DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
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October 15, 1997

In Reply Refer To:

Dear Manufacturer of Covered Drugs:

In each of the last two years, we have written to you concerning the Office of Inspector General's (VAOIG) observations regarding certain errors and inadequate compliance policies in manufacturers' non-Federal Average Manufacturer Price and Federal Ceiling Price (non-FAMP/FCP) calculation methods. The VAOIG Contract Review & Evaluation Division's efforts to assess the level of compliance with the Veterans Health Care Act of 1992, Section 603 (VHCA) (38 U.S.C. 8126), have continued in 1997. Additional compliance and calculation issues have been raised to the Office of General Counsel this year by manufacturers and the IG. These questions have prompted the Department of Veterans Affairs (VA) to again state its positions for the benefit of manufacturers who are about to calculate and report their annual data required by the VHCA.

1. Attorneys for a manufacturer earlier this year requested an interpretation of the records retention provision of the Master Agreement, Section II,D. It states:

> The manufacturer will retain all records relevant to generation of the above reports and the calculations of annual Federal price ceilings for not less than five years from the date of their creation.

The question arose as to when the five-year period begins to run on backup documents that are used in the creation of non-FAMP reports. VA interprets "the date of their creation" to refer to the creation of the annual and quarterly non-FAMP reports. Thus, five year old chargeback records that were used to generate a report created four years ago need to be retained for another year, until the report submitted to VA is five years old.

2. Although 1997 Federal Supply Schedule (FSS) contract prices will have no role in the calculation of 1998 FCPs because 1998 is the first year of a new multiyear contract, manufacturers may wish to know VA's understanding of the impact of FSS temporary price reductions on FCP calculations for 1999. As reported during our conference with Industry on May 1, 1997, the National Acquisition Center (NAC) has decided that temporary price reductions, i.e., voluntary reductions below the negotiated FSS most favored customer (MFC) or FCP pricing for a specified period of time, may be submitted to the contracting officer (CO) at any time during the contract period and may last for any length of time within the contract period. Temporary price reductions on covered drugs, even those that may last more than one year, can never have an impact on the calculation of a FCP in a second or subsequent year of a multiyear contract. When the dual calculation of FCP required during a second or subsequent year of a multiyear contract begins with the FSS contract price, a properly requested and approved temporary price reduction price should not be used for that calculation. The most recent MFC negotiated contract price or stipulated annual single price is the correct place to begin that calculation. Consequently, manufacturers need not fear that temporary price reductions requested and approved during 1998 will have any impact on the calculation of 1999 FCPs.

3. Questions continue to arise regarding VA's policy as to the correct non-FAMPs and FCPs for covered drugs which are transferred with exclusivity from one manufacturer to another. Since the beginning of the VHCA's implementation, VA has taken the position that a covered drug's non-FAMP and FCP data, correctly submitted during the annual reporting period, are applicable to that drug throughout the next calendar year. This is true regardless of the number of manufacturers that own the exclusive rights to the drug during the year. Thus, if a manufacturer transfers the exclusive rights to produce or market a covered drug to another manufacturer, the currently reported non-FAMPs and FCP of the drug come with it as baggage and must be honored by the new manufacturer throughout the acquisition calendar year. Of course, in November, the new manufacturer has the opportunity to calculate the covered drug's annual non-FAMP and new FCP for the second calendar year of its ownership of exclusive rights to the drug. In order to ameliorate the impact of this transferred covered drug policy, VA has decided to

allow a new owner/manufacturer of an existing covered drug, when calculating its additional discount for the first year following the year of the acquisition of the drug, to enter zero in the data field for "old non-FAMP". This will mean that no additional discount may be calculated for a transferred drug's second year, and its FCP (for the first year of a multiyear contract) will result from a straight non-FAMP calculation, i.e., non-FAMP times .76. (It is never possible to calculate an additional discount when a zero must be entered in either the old-FAMP or new non-FAMP data fields.)

4. Some manufacturers have asked how to treat custom or private label packages of covered drugs that have contents which are exactly identical to the contents of commercial packages sold in the general market place and on the FSS. In a custom package situation, the different NDC number assigned to it merely reflects the FDA's acceptance of and tracking of the package labeling variation. Under VA's policy, a manufacturer does not need to offer to the FSS a bona fide "custom" or "private" label package size of a covered drug that is not commercially available in the market place or to national accounts similar to VA. However, if the bona fide custom package has contents identical to a commercially available package that is sold through wholesalers with a different NDC number, then the custom package's wholesale sales must be included with the commercial package's wholesale sales in calculating the non-FAMP for the commercial product. (If the identical custom package is sold only direct--not through a wholesaler--then all of the direct sales must be included with the commercial package's wholesale sales to calculate the latter's non-FAMP.) This policy should not be confused with and does not alter VA's policy on bulk-package FCP calculations that are based on the closest commercially available package size.

We hope that the above statements regarding VA's interpretation of the VHCA will assist covered drug manufacturers to correct any compliance deficiencies without waiting for VAOIG intervention. Thank you for your cooperation with VA in its efforts to implement the VHCA.

Sincerely yours,

M. A. Noel, Jr.

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