



DEPARTMENT OF VETERANS AFFAIRS
Drug & Pharmaceutical Product Management Section
VACO Pharmacy Service
PO Box 126
Hines, IL 60141

September 25, 1995

In Reply Refer To

578/119D

Dear Manufacturer:

The following information is provided to assist your company in reporting the annual data mandated by Section 603 of Public Law 102-585 (Veterans Health Care Act of 1992). Annual NonFederal Average Manufacturers Price (NFAMP) calculations with 1996 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Chief, Drugs & Pharmaceutical Products Management (D&PPM), on or before November 15, 1995. (Any anticipated changes in your company's method of accounting for chargebacks, etc., must be implemented in accordance with Generally Accepted Accounting Principles (G.A.A.P.) and explained to the above office prior to submission of annual data.)

Pursuant to an interpretation of the Law by VA's Office of General Counsel, 1996 will be considered to be the first year of a multi-year contract, solely for purposes of P.L. 102-585 compliance. The "second contract year" will begin on January 1, 1997. Hence there will be no "dual calculation" comparison during 1996, since 1996 is being treated as the first year of a "new" contract period created by the expected exercise of an option to extend FSS contracts for an additional two, three or five more years.

The new one-half percent industrial funding fee (IFF) being incorporated into FSS contracts along with the option clause will not be used in calculations of non-FAMP or reporting of FCP, but will be included in the FSS selling price. An algorithm will be used to back out the 0.5% fee to reach the pure FCP. Please see instructions from your contracting officer. Additionally, please note the enclosed Office of General Counsel letter referencing helpful recordkeeping guidelines contained in "Lessons Learned From Inspector General Reviews".

Each covered drugs's mandated FCP for 1996 will be determined as described in 38 U.S.C. 8126 (a) (2) & (c). The percent change in Consumer Price Index - Urban (CPIU) that will be utilized in performing these calculations is identified as the percent change from September 1994 to September 1995. You may call the Bureau Of Labor Statistics on October 16, 1995 to get the CPIU for September 1995. The telephone number is 202-606-7828. After you get the CPIU for September 1995 you should use the following formula to calculate the percent change in CPIU:

$100 \times (\text{September 1995 CPIU} - \text{September 1994 CPIU}) \div \text{September 1994 CPIU} = \text{percent (\%) change in CPIU.}$

You may also call our office after October 16, 1995 at 708-216-2079 and ask for the percent change in CPIU.

The Section 8126 (a) (2) & (c) calculations will begin with the 1995 annual non-FAMP computation; it will continue by multiplying that number by .76 and then

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subtracting any additional discount calculated based on a difference between "old" and "new" NFAMPs. The result will become the 1996 FCP. If there are "no sales" in a benchmark third quarter of a year that is used to derive the new NFAMP or old NFAMP, there can be no additional discount calculation for that particular item. In those cases, the additional discount will be entered as zero (0). If a covered drug had no reportable sales in 1995, its calculated 1996 FCP will be the 1995 FSS price plus an amount equal to that price times the percent change in CPIU.

Nominal prices for exclusion from NFAMPs for 1996 calculations are identified as prices that do not exceed 10 percent of that particular item's NFAMP during the third quarter of 1994 (7/1/94 through 9/30/94). Where sales to end-users are required for calculation of NFAMP due to the absence of wholesale sales, you need not include purchases by PHS grantees or disproportionate share hospitals if the prices for those transactions were determined by PHS pursuant to Sect. 602 of the Veterans Health Care Act of 1992. Also, in figuring wholesale sales, you need not include the chargebacks required to satisfy end-user purchases by these entities at prices determined by PHS under Sect. 602. However, sales to these entities at prices lower than Sect. 602 prices must be included in NFAMP calculations.

All correspondence related to NFAMP calculations, FCP calculations, quarterly NFAMP reports, annual FCP reports, FCP reports for new products, FCP recalculations for new products, corrections to quarterly NFAMP reports and correction to annual FCP reports should be forwarded to:

Albert A. Patterson, R.Ph.
Chief, Drugs & Pharmaceutical Products (119D)
P.O. Box 126
Hines, Illinois 60141

Express Mail: 5th and Roosevelt Rd.
Building 1 Room A148

The quarterly NFAMP report for the third quarter of 1995 consists of the same data as the "new NFAMP" (7/1/95-9/30/95) reported on the annual calculation form for 1996 FCPs which is due November 15, 1995. Consequently, it will not be necessary to submit the NFAMP Third Quarter 1995 Report separately. However, manufacturers that do not meet the November 15, 1995 annual reporting deadline will be subject to penalties as described in the Master Agreement for late data reporting.

Section 8126(e) of the Law states that quarterly NFAMP reports are due 30 days after the end of the quarter. These figures should be as accurate as possible, since they serve as an indicator of pricing trends and will be used during Inspector General (IG) audits. Nevertheless, to assist manufacturers in providing the most accurate quarterly NFAMP calculations possible, the Drug & Pharmaceutical Product Management Section (D&PPM) will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. Again, please note that each year the NFAMP third quarter data may be submitted as part of the Annual Report (which is due 45 days after the end of the third quarter).

After your company reports its annual 1995 NFAMP data in the format on the

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enclosed sheets, the authorized official who signed your company's PPA in 1994 (or an authorized successor) must prepare and sign a new addendum to the PPA, listing each covered drug and its 1996 FCP. This addendum should then be forwarded before December 1, 1995 to the VA National Acquisition Center (90N-P), Building 37, First Avenue, 1 block North of 22nd Street, P.O. Box 76, Hines, Illinois 60141. Once these steps have been completed, VA National Acquisition Center contracting officers will work with your company's representative to make any FSS modifications and price list adjustments necessitated by the new FCP's.

If you have any questions about any of the above information, please call Joel Gostomelsky, George Hill or John Weisman at (708) 216-2079.

Sincerely,



Albert A. Patterson, R.Ph.
Chief, Drug Product Management
VACO Pharmacy Service

Enclosures: 3

"Dear Manufacturer" Letter from VA Office of General Counsel
Instructions for 1996 Data Sheets Completion
Data Sheet