

Special Notice

Re: Correction to CPI-U% for Public Law 102-585 calculations

Pharmacy Benefits Management (PBM) has recently become aware of a situation that is crucial to the Veteran's Healthcare Act of 1992, (Public Law 102-585) and the 2017 Federal Ceiling Price (FCP) calculations.

As you are aware, PBM utilizes key economic data supplied by the Bureau of Labor and Statistics (BLS) to calculate the Consumer Price Index-Urban (CPI-U) change, which is used in calculations to determine annual Federal Ceiling Prices for covered drugs. Pharmacy Benefits Management (PBM) utilizes the BLS website (www.bls.gov) as the sole source of obtaining the CPI-U.

The CPI-U% has been communicated via the Dear Manufacturer's Letter (DML) and has always been rounded to two (2) decimal places.

For the 2016 filing period (for 2017 FCPs), *the CPI-U% was incorrectly rounded and reported as 1.5.*

The correct CPI-U% for 2016 is: 1.46

PBM has incorporated the correct CPI-U of 1.46 in their tables and will use 1.46 for the 2017 calculations for Public Law. Your company can be assured that the correct CPI-U of 1.46 will be used in determining any calculations. Companies that have already filed their 2016 annual reports for 2017 FCP calculations will not need to re-file. PBM will re-calculate the 2017 FCPs.

Please note that PBM will not resend any corrected workbooks that reflect the CPI-U as 1.5.

Sincerely,



Ted

Pharmacy Benefits Management Services
ted.karnezis@va.gov

U.S. Department of Veterans Affairs
1st Ave-1 Block North of Cermak Road
Bldg. 37, Room 139
Hines, IL 60141
Tel: 708-786-4387
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**Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management Services
1st Ave – 1 Blk N of Cermak Rd Bldg 37 Rm 139 (10P4P)
Hines, IL 60141**



October 18, 2016

Dear Manufacturer:

Introduction:

The Office of Pharmacy Benefits Management Services (PBM) is responsible for maintaining calculated federal ceiling prices (FCPs) for covered drugs through the Public Law annual reporting process. All companies of covered drugs are obligated to comply with the reporting requirements under Public Law 102-585, Section 603.

Background:

Public Law 102-585 is the Veterans Healthcare Act of 1992, and it became law on November 4, 1992. Section 603 of Public Law 102-585 (38 U.S.C. 8126) (Public Law) and the provisions of each companies' Master Agreement (MA) require companies to report annual non-Federal Average Manufacturer's Price (NFAMP) calculations for covered drugs. Information about Public Law is available on the Office of Acquisition and Logistics—Federal Supply Schedule Service (FSS) website at: [FSS Public Law](#).

Purpose:

The purpose of this letter is to provide companies with an advance timeline and guidance on completing the 2016 annual NFAMP reporting requirements (for 2017 FCPs) mandated by Public Law.

System Requirements:

- Microsoft Excel (.xls)

Timeline:

- **By October 18, 2016**— Companies' designated NFAMP representative will receive an e-mail from AMMHIN.PL102585@va.gov. This e-mail will contain attachments of the current PBM Dear Manufacturer's Letter (DML) and a company Excel workbook (.xls) of covered items subject to annual calculations. This Excel workbook (.xls) is locked and will be used by companies to complete the 2016 annual NFAMP reporting requirements (for 2017 FCPs). **Pages 6-7** provide a data dictionary of this Excel workbook.
- **October 19-31, 2016**— **It is highly recommended that companies review the Excel workbook for any data related disputes or discrepancies that are UNRELATED TO A METHODOLOGY CHANGE (see examples on pages 9-10).** Disputes can include any combination of: an incorrect covered drug's FSS price that was in effect or awarded on September 30, 2016, an incorrect 3Q NFAMP Old value (7-1-2015 through 9-30-2015) and/or an omitted item from the listing of drug items subject to the annual calculations. **Please note: not all covered drugs will go through the annual NFAMP calculations;** the workbook will only contain covered items that are subject to the annual NFAMP calculation reporting. Companies should notify the VA of any data related disputes in the Excel workbook via e-mail as soon as possible as outlined in this guidance letter. Companies must report all covered drug items that had/should have had a Permanent FCP due and in place on September 30, 2016. The FSS price, as reflected in this workbook, which is used for Public Law calculations, **does not** include the Industrial Funding Fee (IFF) or the Federal Excise Tax (FET) for vaccines.
- **By October 31, 2016**—Deadline for companies to report and describe modifications in existing methodology used to calculate NFAMP, and to request approval to restate 3Q 2015 (NFAMP OLD) according to the new methodology (for purposes of an apples-to-apples additional discount calculation). This request must be submitted via e-mail to AMMHIN.PL102585@va.gov, per the instructions in Attachment B.
- **By October 31, 2016**—Companies must report any disputes of a covered drug's FSS price that was in effect or awarded on September 30, 2016, as well as any dispute of the calculated NFAMP for the Q3 NFAMP Old (7-1-2015 through 9-30-2015) that was provided on the company Excel workbook (.xls). Attachment C provides instructions on how to submit disputes to the VA via e-mail at AMMHIN.PL102585@va.gov. **NOTE: the disputed FSS price for Public Law purposes does not include the Industrial Funding Fee (IFF) or the Federal Excise Tax (FET) where applicable.**
- **By November 15, 2016**—Companies must report the annual NFAMP (10-1-2015 through 09-30-2016) and 3Q NFAMP New (07-01-2016 through 09-30-2016) values to PBM using the Excel workbook (.xls) for covered items provided by the PBM Public Law Manager. Attachment D has a list of compliance reminders.
- **By November 16, 2016**—If not already in process, the PBM Public Law Manager will begin to calculate the covered items' changes in NFAMP, additional discounts (if any), and the 2017 FCP. Once the calculations are completed, a final Excel workbook (.xls) will be sent by e-mail to the companies' designated NFAMP representative. **Companies have two business days to review the 2017 FCPs (see "Attachment E" for details).**
- **By December 2, 2016**—The company's authorized official, who signed the company's PPA addendum for 2016 FCPs (or an authorized successor), must prepare and sign a new PPA addendum, listing each covered drug and its 2017 FCP. To incorporate updated pricing into your FSS contract, you must submit a properly prepared request for modification (RFM) to VA National Acquisition Center (NAC) FSS Service via e-mail to AMMHIN.PL102585@va.gov. The properly prepared RFM must be received by **December 2, 2016** to guarantee an effective date of January 1, 2016. The PPA addendum should be submitted along with the RFM and a hardcopy may be mailed to: VA National Acquisition Center (003A4B), Building 37, First Avenue, 1 block North of Cermak Rd., PO Box 76, Hines, Illinois, 60141. NAC will be issuing additional guidance on submitting the RFM no later than **November 4, 2016**.

General Guidance:

Each covered drug's mandated FCP for 2017 (the fourth 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 (CPI-U) will be utilized in performing both calculations. This change in CPI-U is identified as the percent change from September 2015 to September 2016. Using data published by **the U.S. Bureau of Labor Statistics, the percent change was calculated as: 1.46% (www.bls.gov)**. (Please see "Special Notification" cover page). **This will be used for the FCP calculations in November, 2016.**

The one-half of one percent (0.5%) IFF being incorporated into FSS contracts will not be included in calculations of NFAMP or reporting of FCP, but will be included in the FSS/Big 4 selling price, if warranted. Please see additional instructions from your respective contracting officer(s).

The Section 8126 (d) (1) calculation will begin with the **permanent FSS contract price of a covered drug in effect on September 30, 2016**. For those manufacturers that elected dual FSS pricing, **the FSS contract price is the September 30, 2016 price charged to other government agencies** and other authorized Schedule users; **not** the price paid by the Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS)/Indian Health Service & Coast Guard. The appropriate FSS price will then be increased by the above percent change in CPI-U to arrive at the 2017 FSS price cap. This cap applies to all "other users" FSS prices in 2017.

The Section 8126 (a) (2) & (c) calculation will begin with the 2016 annual NFAMP computation; it will continue by multiplying that number by 0.76 and then subtracting any additional discount calculated based on any difference between "old" and "new" NFAMPs. **The lower of the above calculation and the 2017 FSS price cap will become the 2017 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 NFAMPs should be reported and no additional discount will be calculated; additional discount will be entered as zero (0.00). **If a covered drug had no reportable sales in fiscal year 2016, its calculated 2017 FCP will be the lower of: (A) the 2016 FCP increased by an amount equal to the 2016 FCP multiplied by the percent change to the CPI-U (as explained and provided above) OR (B) the FSS price in effect on September 30, 2016 increased by an amount equal to the September 30, 2016 FSS price multiplied by the percent change to the CPI-U.**

If they meet the other VA criteria, nominal prices excludable from NFAMP's for 2016 calculations must be prices that are less than 10 percent of that particular items NFAMP during the third quarter of 2015 (7/1/2015 through 9/30/2015). 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 ("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 the entities at prices determined by PHS under Sect. 602, or at prices set in negotiations with the PHS Section 602 pharmaceutical prime vendor (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).

VA must require that all wholesale sales (or direct sales where those are the proper beginning point) used for 2016 annual and 3rd quarter 2016 NFAMP reports (to be filed this November) be reduced by amounts reflecting certain TRICARE Retail Network usage data posted or transmitted by DoD during the FY 2016 12-month reporting period, because the TRICARE usage constitutes sales to the Federal Government.

Manufacturers will use DoD's payment-due dates to decide which TRRx usage may be ascribed to the relevant reporting periods (See further guidance in Attachment F). Covered drug scripts filled for TRICARE beneficiaries through the TRRx/T-Pharm Network should be treated by manufacturers as sales to the Federal Government, for NFAMP reporting purpose, beginning on the payment-due date transmitted by DoD to the manufacturer in the File containing the manufacturer's quarterly DoD usage data and refund invoice.

After PBM receives your NFAMP data, we will calculate your [Change in NFAMP], [Additional Discount], and [2017 Federal Ceiling Price]. PBM will send you an Excel workbook (.xls) via e-mail of your company's calculated 2017 FCPs after the NFAMP data has been calculated. **If we do not hear from your company within two workdays after we send the e-mail, we will assume that you agree with VA's calculations of the FCPs. If you submit any corrected annual NFAMP reports, they will be accepted on a provisional basis but will be subject to review by the OIG.**

The quarterly NFAMP report for the third quarter of 2016 consists of the same data as the "new NFAMP" (7/1/2016 to 9/30/2016) reported on the 2016 annual calculation form, which is due by **November 15, 2016**. Consequently, it will not be necessary to submit the NFAMP third quarter 2016 report separately. However, companies that do not meet the November 15, 2016 annual reporting deadline will be subject to penalties for late data reporting as described in the MA, 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 MA) 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 OIG audits. Nevertheless, to assist companies in providing the most accurate quarterly NFAMP calculations possible, PBM will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. **The same 45 day forbearance applies to filing Temporary and Permanent New Drug NFAMPs.** 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 Ted Karnezis or John Weisman, at (708) 786-4387 or (708) 786-7878, respectively.

Sincerely,

Jennifer L. Zacher, Pharm.D.
Assistant Chief Consultant
Pharmacy Benefits Management Services
VACO Pharmacy Service

Index of Attachments

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Attachment A Public Law Microsoft Excel Workbook Data Definitions

Field Name	Definition	Edits Allowed
ID	Unique identifier assigned to item in Public Law database	No
YearID	Calendar year that the annual report applies to	No
Prep_date	Date the report is prepared by company. Format = “mm/dd/yyyy” NOTE: Date entered must be between 10/01/2016 and 01/15/2017	Yes
ndc_1	National Drug Code (NDC); ndc_1= Labeler code (5 digits)	No
ndc_2	NDC; ndc_2 = Product code (4 digits)	No
ndc_3	NDC; ndc_3 = Package code (2 digits)	No
Unt_pkg	Number of units per package	No
Date_enter	Date the NDC was reported as first commercially available for sale	No
Dose_form	Dosage form of the NDC	No
Strength	NDC strength	No
FDA_name	NDC name reported by manufacturer as exists on FDA registration form	No
Trade_name	NDC brand name reported by company	No
Generic_name	NDC generic name	No
Pct_cpiu	Percent Increase in Consumer Price Index (CPI-U). Calculated by multiplying the difference between the two index numbers by 100 and that product divided by the older of the two CPI-U's. Calculation is rounded to two decimal places; rounding up if 3 rd decimal is >=5.	No
fss	2016 Federal Supply Schedule (FSS) price; the permanent contract price in effect or awarded on September 30, 2016 for single price companies. For dual FSS pricing companies, the 2016 FSS price is September 30, 2016 awarded permanent contract price charged to other government agencies and authorized FSS users other than the Department of Veterans Affairs (VA), Department of Defense (DoD), US Coast Guard (USCG) or Public Health Service (PHS). NOTE: The FSS price in this field DOES NOT include the Industrial Funding Fee (IFF) for companies that embed this fee.	No
fssmax	2016 Maximum Price; calculated using FSS + Allowable CPI-U increase.	No
nfamp	2016 Annual Non-Federal Average Manufacturer price (NFAMP, but shortened to “nfamp” for purposes of the Excel Workbook) is the weighted average manufacturers’ sales price for the NDC. Total non-Federal dollar sales as described by paragraphs I., J., N., O., and II.B.5. of the Master Agreement for the time frame 10/1/2015 thru 9/30/2016 divided by the total unit volume of sales for the NDC, 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. Calculation is rounded to two decimal places ; rounding up if 3 rd decimal is >=5. If no reportable sales, enter “0.00”. Activity resulting in negative values should be reported as such. Do not return spreadsheet with blank/NULL values as the workbook will be returned for correction.	Yes
nfamp_old	NFAMP for 7/1/2015 thru 9/30/2015. See nfamp field above for calculation and reporting requirements.	No
nfamp_new	NFAMP for 7/1/2016 thru 9/30/2016. See nfamp field above for calculation and reporting requirements.	Yes
nfamp_chg	Difference between nfamp_new and the nfamp_old. This number can be negative. NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.	No

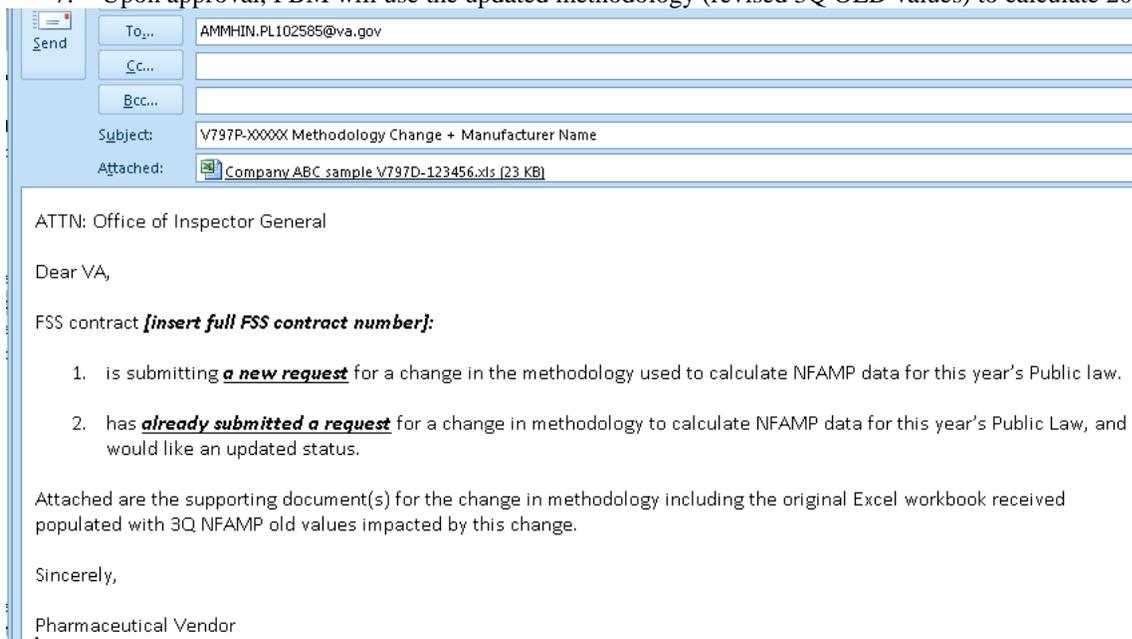
add_disc	Difference between nfamp_chg and the statutory allowable increase. The allowable increase is the product of the nfamp_old and pct_cpiu. This number must be >= \$0.00. If nfamp_chg is negative, then \$0.00 will be populated. NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.	No
calcmax	2016 Calculated Ceiling. Calculation based on 38 U.S.C.8126 (d)(2),(a)(2) and (c) is the product of the annual NFAMP X 0.76, less add_disc. Calculation is rounded to two decimal places; rounding up if 3 rd decimal is >=5. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	No
fcg	2017 Federal Ceiling Price (FCP). Lower of 38 U.S.C. 8126(d)(1) or 38 U.S.C. 8126 (d)(2) , (a)(2) & (c). This field is determined by using the lower number of fssmax or calcmax. NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.	No
disc_date	This field represents a covered item's discontinuation date from the manufacturer's FSS. NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.	No
cnt_no	FSS contract number assigned by the National Acquisition Center (NAC); current as of 9/30/2016	No
company_of	Name of the company's official authorizing and certifying that the data provided in this workbook is accurate	Yes
dispute_fss	Enter a "Y" to dispute the FSS price. Follow the directions outlined in Attachment D.	Yes
dispute_nfamp_old	Enter a "Y" to dispute the 3Q old NFAMP data. Follow the directions outlined in Attachment E.	Yes
rev_nfamp_old rev_fss	Revised 3Q old value; if company populates the dispute_nfamp_old field, then rev_nfamp_old must not be blank; Calculation is rounded to two decimal places ; rounding up if 3 rd decimal is >=5 Revised FSS price; if company populates the dispute_fss field, then rev_fss must not be blank; Calculation is rounded to two decimal places ; rounding up if 3 rd decimal is >=5	No
non_taa	This field indicates covered item(s) which have been identified as items sourced from a non-U.S., non-designated-country under the requirements of the Trade Agreements Act (TAA). They are considered covered drugs as defined by the Veteran's Health Care Act of 1992, P.L. 102-585, Sect. 603, therefore, your company must continue to report NFAMP to PBM for any covered drug and maintain a FCP for the drug annually with PBM. NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.	No

Purpose: Allows the company to request approval from OIG/OGC of a change in their methodology used to calculate NFAMP data for the 2015 annual reporting year, and to request approval of restated 3Q2014 (NFAMP OLD) recalculated under the new methodology (for purposes of an apples-to-apples additional discount calculation). This request can also be used to notify OIG/OGC and PBM of pending and approved requests. Unlike previous years, corrected workbooks will not be re-issued to companies; calculations will use the corrected 3Q data.

NOTE: This format is to request NFAMP methodology changes in advance of the due date (Oct 31, 2016).

Instructions: Requesting Modifications to Existing Methodology Used to Calculate NFAMP

1. Prepare a letter requesting approval for a change in calculation methodology.
2. Specify the reasons for the change in methodology and provide all supporting documentation.
3. In the workbook, identify the 3Q 2015 values impacted by the methodology change.
4. Send original workbook via e-mail to AMMHIN.PL102585@va.gov including option (a),(b) or (c)-(see example e-mail below):
 - a. For **new requests**, keep line number 1 in the body of the e-mail and populate the dispute_nfamp_old with “Y” and provide the rev_nfamp_old values
 - b. For **pending** requests, keep line number 2 in the body of the e-mail and populate the dispute_nfamp_old with “Y” and provide the rev_nfamp_old values
 - c. **If OIG has already approved your company’s methodology change request but the values in the annual workbook do not reflect the change, please send an e-mail to AMMHIN.PL102585@va.gov; populate the dispute_nfamp_old field with “Y” and populate the restated 3Q 2015 values in “rev_nfamp_old” fields; include documented OIG approval and update the subject line with the FSS contract number and “Methodology Change Approved”**
5. For options 4(a) & (b) above, subject line should include the full FSS contract number + manufacturer’s name, and the words: “METHODOLOGY CHANGE”
6. OIG will review the request and any associated documentation prior to their decision. If OIG concurs with the change, OIG will advise PBM and the manufacturer that the change and revised Q3 2015 NFAMPs are approved.
7. Upon approval, PBM will use the updated methodology (revised 3Q OLD values) to calculate 2017 FCPs



Purpose: Provides the company a way to notify the VA of any disputes concerning the accuracy of the annual workbook contents for verification. Disputes can be a September 30 FSS price, **and/or** a 3Q CY 2015 (NFAMP OLD) dispute (unrelated to methodology change) **and/or** a **potentially omitted covered item(s)**. **NOTE: This specific format is used to identify disputes in advance of October 31, 2016. After October 31, any disputes should be reported when the company submits their annual report to PBM (due no later than November 15, 2016).**

Instructions: How to submit disputes (unrelated to methodology changes) and/or a potentially omitted covered item(s) using the PBM annual workbook. NOTE: Items introduced after 4/1/2016 will not be included in this year’s annual workbook for 2017 FCP calculations (exceptions are covered drug NDC changes of an existing item).

1. Upon receipt of your company’s Excel workbook, review the covered items where potential disputes exist. Multiple dispute types may exist in the Excel workbook.
2. **To dispute the FSS price and/or 3Q CY 2015 price:** Mark column W (Dispute_fss) with a “Y” in the Excel workbook; to dispute the 3Q CY 2015, mark column X (Dispute_nfamp_old) with a “Y” in the Excel workbook. *See example below.*

U	O	P	Q	R	S	T	U	V	W	X	Y	Z
	fss	fssmax	nfamp_old	nfamp	nfamp_new	cnt_no	company_of	vendor	Dispute_fss	Dispute_nfamp_old	rev_fss_price	rev_nfamp_old
5	22.52	22.86	35.75			V123P-4567D		DRUG COMP				
5	21.01	221.33	30.01			V123P-4567D		DRUG COMP	Y	Y	22.52	35.75
5	21.01	21.33	35.75			V123P-4567D		DRUG COMP	Y		22.52	
5	21.01	21.33	35.75			V123P-4567D		DRUG COMP	Y		22.52	

Note that for one of these NDCs, there is more than one type of dispute (FSS dispute and 3Q CY 2015 dispute).

3. For each column populated with a “Y”, input a revised value in the respective column:
 - a. For disputed FSS prices, input the revised FSS price in column Y (without IFF/FET).
 - b. For disputed 3Q 2015 VALUES, input the revised 3Q 2015 value in column Z.
4. The following apply to inputs made in Column Y (rev_fss_price):
 - a. Ensure the FSS price does not include the 0.5% Industrial Funding Fee (IFF)
 - b. Ensure the FSS price does not include the Federal Excise Tax (FET) for vaccines
 - c. Attach copies of modifications to support manufacturer’s FSS price dispute
5. The following apply to inputs made in column Z (rev_nfamp_old):
 - a. Provide document(s) to support the disputed 3Q 2015 value(s)
6. Subject heading should include the full contract number and the words “Dispute Notification”

Send

To: AMMHIN.PL102585@va.gov

Cc:

Bcc:

Subject: V797D-123456 + Dispute Notification

Attached: Company ABC sample V797D-123456.xls (23 KB); FSS Mod Form 216.pdf (77 KB); FSS Mod Form 309.pdf (77 KB)

Dear VA,

Company ABC has reviewed their workbook. The following potential disputes have been identified **(list all applicable disputes)**:

- FSS price as of Sept 30
- 3Q 2015 (nfamp_old) Dispute
- Omitted Item

As instructed in the DML, the original workbook and supporting documents have been submitted for consideration.

Attachment C: WORKBOOK VERIFICATION/DISPUTES (cont'd)

7. **To notify PBM of a potential omission:** Identify potential covered item(s) omitted from workbook.
8. In the body of the e-mail, provide the data for the following fields (see example below):
 - NDC_11
 - Date of Market Entry
 - TRADE,GENERIC NAME
 - 2016 annual NFAMP value (10/1/2015 to 9/30/2016)
 - 3Q Calendar Year 2015 (NFAMP OLD) value (7/1/2015 to 9/30/2015),if applicable
 - 3Q Calendar Year 2016 (NFAMP NEW) value (7/1/2016 to 9/30/2016),if applicable
 - Indicate if omitted item is due to a change of NDC (Yes/No)
 - If “Y”, please update *Date Market Entry* column with the date of the New NDC

FSS contract V797X-XXXXX believes the items listed below were omitted from this year's Public Law workbook.

ndc_11	Date market entry	trade_name	generic	Annual nfamp (10/1/2014 – 9/30/2015)	3Q nfamp_old value(7/1/2014 – 9/30/2014)	3Q nfamp_new value (7/1/2015 – 9/30/2015)	42-2A NDC Change (Y/N?)
00111222233	3/18/2014	DRUG BRAND CREAM	GENERIC CREAM				
11111222233	2/7/2014	DRUG BRAND BOTTLE	GENERIC DRUG BOTTLE				

9. Subject heading should include the full contract number with the words “Dispute Notification” (see example e-mail after number 6 above)
10. The original Excel workbook received should be returned via e-mail to AMMHIN.PL102585@va.gov.
11. PBM, FSS and OIG will work to resolve issues. **Similar to the 2015 reporting year, corrected workbooks will not be re-issued to companies.**
12. PBM will only process the data after all disputes have been resolved. All corrected information will be included in the final 2017 FCP calculation workbook.
13. Unresolved item(s) will be tagged for follow-up in the 1Q 2017 CY, on a case by case basis.

Attachment D

Compliance Reminders

- **Dear Manufacturer Letters (DML)** - Prior years' DMLs and other compliance documents can be found here: [FSS Public Law](#). Alternatively, please ask your CO.
- **Rounding** - Annual NFAMP data includes sales from 10/1/2015 to 09/30/2016 ("nfamp" column "R" in Excel workbook) and 3Q NFAMP NEW data includes sales from 7/1/2016 to 9/30/2016 ("nfamp_new" column "S" in Excel workbook) and must contain data (i.e., NULL or BLANK is not valid). **Calculation is rounded to two decimal places; rounding up if 3rd decimal is >=5.** If there are no reportable sales for the covered item(s), enter "0.00"; negative values should be reported as such. Incomplete submissions will be returned to the manufacturer for verification and correction.

Rounding Examples:

value of 2.1462 rounds to 2.15

value of 2.1449 rounds to 2.14

- **Non-TAA** – In accordance with VA's non-availability determination, covered drugs that are substantially transformed in a non-designated country under the Trade Agreements Act (TAA) are now required to be made available on a Federal Supply Schedule contract. Items on your FSS contract that are from a non-U.S., non-designated-country of origin under the TAA are covered drugs as defined by the Veteran's Health Care Act of 1992, P.L. 102-585, Sect. 603 (VHCA). Your firm must comply with the requirements of the VHCA and your MA and PPA. Therefore, your company must report NFAMPs to PBM for any such covered drug, maintain a FCP for the drug annually with PBM, submit an updated PPA Addendum annually to the NAC via e-mail: AMMHINPLCORETEAM@VA.GOV, and establish 2017 contract pricing that goes into effect as of January 1, 2017.
- **Discontinuations** - Covered drug items that are contained in the annual workbook received from PBM but has a pending FSS discontinuation modification should still have a 2016 annual NFAMP report filed to calculate a 2017 FCP, but there is no need for a price-changing FSS Request for Modification (RFM) for 2017, IF the stock of the discontinued drug at wholesalers is exhausted by about Dec. 1, 2016. (In such a case, a proper deletion FSS RFM would be filed before Jan. 1, 2017.) However, if sales of wholesaler stock will continue into 2017, the company must follow all the usual steps to have statutory pricing in place for 2017.
- **Flu Vaccines** - The March 31, 2004 DML outlines revised guidance on influenza (flu) vaccines. Since the flu vaccines are not included in the annual workbook, your company will need to provide a separate report to PBM to establish the permanent FCP due no later than November 15. Please submit this report following the new product reporting guidelines.
- **Eligibility** – 2016 Annual NFAMP data (for 2017 FCPs) will not be required for new covered drug(s) that were introduced into the commercial market after 4/1/2016, and has not experienced at least one full calendar quarter of sales by September 30th, 2016. See OGC DML dated October 19, 2010. In addition, the item(s) will not appear in the annual workbook for FCP calculations (NDC changes are the exception to this rule).
- **New Package Sizes (NPS)** - A manufacturer must submit a modification to add a NPS item to its FSS contract, according to the VA's NPS policy. See OGC DML dated October 19, 2010 and November 2, 2011. http://www.va.gov/oal/docs/business/nac/20111101_PL102585-OgcAnnualGuidance.pdf

- **NDC Changes** - If a manufacturer of a covered drug changes their NDC, the new NDC number must be added to the contract at the time of launch at the same FCP and contract pricing as the original NDC. Further, both the old and new NDC must remain on contract until the old NDC is off the market and out of the supply chain. The NFAMP sales data for both the “old” and “new” NDCs must be combined (or blended) when reporting. If new covered drug NDC(s) are not included in the initial workbook received from the Public Law Manager, or if there is a pending FSS NDC Change modification, please follow the directions under the dispute section of this letter (Attachment C). The new NDC(s) will be included in the final 2017 FCP workbook.
- **Excel workbook** - Several of the cells in the Excel workbook are locked and read-only. A copy of an unlocked Excel workbook will be supplied to companies upon request if needed for data processing. However, the final Excel workbook submitted to the Public Law Manager by companies must be the original locked Excel workbook received from PBM.
- **TRICARE (TRRx)** - VA has provided guidance to manufacturers on how to treat sales which become the basis for TRICARE Retail Pharmacy Program (TRRx) rebates. This guidance can be found at: <http://www1.va.gov/oamm/docs/business/nac/TrrsSales-NfampFaqs.doc>. **There were four TRRx rebate invoice utilization and payment due dates during this year’s annual reporting period:**

Quarter	Billing Period	Refund Payment Due Date
2QCY15	April - June 2015	December 9, 2015
3QCY15	July - September 2015	February 29, 2016
4QCY15	October - December 2015	May 16, 2016
1QCY16	January - March 2016	August 12, 2016

Additional information for Pharmaceutical Manufacturers is available at this website:

<http://www.health.mil/About-MHS/Defense-Health-Agency/Healthcare-Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers>

- **Self-disclosures** - If a manufacturer discovers that it is not in compliance with some aspect of the Public Law, or was not in compliance during a prior period, it should notify the VA. Attachment E provides instructions on how to submit a self-disclosure.
- **FSS Contract Number Changes** - FSS contracts are awarded with a five-year duration period. Your FSS contract may be awarded a new contract number during Public Law season **after** the locked spreadsheet has been submitted to your company. PBM will keep record of the newly awarded contract number and provide the correct contract number with the final 2017 FCP workbook.

Attachment E

Instructions: How to Submit a Self-disclosure for Federal Supply Schedule (FSS) Public Law Non-Compliance or Pricing Errors

Purpose: Provides the manufacturer with a process for making a self-disclosure of any Public Law non-compliance or pricing errors that occurred during any period the manufacturer was subject to the Public Law (manufacturing and selling covered drug products). Examples of non-compliance or pricing errors requiring disclosure include (but are not limited to):

- Failure to obtain an FSS contract and sign a Master Agreement in a timely manner
- Failure to submit NFAMP data and add a new covered drug to an FSS contract in a timely manner
- Errors in calculating NFAMPs
- Misclassifying covered drugs as non-covered drugs
- Deleting covered drugs from an FSS contract prematurely

To make a self-disclosure, a manufacturer should do the following:

1. Prepare a letter that states the non-compliance error, what caused the error, what covered drug item(s) were affected by the error, how long the error occurred, and what remedial action the manufacturer is proposing or has taken.
2. Provide supporting documentation for the disclosure.
3. Send e-mail notification to AMMHIN.PL102585@va.gov
4. Subject should include the full FSS contract number, manufacturer's name, and the words: "Self Disclosure".

Example:

The screenshot shows an email composition window with the following fields:

- To:** AMMHIN.PL102585@va.gov
- Subject:** V797D-123456 + Company ABC + Self Disclosure
- Attached:** Provide all supporting documentation

The body of the email contains the following text:

Dear VA,

FSS contract **[insert full contract number]** would like to report that during a self-audit we have discovered the following issues over the course of X years.

- Describe the issue
- Provide all supporting documentations as attachments
- Provide point of contact information

Sincerely,

Company ABC

Attachment F

Instructions: How to Submit a Dispute in the 2017 calculated FCPs for annual reporting year 2016

Purpose: Company is to use this format to dispute or resubmit data for 2016 FCP calculations that are the result of database and/or scrivener errors. If a company wishes to dispute an FCP because it believes the NFAMP data it provided was in error, it should submit a self-disclosure under Attachment E rather than an FCP Dispute e-mail. If a company is disputing an FCP because the resulting FCPs would cause financial hardship (that is, not the result of database and/or scrivener errors) the company should first consider requesting a change in methodology under Attachment B to mitigate the hardship. If a methodology change would not mitigate the hardship, then the company should follow the appropriate established guidelines for FCP relief or nominal increases.

1. Identify all covered items where the 2017 FCP is being disputed due to a data base error.
2. In the body of the e-mail, provide the values for the following fields:
 - NDC_1, NDC_2, NDC_3
 - TRADE
 - Revised NFAMP 2016 sales value (10/1/2015 to 9/30/2016)
 - Revised 3Q Calendar Year 2016 sales value (7/1/2016 to 9/30/2016)
3. State the reason for the dispute.
4. Include all documentation that would support the dispute or resubmission, as necessary.
5. Subject heading should include the full contract number and the words "Dispute 2017 FCP Report"
6. Disputes resulting from database errors should be submitted via e-mail to: AMMHIN.PL102585@va.gov. (see below for examples of database errors/reasons)
7. Include the final Excel workbook (.xls) of 2017 FCPs as an attachment

Example:

Subject: V797X-XXXX DISPUTE 2017 Calculated FCPs

To whom it may concern:

FSS contract V797-X-XXXX is disputing the 2017 calculated FCP data for the following NDCs:

NDC_11	TRADE_NAME	2017 FCP	REIVSED 2017 FCP	REVISED ANNUAL NFAMP NFAMP	REVISED 3Q NEW NFAMP	REASON
11111222233	DRUG BRAND CREAM	82.79	85.92	75	N/A	Data entry error for ANNUAL NFAMP
00111234501	DRUG BRAND BOTTLE	24.98	18.92	43.91	18.2	data entry errors for ANNUAL/3Q NEW NFAMP

The attached document(s) support the disputed calculated FCPs.
We have included the FINAL FCP Excel workbook sent by the PBM Public Law Manager.

Sincerely,

Pharmaceutical Vendor

Examples of database errors/reasons in which PBM can immediately address:

- Revised 3Q 2015 value(s) approved, but not used for the 2017 FCP calculations
- Revised Sep 30 price was approved, but not used for the 2017 FCP calculations
- Omitted item(s) had incorrect 3Q 2015 value applied for the 2017 FCP calculations
- Scrivener's errors during entry (e.g., 3Q values were entered into the annual fields)

Due to the time constraints and review processes involved, 2017 calculated FCPs unrelated to database errors may be delayed.