DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
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September 25, 2012

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 (the P.L.), Policy Group (the Policy Group or the Group), in its responses to questions posed by industry representatives. Since the guidance likely would be of interest to most covered drug manufacturers, the Policy Group is disseminating it via this letter from the Office of General Counsel.

I. VA has determined that the benefits of P.L. ceiling pricing (FCPs) do not extend to the Health Service Corps (whose function previously was performed by the Div. of Immigration Health Services [DIHS]) of the Bureau of Immigration and Customs Enforcement (ICE), which is a part of the Department of Homeland Security. No part of the Department is mentioned in the statute as entitled to ceiling prices (38 U.S.C. 8126 (b)).

II. Removal from a FSS contract of covered drugs that are not Trade Agreements Act (TAA) compliant does not relieve their manufacturer of its remaining obligations under the P.L. and Master Agreement. Annual and quarterly non-FAMP reports are still required, and an established FCP must be entered on the annual P.P.A. Addendum A for all covered drugs, even if they have become TAA-non-compliant. Such TAA-non-compliant drugs must be available for emergency direct purchasing by Big Four agencies at pricing no higher than FCP and will be subject to any statutorily required TRICARE Retail Pharmacy Network (TRRx) covered drug rebates when dispensed to TRICARE beneficiaries through the Network.[1]

III. As stated in this year's Dear Manufacturer Letter from VHA's PBM, Attachment F, a covered drug that has been removed or rejected from its manufacturer's FSS contract for TAA non-compliance and , thus, is not available on a VA multi-year contract will no longer be subject to the dual FCP calculation prescribed by 38 U.S.C. 8126(d)(1). Beginning with 2013 pricing, such TAA non-compliant covered drugs will have FCPs determined in all years under the calculations found in 38 U.S.C. 8126(a)(2) & (c). If, subsequently, such drugs are sourced in the U.S. or a TAA-designated country, they must be added to the Manufacturer's FSS contract within 30 days of becoming TAA-compliant, and the dual FCP calculation will again apply in the appropriate years.

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[1] If a covered drug is manufactured in both the U.S. (or a TAA designated country) and a TAA non-designated country, then the drug must remain on the Manufacturer's FSS contract, but the Manufacturer is responsible for initiating internal procedures to ensure that FSS Federal ordering activities are sold the TAA-compliant items under the contract.

IV. As VA has previously stated, manufacturers' retroactive corrections to quarterly pricing under P.L. 102-585, Sect. 602 (the 340B pricing program) do not require correction and re-filing of non-FAMP reports filed during the period when the corrected errors occurred in the 340B pricing, unless the erroneous original 340B prices were intentional or set in bad faith.

V. Similarly, DoD TRICARE invoices for TRRx usage rebates based on utilization from any calendar quarters of 2008 and Quarters 1 and 2 of 2009 have no place in 2012 annual non-FAMP report computations. Also, retroactive corrections by TRICARE to TRRx usage in quarters covered by previous annual non-FAMP reports, in which TRRx usage was subtracted by the manufacturer as an element of Government purchases, do not require correction and re-filing of the prior non-FAMP reports.

VI. By way of clarification, DoD's TRICARE Management Activity, in calculating TRRx covered drug rebates, employs only non-FAMP and FCP data that has been validated and obtained from VHA's Pharmacy Benefit Management Group (PBM).

VII. Please remember that Permanent non-FAMPs submitted for new covered drugs or for new package sizes of existing covered drugs are to be derived from appropriate commercial sales occurring **from the date of launch** of the new drug or the new package through one full calendar quarter.

VIII. Also, as discussed during industry conference presentations by VA representatives for many years, VA recognizes that some covered drugs may not be sold through wholesalers (see Master Agreement Sect. 1.Q), or they may be sold **both** through wholesalers and direct to retailers, other merchants, institutional or commercial users (non-wholesalers). In the latter situation, VA's guidance has been that, where an NDC-11 package of a covered drug has generated annual **unit** sales of **10 percent or less** to or through domestic wholesalers, then **only** the "direct" sales to retailers, other merchants, institutional or commercial users will be considered "wholesale sales" for purposes of non-FAMP computations in the annual non-FAMP report. However, if wholesaler unit sales are **greater than 10 percent** of total sales, then non-FAMPs for the annual report will be computed based **only** on wholesale sales. A decision on whether wholesale sales are sufficient to be used for non-FAMP purposes (using this 90/10 analysis) is to be made based on the annual non-FAMP period, just prior to submission of annual non-FAMP reports in November. The result is to be applied to the current annual and new non-FAMPs, as well as to the next three quarterly non-FAMPs. When figuring the wholesale unit sales ratio for an NDC-11, a Manufacturer may either include or exclude Federal Government sales, as long as the chosen approach is applied consistently. If application of the wholesale unit sales ratio in a given year changes the basis of non-FAMP computations from wholesale sales to direct sales (or vice versa), the prior year's Q.3 non-FAMP must be recalculated and re-stated, using the updated approach, so that proper comparisons can be made in the current report's additional discount calculations.

If you have questions concerning the above interpretations of manufacturers' obligations under 38 U.S.C. 8126, please telephone the undersigned at (708) 786-5167 or Vanessa Calabrese at (708) 786-5171.

Sincerely,

//s// Melbourne A. Noel, Jr.

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For VA's P.L. 102-585, Sect. 603,
Policy Group