment of all staff utilizing medication management protocol.

**FORM FOR FACILITY RECOMMENDATION OF A MEDICATION (TO BE
CONSIDERED) FOR INCLUSION IN A NATIONAL NURSING MEDICATION
MANAGEMENT PROTOCOL(S) (FOR USE IN OUTPATIENT TEAM-BASED
PRACTICE SETTINGS)**

a. Department of Veterans Affairs (VA) medical facilities may submit a medication for National Nursing Medication Management Protocol development to the VA medical facility Pharmacy and Therapeutics (P&T) Committee using VA Form 10-10159, available at: <https://vaww.va.gov/vaforms/medical/pdf/10-10159.pdf>. **NOTE:** *This is an internal VA Web site that is not available to the public.* If approved at the VA medical facility level, the medication request will be forwarded through the Veterans Integrated Service Network (VISN) Pharmacy and Therapeutics (P&T) committee for consideration of submission to Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), VISN Pharmacist Executive (VPE) and VISN Formulary Committees for national protocol development.

b. It is important that the request addresses all elements contained in this directive and that all parties involved with the delivery of care via the protocol, to include at a minimum, medical, nursing and pharmacy subject matter experts, are in agreement.

c. VA medical facilities may utilize only protocols developed and approved by PBM, MAP and VISN Formulary Committees on the national PBM SharePoint site located at <https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>. **NOTE:** *This is an internal VA Web site and is not available to the public.*

EXAMPLE NURSING MEDICATION MANAGEMENT PROTOCOL WITH TEAM DELINEATION OF DUTIES

The following appendix should be used as a guide in the development of team member roles and responsibilities for nursing medication management protocols. It is important to note that the team member responsibility outlined must be in accordance with the individual’s functional statements, position description, scope of practice, applicable State and Federal regulations, and meet all elements outlined in Veterans Health Administration (VHA) policy. This example includes the delineation of clinical actions by role for a hypertensive medication management protocol.

Clinical Action	Specific Patient Type/Comments	RN	LPN/LVN	UAP
Order laboratory order to be performed 4 weeks after medication dose change	Use policy order for entering laboratory results with the VA prescriber to receive results.	x	x	
Place order with “hold for signature” for any device including home blood pressure, pill-box, a pedometer or scale from Prosthetics	For patients who are to monitor home BP as part of the protocol, obtain the needed equipment. The process for obtaining supplies/equipment will be site specific.	x	x	x
Review how to take and record blood pressure readings for those using a home device	When possible have the patient bring their home device to the appointment and use it for teaching and instruct to bring record of BP readings to clinic visits.	x	x	x
May discuss/notify Veterans of normal test results		x	x	x
May discuss/notify Veterans of normal and abnormal test results	As specified by local policy	x	x	

Clinical Action	Specific Patient Type/Comments	RN	LPN/LVN	UAP
Review self-monitored home or non-VA Blood Pressure (BP) recording, if available	Notify Prescriber of evidence of BP readings that are out of the identified acceptable range, or if the patient reports any adverse reactions.	x	x	

STEPS FOR NATIONAL NURSING MEDICATION MANAGEMENT PROTOCOL DEVELOPMENT

a. The submitting individual completes required components in Department of Veterans Affairs (VA) Form 10-10159, available at: <https://vaww.va.gov/vaforms/medical/pdf/10-10159.pdf>, and submits medication for national nursing medication management protocol consideration to the VA medical facility Pharmacy and Therapeutics (P&T) Committee. **NOTE:** *This is an internal VA Web site that is not available to the public.*

b. VA medical facility P&T Committee reviews medication requested for national nursing medication management protocol development.

(1) If approved, medication is forwarded to Veterans Integrated Service Network (VISN) P&T Committee and VISN Pharmacist Executive (VPE) for review and approval;

(2) If disapproved, the VA medical facility P&T Committee will document reasons for disapproval and forward information back to initial submitter (e.g., medication safety issues, patient population concerns, etc.).

c. VISN P&T Committee reviews medication requested for national nursing medication management protocol development.

(1) If approved, VPE forwards medication request for national medication management protocol consideration to the Pharmacy Benefits Management Services (PBM), Medical Advisory Panel (MAP), VPE and Veterans Integrated Service Network (VISN) Formulary Committees.

(2) If disapproved, VISN P&T Committee documents reasons for disapproval and forward to the VA facility P&T Committee for information.

d. PBM, MAP, VPE and VISN Formulary Committees reviews medication request for national nursing medication management protocol development. Prior to MAP, VPE and VISN Formulary Committee review, PBM will obtain recommendations from the Office of Nursing Services (ONS) representative related to the medication request for the national nursing medication management protocol.

(1) If medication is approved, PBM will initiate protocol development.

(a) Once complete, national medication management protocol will be reviewed by the PBM, MAP, and VISN Formulary Committees for final approval.

(b) Once approved, PBM will post approved national nursing medication management protocol on the national PBM SharePoint site located at <https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>

NOTE: *This is an internal VA Web site that is not u/available to the public.*
Approved national nursing medication management protocols will be distributed to

ONS and as outlined in VHA Directive 1108.08, VHA Formulary Management Process, dated November 2, 2016.

(2) If disapproved, PBM, MAP, VPE and VISN Formulary Committees will document reasons for disapproval and forward information to VPE for communication to VISN P&T Committee as outlined in VHA Directive 1108.08 or subsequent policy issue. Reasons for disapproval will be documented on national PBM SharePoint site located at <https://vaww.pbmnat.va.gov/sites/PBM/SitePages/NursingMedicationProtocol.aspx>

NOTE: *This is an internal VA Web site and is not available to the public.*

e. PBM will conduct an audit and review of all national nursing medication protocols annually. This review will occur in conjunction with key stakeholders, ONS, MAP, VPE and VISN Formulary Committees. The review includes, but is not limited to, the following items:

(1) All protocols will be reviewed to determine any need for revision, continuation, or discontinued based on current evidence, PBM, MAP, VPE and VISN Formulary Committee guidance, VA National formulary changes, or medication safety concerns, in accordance with VHA Directive 1108.08. Protocols that require updating will be prioritized for revision.

(2) Any additional medications for national nursing medication management protocol consideration will be reviewed as described in subsection 5.a.(3).