



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of General Counsel**  
**P.O. Box 76**  
**Hines, IL 60141**

**In Reply Refer To: 025NAC**

November 2, 2011

Dear Manufacturer of Covered Drugs:

This correspondence is to inform you of compliance guidance that has recently been given by VA's Public Law 102-585, Sect. 603, Policy Group (the Policy Group or the Group), in its individual responses to questions posed by certain industry representatives. Since the guidance likely would be of interest to most manufacturers, the Policy Group is disseminating it via this letter from the Office of General Counsel.

I. **Specialty Pharmacies.** The Policy Group has decided that "specialty pharmacies" that perform drug dispensing and patient monitoring functions are neither wholesalers (merchant middlemen) nor manufacturers for Public Law purposes. The Policy Group has no problem with the suggestion that manufacturers do not have to determine a "specialty pharmacy's" status on a drug-by-drug basis. If a manufacturer learns from a specialty pharmacy that its principal business is performing specialty pharmacy functions (as opposed to distribution functions), then the manufacturer may consider sales to that pharmacy as direct sales, not wholesale sales. Of course, if a manufacturer's covered drug is sold only to specialty pharmacies because of FDA requirements, those direct sales will have to be used to generate non-FAMPs under the 90/10 test.

VA OIG will occasionally study the actual practices of claimed specialty pharmacies to ensure that they do not become wholesalers in disguise.

II. **State Veterans Home Purchases at FSS Prices.** The Policy Group also decided that covered drug orders from a State Veterans Home receiving funds under 38 U.S.C. 1741, placed directly with a manufacturer at FSS contract prices pursuant to 38 U.S.C.

8126(a)(3) (Veterans Health Care Act of 1992, P.L. 102-585, Sect. 603; “VHCA”), are excludable from non-FAMP computations. Because the pricing of such orders (“Option 1” orders) is prescribed by statute, the Policy Group will allow manufacturers to treat them as tantamount to Federal Government sales for non-FAMP reporting purposes. This is similar to the guidance on treatment of sales to 340B covered entities at 340B mandated prices.

**III. Independent FCPs of New Package Sizes.** At a recent meeting, the Policy Group considered some of the questions raised during the past year about pricing new package sizes of existing covered drugs. The Group clarified guidance contained in the October 2010 Dear Manufacturer Letter from VA OGC, regarding establishing independent non-FAMPs and FCPs for new package sizes, subsequent to the initial introduction period. It decided to more specifically describe “...significant, independent sales to be used in computing an independent annual non-FAMP and following-year FCP.” (Emphasis is in original.) (Although initial clarification was provided in the 2011 “Dear Manufacturer” Letter issued by Pharmacy Benefits Management Services on 10/20/2011 [see Attachment F to the letter], the Policy Group expands on that clarification here.)

Beginning with all new covered drug package sizes introduced after June 30, 2011, the independent non-FAMP and FCP of such packages (which were priced initially from the FCP of the nearest existing package) will be based on new package sales from launch through one full calendar quarter of commercial sales. The independent (or permanent) non-FAMP and FCP of a new covered drug package size should be reported within 30 days of the end of the first full calendar quarter of sales (but must be reported no later than 45 days following the end of the quarter). As with totally new covered drugs that have not reached the deadline for reporting a Permanent FCP, no annual non-FAMP report will be required in November for a new package size that has not experienced at least one full calendar quarter of commercial sales, with a timely Permanent or Independent non-FAMP reported to VA PBM by Sept. 30.

**IV. In Vitro Diagnostics with BLAs.** The Policy Group was recently asked whether in vitro diagnostic products (devices with BLAs) are covered drugs. The Group responded in the negative. The Policy Group believes that the statute’s covered drug definitions incorporating biologics are broad enough to justify a conclusion that all products marketed pursuant to a BLA from FDA are covered drugs, even if they also are classified by FDA as devices. Nevertheless, the Group decided that it is consistent with the statute’s intent to decline to treat in vitro diagnostic products as covered drugs because of their in vitro applications – they are not to be used in or on the human body.

**V. OTC Drugs Dispensed by Prescription.** The Policy Group also was asked whether over-the-counter (OTC) drugs, when dispensed pursuant to a prescription, are to be considered as covered drugs. The Group's reply confirmed the general understanding that a prescription requirement is part of the full definition of "covered drug". The Group also confirmed the general guidance that a former prescription drug, switched by FDA to OTC status, would no longer be considered a covered drug. Whether and when a covered prescription drug ceases being covered under the VHCA depends on FDA's OTC reclassification action, not on provider prescribing practices that may continue in spite of FDA's reclassification.

Thank you for your cooperation with VA's efforts to implement P.L. 102-585, Sect. 603. If you have questions about the above guidance, please contact the undersigned at 708 786-5167 or contact Vanessa Calabrese at 708 786-5171.

Sincerely,

Melbourne A. Noel, Jr.  
VA Office of General Counsel  
For VA's P.L. 102-585, Sect. 603, Policy Group