



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

October 16, 1996

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 1997 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Chief, Drugs & Pharmaceutical Products Management (D&PPM), on or before November 15, 1996. Any anticipated changes in your company's method of accounting for charge backs, returns, 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.

Each covered drug's mandated FCP for 1997 (the second 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 1995 to September 1996. The Bureau Of Labor Statistics data shows the percent change to be 3.00%, which will be used as the CPIU for the Federal Ceiling Price calculations due on November 15, 1996.

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, 1996. For those manufacturers that elected dual FSS pricing, the FSS contract price is the September 30, 1996 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)/Indian Health Service & Coast Guard. The appropriate FSS price will then be increased by the above percent change in CPIU to arrive at the 1997 FSS price cap. This cap applies to all "other user" FSS prices in 1997.

The Section 8126 (d) (2) & (a) (2) calculation will begin with the 1996 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 November 1995 to arrive at the 1996 FCPs.) The lower of the above calculation and the 1997 FSS price cap will become the 1997 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 1996, its 1997 FCP will be the 1997 FSS price cap.

Nominal prices for exclusion from NFAMPs for 1997 calculations are identified as prices that do not exceed 10 percent of that particular item's NFAMP during the

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third quarter of 1996 (7/1/96 through 9/30/96). 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 selling 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.

As an added service to streamline efficiency for the 1997 report, DPPM is enclosing a diskette with all your company's covered line items in spreadsheet form. The diskette contains a program that will display your company's covered items. All that you need to run the program is access to a personal computer that has Microsoft Windows (versions 3.x, 95 or NT), following the enclosed diskette instructions for use. This spreadsheet contains certain pre-filled fields based on the Public Law data supplied last year by your company. For example: your 1996 FSS price (FSS price as of 9/30/96) is provided and multiplied by CPIU (which has been calculated for you) in order to obtain the 1997 maximum FSS price (also provided). We have also provided the 1996 NFAMP Old (1995 NFAMP New which is the time period of 7-1-95 thru 9-30-95). The cells in the spreadsheet are formatted with the necessary calculations. Therefore, all that is required of your company is that you furnish the 1996 Annual NFAMP and NFAMP New in the appropriate fields. The spreadsheet will then automatically calculate Change in NFAMP, Additional Discount, 1997 Calculated Ceiling, and 1997 Federal Ceiling Price. After saving your work according to the enclosed instructions, the completed disk is to be returned to DPPM. If there are changes in the data which DPPM has provided in the pre-filled fields (e.g. Office of Inspector General audit recommendations), you have the option of changing the information on a separate electronic or hard copy submission. If your company elects to do so, you must submit a letter of explanation regarding all changes.

It is highly recommended and preferred that you submit your data in electronic format, using either the enclosed diskette or our electronic bulletin board service. You may submit the data as you have in the past on the form provided using the instructional packet as a guide to Public Law 102-585 compliance if you do not have access to a personal computer system.

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

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The quarterly NFAMP report for the third quarter of 1996 consists of the same data as the "New NFAMP" (7/1/96-9/30/96) reported on the annual calculation form for 1997 FCPs which is due November 15, 1996. Consequently, it will not be necessary to submit the NFAMP Third Quarter 1996 Report separately. However, manufacturers that do not meet the November 15, 1996 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 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 is submitted as part of the Annual Report which is due 45 days after the end of the third quarter.

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: 5

VA Office of General Counsel Letter
Instructions for 1996 Data Sheets Completion
Data Sheet
Diskette Instructions for Use
Company Diskette