



Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management
1st Ave. – 1 Block North of Cermak Rd.
Bldg. 37, Room 139
Hines, IL 60141

October 22, 2008

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 2009 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Associate Chief Consultant, Pharmacy Benefits Management (PBM), **on or before November 17, 2008**. (Any anticipated changes in your company's method of accounting for charge backs, etc., must be implemented in accordance with Generally Accepted Accounting Principles (G.A.A.P.) and explained to the above office, the VA Office of General Counsel (025NAC), and the VA Office of Inspector General (55) **no later than October 31, 2008**.

Each covered drug's mandated FCP for 2009 (the first year of FSS multiyear contracts for statutory purposes) will be determined by adopting the calculation results described in 38 U.S.C. 8126, (a) (2) & (c). The change in Consumer Price Index-Urban (CPIU) will be utilized in performing this calculation. This change in CPIU is identified as the percent change from September 2007 to September 2008. **The U.S. Bureau of Labor Statistics data shows that the percent change to be 4.94% which will be used as the CPIU for the Federal Ceiling Price calculations due on November 17, 2008.** There will be NO comparison to the 2008 FSS Price plus CPI-U (the 38 U.S.C. 8126 (d) (1) calculation) for purposes of calculating the 2009 Federal Ceiling Prices, since 2009 has been determined to be the first year of FSS multiyear contracts for statutory purposes only.

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 (a) (2) & (c) calculation will begin with the 2008 annual non-FAMP computation; it will continue by multiplying that number by 0.76 and then subtracting any additional discount calculated based on a difference between "old" and "new" non-FAMPs. **This will become the 2009 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, negative non-FAMPs should be reported and the additional discount will be entered as zero (0). **If a covered drug had no reportable sales in 2008, its calculated 2009 FCP will be the 2008 FCP increased by an amount equal to the 2008 FCP multiplied by the 12-month percent change in CPI-U specified above.**

If they meet the other VA criteria, nominal prices excludable from non-FAMP's for 2009 calculations must be prices that are less than 10 percent of that particular item's non-FAMP during the third quarter of 2008 (7/1/08 through 9/30/08). 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 charge backs required to satisfy end-user purchases by the entities at prices determined by PHS under Sect. 602, or at prices set in negotiations with the PHS Section 602 pharmaceutical prime vendor(s) (PPV) and

any subcontractors. However, sales to these entities at prices not negotiated by the Sect. 602 PPV and lower than Sect. 602 statutorily calculated prices must be included in NFAMP calculations. Finally, sales of specific inpatient covered drugs to disproportionate share hospitals at Sect. 602 prices may be excluded from NFAMP if you have properly obtained a “hold harmless letter” from VA (see July 8, 2004 Dear Manufacturer Letter).

Due to the uncertainty of the ultimate application date of Sect. 703 of the 2008 National Defense Authorization Act, VA will not require manufacturers, in their 2008 annual NFAMP reports, to make any change to their current treatment of sales transactions that involve delivery of covered drugs to TRICARE beneficiaries through the TRICARE Retail Pharmacy Network.

As an added service to streamline efficiency for the 2009 report, PBM is requesting that all NFAMP data be handled via e-mail. PBM will send your company’s designated NFAMP representative (VIA E-MAIL) a file attachment in table format (.DBF) and Excel format (.XLS). This attachment will contain all of your company’s covered line items and certain pre-filled fields of data supplied by your company based on last year’s Public Law reporting. For example—we have provided the 2008 NFAMP Old (2007 NFAMP New which covers the time period of 7/1/07 through 9/30/07). Therefore, all that is required of your company is to furnish the 2008 Annual NFAMP (NFAMP_08) and NFAMP New (NFAMP_New) in the appropriate fields. NFAMPS for any new covered products that were introduced during the 2008 annual reporting period should be submitted to PBM separately from the annual NFAMP data for established products. Finally, any items that have been misclassified or reclassified as covered products should be submitted to PBM separately from new products and established products’ annual NFAMP data.

For this year’s Public Law submission, please submit line items under separate cover if you are reporting quarterly data along with your annual submission (that is,-submit the items as separate files--no tabs in Excel). If there are changes to the data that PBM has provided in the pre-filled fields (e.g. Office of Inspector General Audit recommendations), you have the option of changing the information as long as there is accompanying documentation. If your company elects to do so, you **must** submit a letter of explanation regarding all changes to the offices identified in paragraph one(above), no later than October 31, 2008.

After PBM receives your NFAMP data, we will calculate your Change in NFAMP, Additional Discount, and 2009 Federal Ceiling Price. Pharmacy Benefits Management will send you an Excel file e-mail of your company’s calculated 2009 Federal Ceiling Prices within seven days after our receipt of your data. **If we do not hear from your company within five workdays after we send the e-mail, we will assume that you agree with VA’s calculations of the federal ceiling prices.**

It is highly recommended and preferred that you submit your data in electronic format via the Pharmacy Benefits Management e-mail at NonFamp@va.gov. You may submit the data as you have in the past on the form provided using the instructional packet as a guide to the 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 re-calculations for new products, corrections to quarterly NFAMP reports and correction to annual FCP report should be forward to:

Ted Karnezis
Pharmacy Benefits Management (119D)
1st Ave.-1 block north of Cermak Road
Bldg. 37, Room 139
Hines, Illinois 60141
e-mail: NonFamp@va.gov

The quarterly non-FAMP report for the third quarter of 2008 consists of the same data as the “new NFAMP” (7/1/08 to 9/30/08) reported on the annual calculation form for 2009 FCP’s which is due by **November 17, 2008**. Consequently, it will not be necessary to submit the NFAMP third quarter 2008 Report separately. However, manufacturers that do not meet the November 15, 2008 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 e-mail.**

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).

After your company reports its annual 2008 NFAMP data via e-mail (or in the format on the enclosed diskette), the authorized official who signed your company’s PPA addendum for 2008 (or an authorized successor) must prepare and sign a new PPA addendum, listing each covered drug and its 2009 FCP. This addendum should then be forwarded before December 1, 2008 to the VA National Acquisition Center (049A1F1), 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 Ted Karnezis or John Weisman, at (708) 786-4387 or (708) 786-7878, respectively. You may also send your Public Law 2008 non-FAMP reports via facsimile to (708) 786-4386.

Sincerely,

/s/Joseph J. Canzolino, R.Ph.
Associate Chief Consultant
Pharmacy Benefits Management Strategic Healthcare Group
VACO Pharmacy Service

Enclosures:
Instructions for VHA’s 2008 non-FAMP Report
Data Sheet (Excel format)

Instructions for VHA’s 2008 non-FAMP report for 2009 PL 102-585 Due: Nov. 17, 2008

1. Preparation Date: [] [] - [] [] - [] []
 Explanation: The date the report is PREPARED. Format intended to be month-day-year.
Example: 11/1/08 [PREP_DATE]
 Note Page [] [] [] of [] [] []
 Explanation: If hard copy report is provided, pages should be numbered to assure complete document is received. (Not part of electronic database submission, only used in hard copy paper submission).

2. FDA Assigned Labeler Code: [] [] [] [] []
 Explanation: First segment of National Drug Code that identifies the manufacturer, labeler, re labeler, packager, repackager or distributor of the drug. Field is right justified and leading zeros are added to provide 5-digit code. [NDC_1].

3. Product Code: [] [] [] []
 Explanation: Second segment of the National Drug Code. Field is right justified and leading zeros are added to provide the 4-digit code. [NDC_2].

4. Pkg. Code: [] []
 Explanation: Third segment of the National Drug Code. field is right justified and leading zero is added if necessary to provide 2-digit code. [NDC_3].

5. Units per Pkg.: [] [] [] [] [] [] [] []
 Explanation: Number of units per package. *Example—bottles of 1000 tablets would be “1000”; liquid bottles of 473ML would be “473ML”; aerosol containers of 17.5GM would be “17.5GM”.* Maximum of 8 characters, free text. UNT_PKG]

6. Date Entered Market: [] [] - [] []-[] []
 Explanation: Date the specific product and package size (NDC) was first commercially made available for sale. This field is NOT mandatory for line items that entered the market before October 1992. Format intended to be month-day-year.
Example: 12/02/99. [DATE_ENTER].

7. Dosage Form: [] [] [] [] [] [] [] [] [] [] [] []
 Explanation: Dosage form of the product. *Example: Capsules or CAP, Aerosol, Solution.* Field identification may be obtained from United States pharmacopoeia dispensing Information, Volume III, or you may provide the same 3-digit code used to identify “UNIT TYPE” provided to the Healthcare Finance Administration (HCFA). Maximum 12 characters, free text. [DOSE_FORM].

8. Strength: [] [] [] [] [] [] [] [] [] [] [] []

Explanation: Product Strength. *Example: 250MG; 325MG/5ML; etc.* Field identification may be obtained from United States Pharmacopoeia Dispensing Information, Volume III. Maximum 12 characters, free text. [STRENGTH].

9. Product Name Listed on FDA Application (limit 63 characters):

Explanation: This 63-character field is intended for entry of the product name as it appears on the FDA registration form. The file is free text, left justified and limited to a maximum of 63 characters. [FDA_NAME].

10. Trade Name (limit 35 characters):

Explanation: This 35-character field is intended for entry of the product's patented trade name or brand name. The file is free text, left justified and limited to a maximum of 35 characters. [TRADE_NAME]

11. Generic Name (limit 35 characters):

Explanation: This 35-character field is intended for entry of the product's generic name. The file is free text, left justified and limited to a maximum of 35 characters. [TRADE_NAME]

12. % Increase in CPIU (Sept 07 – Sept 08): [][] [4] . [9] [4]

Explanation: The September 2007 and September 2008 Consumer Price Index-(CPI-U) can be obtained from the U.S. bureau of Labor Statistic or from the Pharmacy Benefits Management Section, telephone numbers indicated on page 3 of the cover letter. The percent increase in the CPI-U is calculated by multiplying the difference between the two index numbers by 100 and that product divided by the older (2007) of the two CPI-U's. This calculation is rounded to two decimal places. This field is numeric (5 characters--this includes the decimal point and two decimal places). Rounding rules: After specified number of decimal places, if number is equal to or greater than 5, round up. If number is less than 5, round down. [PCT_CPIU]

13. 2008 Annual NFAMP (10/01/07 – 09/30/08):

[][] [][] [][] [][] . [][]

Explanation: The 2008 Annual Non-Federal Average Manufacturer's Price (NFAMP) is the weighted average manufacturers' sales price for that NDC line item. this is total non-Federal dollar sales (described by paragraphs I., J., N., O., and II.B.5. of the Master Agreement) for the period indicated (October 1, 2007 through September 30, 2008) divided by the total unit volume of sales for that NDC line item, excluding nominal priced sales and returned goods if records are available for verification. Dollar sales must reflect rebates, cash discounts, charge backs or other similar price reductions. This number is expressed in dollars and cents and should be rounded off using the rules in example 12. This field is numeric (10 characters—this includes the decimal point with two decimal places). [NFAMP_08]

14. Old NFAMP (07/01/07 – 09/30/07):

[][] [][] [][] [][] . [][]

The following data elements must be provided to the Pharmacy Benefits Managements Section (PBM) of the Veterans Health Administration:

Structure for database: NFAMP2009.DBF

Field	Field Name	Type	Width	Dec
1	PREP_DATE	Date	8	
2	NDC_1	Character	5	
3	NDC_2	Character	4	
4	NDC_3	Character	2	
5	UNT_PKG	Character	8	
6	DATE_ENTER	Date	8	
7	DOSE_FORM	Character	12	
8	STRENGTH	Character	12	
9	FDA_NAME	Character	12	
10	TRADE_NAME	Character	35	
11	GENERIC	Character	35	
12	PCT_CPIU	Numeric	5	2
13	NFAMP_08	Numeric	10	2
14	NFAMP_OLD	Numeric	10	2
15	NFAMP_NEW	Numeric	10	2
16	NFAMP_CHG	Numeric	10	2
17	ADD_DISC	Numeric	10	2
18	CALCMAX09	Numeric	10	2
19	FCP_2009	Numeric	10	2
20	CONT_NO	Character	11	
21	COMPANY_OF	Character	40	
Total **			237	

PLEASE NOTE: Page Numbers are not required in the electronic submission structure.

The database format is compatible with DBASE III Plus, FoxPro, Visual FoxPro, Quick Silver, DBXL or equivalent (*.DBF) and is to be provide through direct electronic communications (e-mail). To expedite the electronic transmissions, the data may be compressed using PKZIP for data submissions larger than 4MB.

Please do not submit data using a comma delimiter (ASCII) format.

Please note that the PBM electronic bulletin board dial-in server has been discontinued. Electronic submission may be accomplished via e-mail to NonFamp@va.gov. If electronic submission is not possible, data may be submitted on diskette or manually.
(Form. OMB NO. 2900-3093 rev 9/07) enclosed to:

Ted Karnezis
Public Law Database Manager
Pharmacy Benefits Management (119D)
1st Ave.-1 Block North of Cermak Rd.
Bldg. 37, Room 139
Hines, IL 60141

For contract questions, you may contact Cheryl Ward-Roberts or your contracting officer, at the National Acquisition Center, Pharmaceutical Products Division: (708)-786-5180.

