



Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management
PO Box 126
Hines, IL 60141

October 19, 2001

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; 38 U.S.C. 8126). Annual Non-Federal Average Manufacturers Price (NFAMP) calculations with 2002 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Associate Chief Consultant, Pharmacy Benefits Management (PBM) (formerly Chief, Drug & Pharmaceutical Product Management (DPPM)), on or before November 15, 2001. (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.)

Each covered drug's mandated FCP for 2002 (the fifth 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) & (c). 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 2000 to September 2001. **The Bureau Of Labor Statistics data shows the percent change to be 2.65%, which will be used as the CPIU for the Federal Ceiling Price calculations due on November 15, 2001.**

The one-half percent industrial funding fee (IFF) being incorporated into FSS contracts will not be included in calculations of non-FAMP or reporting of FCP, but will be included in the FSS selling price. Please see instructions from your contracting officer.

The Section 8126 (d)(1) calculation will begin with the permanent Federal Supply Schedule (FSS) contract price of a covered drug in effect on September 30, 2001. For those manufacturers that elected dual FSS pricing, the FSS contract price is the September 30, 2001 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 2002 FSS price cap. This cap applies to all "other user" FSS prices in 2002.

The Section 8126 (a)(2) & (c) calculation will begin with the 2001 annual 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" non-FAMPs. The lower of the above calculation and the 2002 FSS price cap will become the 2002 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 2001, its calculated 2002 FCP will be the 2002 FSS price cap.

If they meet the other VA criteria, nominal prices for exclusion from non-FAMP's for 2002 calculations must be prices that do not exceed 10 percent of that particular item's non-FAMP during the third quarter of 2001 (7/1/01 through 9/30/01). Where sales to end-users are required for calculation of non-FAMP due to the absence of wholesale sales, you need not include purchases by PHS grantees or disproportionate share hospitals ("covered entities") 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, or at prices set in negotiations with the PHS Section 602 pharmaceutical prime vendor (PPV), Amerisource Bergen. However, sales to these entities at prices not negotiated by the Section 602 PPV and lower than Sect. 602 statutorily calculated prices must be included in NFAMP calculations.

As an added service to streamline efficiency for the 2002 report, PBM is enclosing a diskette with all your company's covered line items in database form. The diskette contains a file that will display your company's covered items. All that you need to run the diskette is access to a personal computer that has Microsoft Windows (versions 3.x, 95, 98, 2000, XP or NT), and then follow the enclosed diskette instructions for use. The database contains certain pre-filled fields based on the Public Law data supplied last year by your company. For example: we have provided the 2001 NFAMP Old (2000 NFAMP New which is the time period of 7/1/00 through 9/30/00). Therefore, all that is required of your company is that you furnish the 2001 Annual NFAMP and NFAMP New in the appropriate fields. After you return the completed diskettes to Pharmacy Benefits Management, we will calculate Change in NFAMP, Additional Discount, and 2002 Federal Ceiling Price. Pharmacy Benefits Management will send you a printout of your company's calculated 2002 Federal Ceiling Prices via facsimile or e-mail file within seven days after our receipt of your data. If we do not hear from your company within five workdays after we send the printout, we will assume that you agree with VA's calculations of the federal ceiling prices.

If there are changes to the data which PBM 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 Pharmacy Benefits Management e-mail. 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:

George J. Hill, R.Ph., M.B.A.
Public Law Database Manager
Pharmacy Benefits Management (119D)
1st Ave. - 1 Block North of Cermak Rd.
Bldg. 37, Room 201
Hines, Illinois 60141

E-Mail: NonFamp@med.va.gov

The quarterly non-FAMP report for the third quarter of 2001 consists of the same data as the "new NFAMP" (7/1/01-9/30/01) reported on the annual calculation form for 2002 FCP's which is due by **November 15, 2001**. Consequently, it will not be necessary to submit the NFAMP Third Quarter 2001 Report separately. However, manufacturers that do not meet the November 15, 2001 annual reporting deadline will be subject to penalties for late

data reporting as described in the Master Agreement, paragraph IV. B. Please note that 38 U.S.C. 8126 (e)(2) and Sect. 1927 (b)(3) of the Social Security Act (reflected in the Master Agreement) impose a civil money penalty on late reporting manufacturers in the amount of \$10,000.00 for each day in which required information has not been provided. VA asks that you submit the required annual data as soon as possible after the CPI-U change is posted in October and you receive this package.

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 Pharmacy Benefits Management Section (PBM) 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). Please note that VA presented to industry a discussion draft of an Amended Master Agreement at the NAC/Industry Conference at Rosemont, IL on September 12, 2000. The approval and implementation status of the proposed draft document has not yet been determined.

After your company reports its annual 2001 NFAMP data in the format on the enclosed diskette or sheets, the authorized official who signed your company's PPA addendum in 2001 (or an authorized successor) must prepare and sign a new PPA addendum, listing each covered drug and its 2002 FCP. This addendum should then be forwarded before December 1, 2001 to the VA National Acquisition Center (90N-P), Building 37, First Avenue, 1 block North of Cermak Rd., P.O. Box 76, Hines, Illinois 60141.

If you have any questions about any of the above information, please call George Hill at (708) 786-4387 or John Weisman at (708) 786-7878, respectively. You may also send your Public Law 2001 Non-FAMP Reports via facsimile to (708) 786-4386. Please note that these are new telephone numbers.

Sincerely,



for Michael Valentino, R.Ph.
Associate Chief Consultant
Pharmacy Benefits Management Strategic Healthcare Group
VACO Pharmacy Service

Enclosures: 4
Instructions for VHA's 2001 Non-FAMP Report
Office of General Counsel Dear Manufacturer Letter
Data Sheet
Data Diskette
Diskette Instructions