



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

September 1, 1994

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 1995 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Chief, Drugs & Pharmaceutical Products Management (D&PPM), on or before **November 15, 1994**. (Any anticipated changes in your company's method of accounting for chargebacks, etc., must be implemented in accordance with Generally Accepted Accounting Principals (G.A.A.P.) and explained to the above office prior to submission of annual data.)

Each covered drugs's mandated FCP for 1995 (the third year of FSS multiyear contracts for statutory purposes) will be determined by adopting the lower of two calculation results. These two calculations are described in (1) 38 U.S.C. 8126 (d) (1) and (2) 38 U.S.C. 8126 (d) (2) & (a) (2). The same percent change in Consumer Price Index - Urban (CPIU) will be utilized in performing both calculations. This change in CPIU is identified as the percent change from September 1993 to September 1994. You may call the Bureau Of Labor Statistics on October 14, 1994 to get the CPIU for September 1994. The telephone number is 202-606-7828. After you get the CPIU for September 1994 you should use the following formula to calculate the percent change in CPIU:

$100 \times (\text{September 1994 CPIU} - \text{September 1993 CPIU}) \div \text{September 1993 CPIU} = \text{percent } (\%) \text{ change in CPIU.}$

You may also call our office after October 14, 1994 at 708-216-2079 and ask for the percent change in CPIU.

The Section 8126 (d) (1) calculation will begin with the **Federal Supply Schedule (FSS) contract price of a covered drug in effect on September 30, 1994**. For those manufacturers that elected dual FSS pricing, the **FSS contract price is the September 30, 1994 price** charged to other government agencies and other authorized Schedule users, **not** the price paid by the Department of Veterans Affairs, Department of Defense (DoD), or Public Health Service (PHS). The appropriate FSS price will then be increased by the above percent change in CPIU to arrive at the 1995 FSS price cap. (This cap applies to all "other user" FSS prices in 1995.)

The Section 8126 (d) (2) & (a) (2) calculation will begin with the 1994 non-FAMP computation; it will continue by multiplying that number by .76 and then subtracting any additional discount calculated based on a difference between "old" and "new" NFAMPs. (This calculation involves the same steps as were performed in December 1993 to arrive at the 1994 FCPs.) The lower of the above calculation and the '95 FSS price cap will become the 1995 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 1994, its

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calculated 1995 FCP will be the 1995 FSS price cap.

Nominal prices for exclusion from NFAMPs for 1995 calculations are identified as prices that do not exceed 10 percent of that particular item's NFAMP during the third quarter of 1993 (7/1/93 through 9/30/93). 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 1994 consists of the same data as the "new NFAMP" (7/1/94-9/30/94) reported on the annual calculation form for 1995 FCPs which is due **November 15, 1994**. Consequently, it will not be necessary to submit the NFAMP Third Quarter 1994 Report separately. However, manufacturers that do not meet the November 15, 1994 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).

Pursuant to Section 8126(i) of the Law, "the first year for which the contract is in effect" for new drugs means whatever portion of 1994 that a new covered item was on a Government contract or schedule. The "next contract year" will begin on January 1, 1995. The "first year" for any new product introduced during the year will be that portion of the year from the time of introduction through December 31 of the same year. This is also true of new FSS contracts first negotiated during 1994. The second year for these contracts begins on January 1, 1995, and their annual report of data and new Pharmaceutical Pricing Agreement (PPA) addendum are due on the same schedule as all pre-1994 FSS contracts.

After your company reports its annual 1994 NFAMP data on the format on the enclosed sheets, the authorized official who signed your company's PPA in 1993 (or an authorized successor) must prepare and sign a new addendum to the PPA, listing each covered drug and its 1995 FCP. This addendum should then be forwarded before December 1, 1994 to the VA National Acquisition Center

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(90N-E), Building 17, Tripp & Crossman Circle, 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 Products Management
VACO Pharmacy Service

Enclosures: 2

Instructions for 1995 Data Sheets Completion
Data Sheet