U.S. Department of Veterans Affairs
VA Federal Supply Schedule

P.O. Box 76, Building 37
1st Avenue, North of Cermak Road,
Hines, IL 60141
www.fss.va.gov

In Reply Refer To: 003A4B

August 07, 2024

Supplemental DML 2024

New Package Size (NPS) (Revises previous guidance issued in DML dated May 4, 2021)

A new package size classification:

1. Concentration of product is already on NFAMP at the PERM stage. (i.e. 50mg/ml) New NDC with the same concentration of an existing NDC, but different total volume offered.
2. Addition of value-added products, such as creating a combination kit. However, the FCP may be increased using the original FCP plus a reasonable cost of the added-value product. For example, if adding an over-the-counter scrub to a skin ointment, the existing FCP could be increased by the reasonable cost of the added product (typically up to 10% as determined by the Public Law 102-585, Section 603 (38 U.S.C. § 8126) Policy Group (Policy Group).
3. New packaging introduction such as from vial to syringe. This would be considered a NPS and not a new product and would use the existing FCP.
4. NDC changes because the color, color coating, tablet size or other attribute of a product has changed (container, delivery system, etc.), except where the change is done under a new NDA.

All NDCs that fall into the categories of NPS, NDC change, and Transferred Drugs must be on contract by the first date of sale. Manufacturers will be responsible for reimbursement to the government for overcharges during any gap period between the first commercial sale and the effective date of addition to contract.

Allergen Products

Clarification is being provided to address an exemption granted to certain allergen products. In 1992, at the urging of industry, VA granted an exemption from the Public Law requirements to manufacturers of allergen extracts and dilutions used to diagnose and treat allergies. VA's 1992 determination and subsequent guidance was intended to apply to a specific class of allergen extracts and dilutions. Specifically, the scope included nearly 2 million unique, non-standardized injectable extracts that lacked NDCs and were only available in custom or stock mixtures, used and independently mixed by practicing physicians. Under these circumstances VA determined Public Law compliance was extremely difficult, if not impossible.

The specific clarification is that **sublingual allergen extract tablets and ready to use allergen products (injectables) do not fall under this exemption.** By contrast, these

sublingual/injectable allergen extract products are standardized pharmaceutical formulations, assigned NDCs, and available through traditional commercial entities such as wholesalers and retail pharmacies. As a result, **sublingual/injectable allergen formulations available commercially are covered biologicals** distinguishable from the class of allergen products exempted in 1992.

Repackager/Reseller Covered Drug Requirements:

1. Signed Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) must be in place.
2. Continuous "commercial sales" must occur to calculate NFAMPs quarterly and annually (the product/s must be "commercially available").
3. Although repackagers/resellers have independent compliance obligations (because these entities are also defined as "manufacturers" under the statute), their compliance is not necessarily a substitute for the compliance obligations of "Manufacturers", who are the owners and distributors of the given NDA of a covered drug. Both the repackagers/resellers and the "Manufacturer" must be compliant with Public Law and, if applicable, have active FSS contracts with all covered NDCs offered by the "manufacturer" on contract.
4. Repackagers/resellers must establish their own NDC(s).

PL Covered Drug Status Request:

The Public Law Policy Group (PLPG) would like to formalize the process for Manufacturers/Vendors to obtain a determination that a particular drug does not fall within VA's current statutory interpretation of a covered drug.

1. Send all correspondence to: AMMHIN.PL102585@va.gov.
    a. The PLPG group will send a reply to the submitter's email notifying of receipt within 5 business days and will include an assigned tracking number.
    b. The tracking number must be placed in the subject line for all corresponding communications.
2. The PLPG meets monthly to review all new and pending tracking numbers. A response from the group should be received within 90 days of tracking number assignment. If additional information is required to complete the review, an extension will be issued by the PLPG during the initial 90 days.
3. Final decisions will vary depending on the request.
    a. The goal will be to issue decisions within 6 months or less during the non-Annual Public Law season (January to September). Delays in decision issuance may be experienced during the Annual Public Law pricing review season from October to December.
    b. No action will be taken on non-Public Law season matters (October to December) until workbook processing and disputes are completed.

Sincerely,

DIANA LAWAL

Digitally signed by DIANA LAWAL
Date: 2024.08.08 06:12:05 -05'00'

Diana D. Lawal
Department of Veterans Affairs
Chair, P.L. 102-585, Sect. 603, Policy Group