

**NATIONAL PHARMACY, PROSTHETICS, AND LOGISTICS COMMITTEE**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes policy and procedures for the National Pharmacy, Prosthetics and Logistics Committee (NPPLC) in determining the responsible service for provision of primarily non-drug products in VHA. The coordinated efforts of the NPPLC are intended to improve the consistency of care associated with provision of those select products across VHA.
- 2. SUMMARY OF CONTENT:** This new VHA directive establishes policy and procedures for the NPPLC. The NPPLC is not responsible for determining formulary status, clinical merit, comparative or cost effectiveness, product standardization or appropriate use of the products reviewed.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBILITIES:** The Chief Consultant, Pharmacy Benefits Management (PBM) Service (10P4P) in the Office of Patient Care Services, 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 April 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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## NATIONAL PHARMACY, PROSTHETICS AND LOGISTICS COMMITTEE

### 1. PURPOSE

The National Pharmacy, Prosthetics and Logistics Committee (NPPLC) is established for the purpose of clarifying responsibilities for the management and provision of primarily non-drug products; although, some drug products will be reviewed. The coordinated efforts of the NPPLC are intended to improve the consistency of care associated with the provision of those select products across the Veterans Health Administration (VHA). The NPPLC is not responsible for determining formulary status, clinical merit, comparative or cost effectiveness, product standardization or appropriate use of the products reviewed. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b). **NOTE:** For information related to the groups that review drugs for formulary status, etc., refer to VHA Directive 1108.08, VHA Formulary Management Process. For information related to review of non-drug products for formulary, etc., refer to VHA Directive 1761(1), Supply Chain Inventory Management. For information related to review of Prosthetic and Sensory Aid products, refer to VHA Directive 1173, Prosthetic and Sensory Aids Service and VHA Handbooks 1173.1-1173.17.

### 2. BACKGROUND

a. There are certain products required for the care and treatment of Veterans. However, the service responsible for the acquisition and management of these products may not be entirely clear (e.g., Pharmacy, Prosthetics, Logistics or other). When this occurs, the medical center can generate a request for review to the NPPLC to determine the responsible service. Requests for review to determine the responsible service can be electronically submitted to the NPPLC mail group via [PharmacyProstheticsWorkgroup@va.gov](mailto:PharmacyProstheticsWorkgroup@va.gov) (VHA National Pharmacy-Prosthetics-Logistics Committee). In general, responsible service determinations are made by the NPPLC and communicated to the VA medical facilities within 60 days but some determinations may take longer depending upon the situation.

b. The mission of the NPPLC is to determine the product type (e.g., device, biologic, drug or implant, medical supply, facility equipment, etc.) and identify and determine the service(s) responsible for procuring, managing and/or providing the product. When making decisions, the NPPLC considers many factors including VHA and Federal purchasing regulations and Veteran convenience.

### 3. DEFINITIONS

a. **Biological Product.** The term “biological product” means a virus; therapeutic serum; toxin; antitoxin; vaccine; blood; blood component or derivative; allergenic product; protein (except any chemically synthesized polypeptide) or analogous product; or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings. Some products that meet the drug definition or both the drug and device definitions, and also meet the definition of biological product, might be classified as

biological products, rather than as devices or drugs, and be subject to licensure under the Public Health Service (PHS) Act.

b. **Clinical Products Review Committee.** The Clinical Products Review Committee (CPRC) replaces the prior facility Commodity Standardization Committee. In response to a May 2011 Government Accountability Office (GAO) review (11-391), a CPRC was to be established at each Department of Veterans Affairs (VA) medical facility and charged with creating a medical and surgical supply formulary. The CPRC is responsible for the review and approval of all newly requested expendable medical supplies and reusable medical equipment (RME) at the VA medical facility. For additional information related to the activities and requirements of the CPRC, refer to VHA Directive 1761(1), Supply Chain Inventory Management.

c. **Device.** Section 201(h) of the Food Drug and Cosmetics (FD&C) Act, 21 U.S.C. 321(h), defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

d. **Drug.** Section 201(g) of the FD&C Act, 21 U.S.C. 321(g), defines "drug" as:

(1) Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(3) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(4) Articles intended for use as a component of any articles specified in paragraphs 3.d.(1), 3.d.(2), or 3.d.(3) above.

e. **Implant (Biologic or Non-biologic).** An implant is an object or material inserted or grafted into the body for prosthetic, therapeutic, diagnostic, or experimental purposes (included in Food & Drug Administration's definition of an implant).

- f. **Non-Drug Product.** Not related to or being a drug.

#### 4. POLICY

a. It is VHA policy that the NPPLC must use a collaborative process to identify and determine the service responsible for the management and provision of primary non-drug products to improve the consistency of care associated with provision of those products across VHA.

b. Once a non-drug product is reviewed by the local CPRC, it may be referred to the NPPLC for a determination of the responsible service. After the NPPLC reaches consensus regarding the responsible service for a given product, all services are expected to work together to ensure a smooth transition so that there are no barriers or delays in care of the Veteran; even if a change in the responsible service is made as a result of the decision. In cases where consensus is not achieved within the NPPLC, the requesting medical center will be notified. In those infrequent cases where the NPPLC does not reach a consensus, determination of the responsible service is left to the local VA medical facility in collaboration with their local CPRC.

#### 5. RESPONSIBILITIES

a. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management, or designee, will ensure that NPPLC's responsible service determinations are implemented consistently throughout VHA excluding situations where exceptions arise; such as when the NPPLC cannot reach a consensus. In such cases, the VA medical facilities may be required to determine the responsible service that meets the unique needs of the individual facility in collaboration with their local CPRC.

b. **Chief Consultant, Pharmacy Benefits Management Services, Chief Consultant for Prosthetics Service, and the Chief Procurement and Logistics Officer.** The Chief Consultant, Pharmacy Benefits Management (PBM) Services, the Chief Consultant for Prosthetics Service, and the Chief Procurement and Logistics Officer will ensure that:

(1) The NPPLC membership includes at least three representatives from Pharmacy, Prosthetics and Logistics, and at least one representative from clinical practice.

(2) Representatives on the NPPLC work together to gain consensus on the responsible service(s) when it is not clear which service is best suited to provide the product.

(3) An amenable decision is reached within 30 days, amongst the Chief Consultant for PBM Services, the Chief Consultant for Prosthetics Service, and the Chief Procurement and Logistics Officer, when VA medical facilities express concern(s) regarding a final responsible service determination and the NPPLC has concluded that their service determination should be sustained. (For example, the NPPLC may be made aware of a VA medical facilities concern(s) with a responsible service

determination via electronic mail. At that time, their NPPLC service representative is notified to request continued discussion by the NPPLC.)

c. **VA Medical Facility Director.** The VA medical facility Director is responsible for facilitating implementation of the responsible service determinations of the NPPLC.

d. **National Pharmacy, Prosthetics and Logistics Committee.** The NPPLC, will ensure:

(1) Active participation from each of the member from Pharmacy, Prosthetics and Logistics.

(2) NPPLC Chair duties are rotated on an annual basis amongst the Pharmacy, Prosthetics and Logistics Committee representatives.

(3) A clinical representative with medical and surgical background from the Specialty Care Services Program Office or other Clinical Program Office, whose stakeholders generally prescribe products under consideration, participates to help guide group discussions. These individuals support the group by helping to explain a product's proposed use and place in patient care.

(4) Meetings occur on a monthly basis, at the discretion of the Chairperson (e.g., depending upon the circumstances including no new agenda items, holidays conflicts, etc., the NPPLC may cancel one or two monthly meetings annually).

(5) Representatives from each participating service on the NPPLC will work together to review, discuss and gain consensus on the responsible service(s) for a given product request when it is not clear which service is best suited to provide the product and make preliminary determinations for responsible service.

(6) NPPLC members from all three services will solicit and receive feedback on preliminary responsible service determinations from their respective services in the field. ***NOTE: VA medical facilities are expected to provide feedback on the service determinations prior to the determinations becoming finalized at the next NPPLC monthly meeting.***

(a) **Pharmacy Service Process.** Preliminary determinations for the responsible service are shared with the Veterans Integrated Service Network (VISN) Pharmacist Executives (VPE) for concurrence. If concurrence is not obtained, the issue is brought back to the NPPLC for further discussion.

(b) **Prosthetics Service Process.** Authority for approving responsible service determinations is granted to the individuals representing Prosthetic and Sensory Aids Service (PSAS) on the NPPLC. However, it is expected that the individuals representing the PSAS will share preliminary service determinations with their higher-level authority and/or VA medical facilities' prosthetics managers or service chiefs for input.

(c) Logistics Service Process. Authority for approving responsible service determinations is granted to logistics representatives on the NPPLC. However, it is expected that logistics representatives share preliminary service determinations with their higher-level authority and/or VA medical facilities' logistics managers or service chiefs for input.

(7) NPPLC responsible service determinations are announced and distributed to all services involved via electronic mail and recipients are reminded that coordination needs to take place between the services at local VA medical facilities to ensure a smooth transition of responsibility to the assigned service.

(8) Further discussion of preliminary responsible service determinations will take place if concurrence is not obtained from all services or if there is significant concern/s communicated from the VA medical facilities. **NOTE:** *The NPPLC will continue to discuss the product and its associated issues until final consensus on responsible service can be obtained. Additional discussion, information gathering, the querying of VA medical facilities and/or subject matter experts, etc., is carried out and discussed at a subsequent meeting until consensus can be attained. In some cases where consensus cannot be attained, VA medical facilities may be required to determine the responsible service that meets the unique needs of the individual facility in collaboration with their local CPRC.*

(9) When VA medical facilities' consensus is not achieved on a final responsible service determination and the NPPLC has determined that their service determination should be upheld, NPPLC representatives or a higher-level authority from the respective service must address the expressed concern(s) and arrive at an amenable decision within 30 days.

(10) The NPPLC may infrequently determine that a product should not be provided by any of the participating services. This determination may be based on input from Veterans Administration Central Office leadership for a given specialty area that the product does not meet local or national requirements or there may be procurement restrictions, etc. However, it is acknowledged that although a product may not be considered the standard of care for all patients, there may be cases in which a particular product is needed for an individual patient based upon their individual characteristics and needs. In that case, the VA medical facility inquiring will be responsible for determining the responsible service in collaboration with their local CPRC.

## 6. REFERENCES

- a. VHA Directive 1173, Prosthetic and Sensory Aids Service.
- b. VHA Directive 1108.08, VHA Formulary Management Process.
- c. VHA Directive 1761(1), Supply Chain Inventory Management.
- d. VHA Handbooks 1173.1-1173.17.

e. Guidance for Industry: Classification of Products as Drugs and Devices & Additional Product Classification Issues

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM258957.pdf>.

**NOTE:** *This linked document is outside of VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*



## PROCEDURES

a. The National Pharmacy, Prosthetics and Logistics Committee (NPPLC) receives requests for product review through a number of methods including requests from individual facilities, from Service Program Offices or NPPLC representatives and requests sent to the NPPLC mail group via [PharmacyProstheticsWorkgroup@va.gov](mailto:PharmacyProstheticsWorkgroup@va.gov) (VHA National Pharmacy-Prosthetics-Logistics Committee).

b. Representatives on the NPPLC will work together to gain consensus on the responsible service(s) when it is not clear which service is best suited to provide the product. In their deliberations, the NPPLC will consider the following (**NOTE: The list is not all-inclusive**):

(1) Is the product a FDA approved drug or non-drug (e.g., device, medical supply item)?

(2) Is the product consumed within the Department of Veterans Affairs (VA) medical facility (e.g., clinic use, long-term care settings, hospital use, or provided by VA home based primary care), or used by outpatients?

(3) Is the product disposable, for single use or multi-use (e.g., 30 days or less), or durable and reusable (e.g., in excess of 30 days)?

(4) Is the product implanted, and if so how long does it remain in the body (e.g., less than 1 year or greater than 1 year), does it stay in the body permanently, or is it removed or resorbed by the body?

(5) Is the product being used to support or replace a body part or function? Implants that are funded through Prosthetic and Sensory Aids Service (PSAS) are those implants that replace, support, or substitute for impaired or missing anatomical parts of the body and which permanently stay in the body one year or longer.

(6) Is the product diagnostic in nature?

(7) Are there specific tracking requirements for the product under review?

(8) Is the product dispensed directly to the patient or used as part of a procedure conducted by a healthcare professional?

(9) How is the product purchased and did the NPPLC consider purchasing regulations and contracts?

(10) Is its use convenient for the patient, for example:

(a) Is the product part of a system that should be kept together?

(b) How do patients obtain or order the product?

(c) Is there a recurring need for the product (e.g., are refills required)?

(11) Is there a procedure for documentation of product administration to the patient?

(12) Are there other issues relevant to the particular product being reviewed?

(a) The NPPLC recommends that a review by the local Clinical Products Review Committee (CPRC) be completed prior to requesting a NPPLC determination on service responsibility for a given product prior to initial use at a local VA medical facility if it is unclear which service should provide.

(b) Each NPPLC meeting begins by ensuring that each of the three services (Pharmacy, Prosthetics and Logistics) has adequate representation and a clinical representative is present. If there are no representatives present from one of the services or clinical representative, the meeting may still proceed and:

1. The meeting minutes will be distributed to the absent representatives to share with their higher-level authority for concurrence.

2. Representatives from the absent service will also be required to review the prior month's final recommendations for concurrence, using electronic mail.

3. The draft meeting minutes will be sent to all workgroup members, including the absent service representatives, to include recommendations for the current month with the intention that the minutes will be shared with the VA medical facilities for input/comment. **NOTE:** *The absent service will be expected to review the draft recommendations and share with their higher-level authority and respective VA medical facilities for comment.*

(c) NPPLC members will solicit and receive feedback on preliminary responsible service determinations from their respective services in the VA medical facilities. **NOTE:** *The VA medical facilities are expected to provide feedback on the service determinations prior to the determinations becoming finalized.*

(d) The preliminary responsible service determinations are finalized at a subsequent meeting once feedback from the VA medical facilities are received and discussed by the NPPLC.

(e) Further discussion of preliminary responsible service determinations will take place if concurrence is not obtained from all services or if there is significant concern/s communicated from the VA medical facilities. **NOTE:** *The NPPLC will continue to discuss the product and its associated issues until final consensus on responsible service can be obtained. Additional discussion, information gathering, the querying of VA medical facilities and/or subject matter experts, etc., is carried out and discussed at a subsequent meeting until consensus is obtained. Generally, discussion occurs over one or two meetings if additional information is needed to make a decision.*

(f) When VA medical facilities express concern on a final responsible service determination and the NPPLC has concluded that their service determination should be upheld, NPPLC representatives or a higher-level authority from the respective service must address the expressed concern(s) (see paragraph 5.b.(c).(2)) and come to an amenable decision within 30 days.

(g) The NPPLC may infrequently determine that a product not be provided by any of the participating Services. This determination may be based upon input from Veterans Administration Central Office leadership for a given specialty area's determination that the product does not meet local or national requirements or there may be procurement restrictions, etc. However, it is acknowledged that although a product may not be considered the standard of care for all patients, there may be cases in which a particular product is needed for an individual patient based upon their individual characteristics and needs. In that case, the VA medical facilities are left to determine responsible service.

(h) Meeting minutes and final responsible service determinations from the prior month are to be discussed and approved so an announcement of these service determinations can be shared with the VA medical facilities.

(i) The monthly announcement includes determinations for responsible service from the previous month's preliminary responsible service determinations. Approval of the monthly announcement presumes service concurrence with responsible service determinations, at which point they become final.

(j) Responsible service determinations, made by NPPLC consensus on certain products, may be omitted from the monthly announcement because of the intent of the NPPLC. For example, if a request for product review or for clarification of responsible service is submitted for determination from a single requester or VA medical facility and was not meant for standardization. **NOTE:** *Each product discussed will be included on the list of items discussed (posted on the PBM Web site [VHA National Pharmacy-Prosthetics-Logistics Committee](#)). If another request for review is received, the request can be quickly answered and the minutes accessed if an explanation is needed. **NOTE:** *This is an internal VA Web site that is not available to the public.**

(k) The NPPLC is responsible for the maintenance of monthly meeting minutes; a running list of products discussed; and electronic dissemination of monthly announcements regarding the responsible service/s determinations.

(l) It is required that detailed minutes are taken for each meeting. The responsibility for taking meeting minutes is rotated quarterly between Pharmacy, Prosthetics, and Logistics representatives. Meeting minutes are distributed for review and approval by the NPPLC at the next NPPLC meeting, prior to posting. Minutes are posted after approval on the Pharmacy Benefits Management (PBM) Services Web site by a Pharmacy representative. See [VHA National Pharmacy-Prosthetics-Logistics Committee](#). **NOTE:** *This is an internal VA Web site that is not available to the public.*

(m) After each meeting, the service responsible for preparation of the minutes will send a finalized list of responsible service determinations from the previous month to the NPPLC via electronic mail. NPPLC members will then disseminate the approved responsible service determinations to their respective services.

(n) Preliminary responsible service determinations are recorded after the NPPLC meeting but are listed as “pending,” until the final determination/decision for responsible service is approved.

(o) After each meeting, the final responsible service determination(s) is to be recorded on the “List of Products Discussed;” a spreadsheet listing all of the products discussed to date. **NOTE:** *The spreadsheet will include: The date of the meeting in which the item was discussed so the VA medical facilities can refer to the associated meeting minutes if they have questions pertaining to the recommendation. This listing is currently maintained by Pharmacy on the PBM Services Web site, see appendix A paragraph b.(12)(l) above.*