Pharmacy Benefits Management
Dear Manufacturer Letter

Public Law 102-585 (38 U.S.C. 8126)
Section 603

The Veteran’s Healthcare Act of 1992 (‘‘the Act’’)

Pharmacy Benefits Management (PBM) Services
1st Ave – 1 Blk N of Cermak Rd
Bldg 37 Rm 139 (10P4P)
Hines, IL 60141
Annual Compliance

October 2018

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I. 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.

II. BACKGROUND


a. PURPOSE

The purpose of this Dear Manufacturer Letter (DML) is to provide companies with guidance on complying with the 2018 annual NFAMP reporting requirements (for 2019 FCPs) under Public Law 102-585, Section 603. NOTE: This is the first year of a Federal Supply Schedule (FSS) multiyear contract for statutory purposes. The annual Excel workbook structure and calculation methodologies differ for a first-year calculation from all other years. Several data fields and attachments have been eliminated from the workbook and the DML for the 2019 FCP calculations.

b. OBJECTIVES

PBM will provide your company’s point of contact with an Excel workbook that is pre-populated with data. It is the company’s responsibility to verify the accuracy of the data in this workbook. Follow the guidance in this letter to report any disputes to the VA. If there are no disputes to the pre-populated data in the Excel workbook, you are advised to populate the workbook with data values as explained in this letter and return electronically to VA before the November 14, 2018 deadline. The excel data dictionary and Attachment E provide a list of compliance reminders to assist with your annual filing.

c. SYSTEM REQUIREMENTS

In order to comply with the annual reporting requirements, electronic mail (e-mail) and a computer loaded with Microsoft Excel (.xls) program is required.

III. 2018 Year PUBLIC LAW TIMETABLE (OVERVIEW)

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCT 11</td>
<td>CPI-U Published</td>
</tr>
<tr>
<td>OCT 16</td>
<td>Workbook Verification</td>
</tr>
<tr>
<td>OCT 30</td>
<td>Deadline</td>
</tr>
<tr>
<td>NOV 3</td>
<td>NAC Letter</td>
</tr>
<tr>
<td>NOV 14</td>
<td>Deadline</td>
</tr>
<tr>
<td>NOV 15</td>
<td>FCP Calculations</td>
</tr>
<tr>
<td>DEC 3</td>
<td>Deadline</td>
</tr>
</tbody>
</table>

- OCT 11: CPI-U Published
  - PBM calculates the consumer price index-urban (CPI-U%) value and disseminates company's Excel workbook containing covered drugs subject to annual calculations

- OCT 16: Workbook Verification
  - Company reviews VA’s workbook for discrepancies, which may include omissions, FSS price disputes, 3Q disputes or any other discrepancies that may exist and notifies VA

- OCT 30: Deadline
  - Last day for companies to submit methodology change requests & related 3Q OLD restatements under (proposed) new methodology; This is also the last day companies may report any disputes identified in the company workbook (FSS Disputes, OMISSIONS and 3Q disputes unrelated to methodology change)

- NOV 3: NAC Letter
  - November letter from National Acquisition Center (NAC) providing guidance on how Jan 1 FSS pricing updates will proceed

- NOV 14: Deadline
  - Annual filing due; companies that were unable to notify the VA of identified disputes should do so when they file their annual report to PBM on November 15

- NOV 15: FCP Calculations
  - PBM will start/continue to process the annual reports; NOTE: pending disputes will be resolved prior to FCP calculations

- DEC 3: Deadline
  - Last day to submit request for modification (RFM) to NAC for guaranteed Jan 1 upload price
IV. DETAILED TIMELINE

By October 15, 2018
Companies’ designated NFAMP representative will receive an e-mail from AMMHIN.PL102585@va.gov on behalf of the Public Law Manager. This e-mail will contain attachments of a current copy of PBM’s DML and an Excel workbook (.xls) of covered items subject to annual calculations. This Excel workbook (.xls), which is a locked version and contains select prepopulated cells, will be used by companies to complete the 2018 annual NFAMP reporting requirements (for 2019 FCPs). Pages 5-6 of this DML provide the data dictionary of this Excel workbook.

October 16, 2018
Workbook Verification: Companies must review the Excel workbook upon receipt for any disputes and discrepancies. Companies are advised to notify the VA of any disputes in the Excel workbook via e-mail as outlined in this guidance letter. Please note: not all covered drugs are eligible for annual NFAMP calculations; the workbook will only contain covered items that are subject to the annual NFAMP calculation reporting. Companies must report all covered drug items that had/should have had a Permanent FCP in place on September 30, 2018, for the purpose of determining FCPs for Calendar Year 2019. Disputes and discrepancies should follow the dispute process outlined in Attachment B.

By October 23, 2018
☐ Deadline for companies to report and describe modifications in existing methodology used to calculate NFAMP, and to request approval to restate 3Q 2017 (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, as instructed in Attachment A. The VA will review the requests and communicate a resolution to the company. At this point, and to reduce e-mail traffic, a corrected workbook with revised data values will not be re-issued. The corrected values will be used in calculations and will reflect in the final FCP report to the company. To ensure accuracy in calculations, please provide a copy of the approved methodology communication when your company files the annual report. Companies that submit 3Q disputes due to methodology change requests after October 23 can expect increased delays in receiving their 2019 FCP calculations.

By October 30, 2018
• Deadline for companies to report any Workbook Verification disputes via e-mail to AMMHIN.PL102585@va.gov, as instructed in Attachment B. Disputes can include any combinations of: a covered drug(s) FSS price that was in effect or awarded on September 30, 2018; any dispute(s) of the calculated NFAMP for the 3Q NFAMP Old value (7-1-2017 through 9-30-2017); the listing of drug items subject to the annual calculations, such as omitted items; or other disputes as to the accuracy of the contents of the Excel workbook (.xls) that was received. The VA will validate the disputes and communicate a resolution to the company. At this point, and to reduce e-mail traffic, a corrected workbook with revised data values will not be re-issued. The corrected values will be used in calculations and will reflect in the final FCP report to the company. To ensure accuracy, please provide a copy of VA’s approved resolution when your company files the annual report. Companies that submit identified disputes after November 1 can expect increased delays in receiving their 2019 FCP calculations.

By November 14, 2018
• Companies must report the annual NFAMP (10-1-2017 through 09-30-2018) and 3Q NFAMP New (07-01-2018 through 09-30-2018) calculations to the VA via e-mail to AMMHIN.PL102585@va.gov using the Excel workbook (.xls) provided by the PBM Public Law Manager. At this point in time, PBM will only re-issue corrected workbooks for extreme cases. IMPORTANT: Your Company must include a copy of VA’s approved resolution for identified disputes when filing the annual report to the VA. It is possible that your company has submitted disputes by the requested deadline to the VA, but the disputes are pending VA resolution. In order to remain compliant with the November 14 filing deadline, the company must submit their annual filing along with a copy of the original dispute verification e-mail along with current resolution status, if any. Companies that have not verified the contents of their Excel workbooks for disputes or omissions by this time must identify any disputes when they submit their annual report due on November 14, 2018. Calculations will not begin until all disputes have been resolved. Attachment C provides a list of compliance reminders.

By November 15, 2018
The PBM Public Law Manager will start to calculate the covered items’ changes in NFAMP, additional discounts (if any), and the 2019 FCP (if not already in process). Companies are encouraged to submit their annual reports early, as FCP calculations are completed on a first-in first-out basis. Once the calculations are completed, the Excel workbook (.xls) will be sent by e-mail to the companies’ designated NFAMP representative. Companies have two business days to review the 2019 FCPs. Attachment D instructs how to submit FCP disputes by e-mail.

By December 3, 2018
Companies’ authorized signatories must prepare and sign a new PPA addendum, listing each covered drug and its 2019 FCP. The VA National Acquisition Center (NAC) FSS Service will be issuing additional guidance no later than November 3, 2018 on how to submit a “Request For Modification” (RFM) via e-mail to VAFSSMODS@va.gov to update contract pricing. The properly prepared RFM must be received by December 3, 2018 to guarantee an effective date of January 1, 2019.
## EXCEL DATA DICTIONARY

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition</th>
<th>Edits Allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
<td>Unique identifier assigned to item in Public Law database</td>
<td>No</td>
</tr>
<tr>
<td>YearID</td>
<td>Calendar year in which the Federal Ceiling Price applies</td>
<td>No</td>
</tr>
<tr>
<td>Prep_date</td>
<td>Date the report is prepared by company. Format = “mm/dd/yyyy”</td>
<td>Yes</td>
</tr>
<tr>
<td>Prep_date</td>
<td>NOTE: Date entered restricted to 10/01/2018 and 01/15/2019</td>
<td></td>
</tr>
<tr>
<td>ndc_1</td>
<td>National Drug Code (NDC); ndc_1 = Labeler code (5 digits)</td>
<td>No</td>
</tr>
<tr>
<td>ndc_2</td>
<td>NDC; ndc_2 = Product code (4 digits)</td>
<td>No</td>
</tr>
<tr>
<td>ndc_3</td>
<td>NDC; ndc_3 = Package code (2 digits)</td>
<td>No</td>
</tr>
<tr>
<td>Unt_pkg</td>
<td>Number of units per package</td>
<td>No</td>
</tr>
<tr>
<td>Date enter</td>
<td>Date the NDC was reported as first commercially available for sale</td>
<td>No</td>
</tr>
<tr>
<td>Dose_form</td>
<td>Dosage form of the NDC</td>
<td>No</td>
</tr>
<tr>
<td>Strength</td>
<td>NDC strength</td>
<td>No</td>
</tr>
<tr>
<td>FDA_name</td>
<td>NDC name reported by company as listed on FDA registration form</td>
<td>No</td>
</tr>
<tr>
<td>Trade_name</td>
<td>NDC brand name reported by company</td>
<td>No</td>
</tr>
<tr>
<td>Generic_name</td>
<td>NDC generic name</td>
<td>No</td>
</tr>
<tr>
<td>Pct_cpiu</td>
<td>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 3rd decimal is &gt;=5. Examples: 2.1462 rounds to 2.15; 2.1449 rounds to 2.14</td>
<td>No</td>
</tr>
<tr>
<td>nonfamp</td>
<td>2018 Annual Non-Federal Average Manufacturer price (NFAMP) is the weighted average manufacturers’ sales price for the NDC. Calculation is rounded to two decimal places; rounding up if 3rd decimal is &gt;=5. For “false positive” NFAMPs (negative sales divided by negative units), and no reportable sales, “0.00” should be entered. Activity resulting in negative values should be reported as such. Do not return spreadsheet with blank values.</td>
<td>Yes</td>
</tr>
<tr>
<td>nfamp_old</td>
<td>NFAMP for 7/1/2017 thru 9/30/2017. See nfamp field above for calculation and reporting requirements.</td>
<td>No</td>
</tr>
<tr>
<td>nfamp_new</td>
<td>NFAMP for 7/1/2018 thru 9/30/2018. See nfamp field above for general calculation and reporting requirements.</td>
<td>Yes</td>
</tr>
<tr>
<td>nfamp_chg</td>
<td>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.</td>
<td>No</td>
</tr>
<tr>
<td>add_disc</td>
<td>Difference between nfamp_chg and the legislative allowable increase. The allowable increase is the product of the nfamp_old and pct_cpiu. This number must be &gt;= $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.</td>
<td>No</td>
</tr>
<tr>
<td>calcmax</td>
<td>2018 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 3rd decimal is &gt;=5. Examples: 2.1462 rounds to 2.15; 2.1449 rounds to 2.14 NOTE: NOTE: This field is not included in the initial workbook from PBM; included in the final workbook sent to companies with the calculations.</td>
<td>No</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Edits Allowed</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>fcp</td>
<td>2018 Federal Ceiling Price (FCP). Lower of 38 U.S.C. 8126(d)(1) or 38 U.S.C. 8126 (d)(2), (a)(2) &amp; (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.</td>
<td>No</td>
</tr>
<tr>
<td>disc_date</td>
<td>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.</td>
<td>No</td>
</tr>
<tr>
<td>cnt_no</td>
<td>FSS contract number assigned by the National Acquisition Center (NAC); current as of 9/30/2018</td>
<td>No</td>
</tr>
<tr>
<td>company_of</td>
<td>Name of the company’s official authorizing and certifying that the data provided in this workbook is accurate</td>
<td>Yes</td>
</tr>
<tr>
<td>dispute_fss</td>
<td>Enter a “Y” to dispute the FSS price. Follow the directions outlined in Attachment C or E, as applicable. <strong>If dispute_fss field = Y, then rev_fss field must be populated.</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>dispute_nfamp_old</td>
<td>Enter a “Y” to dispute the 3Q old NFAMP data if unrelated to methodology change. Please follow the directions in Attachments A, D or E, as applicable. <strong>If dispute_nfamp_old = Y, then Rev_nfamp_old field must be populated.</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>rev_fss</td>
<td>Revised FSS price; if company populates the dispute_fss field, then rev_fss should not be blank; <strong>Calculation is rounded to two decimal places; rounding up if 3rd decimal is &gt;=5.</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>Rev_nfamp_old</td>
<td>Revised 3Q old value; if company populates the dispute_nfamp_old field, then rev_nfamp_old should not be blank; <strong>Calculation is rounded to two decimal places; rounding up if 3rd decimal is &gt;=5.</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>non_taa</td>
<td>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.</td>
<td>No</td>
</tr>
</tbody>
</table>
VI. GENERAL GUIDANCE

Each covered drug’s mandated FCP for 2019 (the first year of FSS multiyear contracts for statutory purposes) will be determined by adopting calculation results described in 38 U.S.C 8126 (a)(2) & (c). The same percent change in Consumer Price Index-Urban (CPI-U) will be utilized in performing this calculation. This change in CPI-U is identified as the percent change from September 2017 to September 2018. **The U.S. Bureau of Labor Statistics shows the derive percent change was calculated as 2.28%**. **There will be NO comparison to the 2018 FSS Price plus CPI-U (the 38 U.S.C. 8126 (d) (1) calculation) for purposes of calculating the 2019 Federal Ceiling Prices, since 2019 has been determined to be the first year of FSS multiyear contracts for statutory purposes only.**

The Federal Excise Tax (FET) on vaccines and 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. Please see additional instructions from your respective contracting officer(s).

The Section 8126 (a) (2) & (c) calculation will begin with the 2018 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. **This will become the 2019 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 from October 1, 2017 through September 30, 2018 (FY 2018), the covered drug’s calculated 2019 FCP will be the 2018 FCP increased by an amount equal to the 2018 FCP multiplied by the percent change to the CPI-U.

If they meet the other VA criteria, nominal prices excludable from NFAMP’s for 2018 calculations must be prices that are less than 10 percent of that particular items NFAMP during the third quarter of 2017 (7/1/2017 through 9/30/2017). 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).
VI. GENERAL GUIDANCE (cont’d.)

VA must require that all wholesale sales (or direct sales where those are the proper beginning point) used for 2018 annual and third quarter 2018 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 2018 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 E). 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.

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Billing Period</th>
<th>Refund Payment Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2QCY17</td>
<td>APRIL - JUNE 2017</td>
<td>Nov 20th, 2017</td>
</tr>
<tr>
<td>3QCY17</td>
<td>JULY - SEPTEMBER 2017</td>
<td>Feb 19th, 2018</td>
</tr>
<tr>
<td>4QCY17</td>
<td>OCTOBER - DECEMBER 2017</td>
<td>May 23rd, 2018</td>
</tr>
<tr>
<td>1QCY18</td>
<td>JANUARY - MARCH 2018</td>
<td>Aug 20th, 2018</td>
</tr>
</tbody>
</table>

After PBM receives a company’s NFAMP data, PBM will calculate the [Change in NFAMP], [Additional Discount], and [2019 Federal Ceiling Price] for each covered drug item subject to the 2018 annual reporting requirements for 2019 FCPs. PBM will send you an Excel workbook (.xls) via e-mail of your company’s calculated 2019 FCPs after the NFAMP data has been calculated. If your company does not agree with any of VA’s calculations of the FCPs, you must formally notify VA within two workdays after VA sends the email. 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 2018 consists of the same data as the “new NFAMP” (7/1/2018 to 9/30/2018) reported on the 2018 annual calculation form, which is due by November 14, 2018. Consequently, it will not be necessary to submit the NFAMP third quarter 2018 report separately. However, companies that do not meet the November 15, 2018 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 Cheryl Kohutynski or John Weisman, at (708) 786-7985 or (708) 786-7878, respectively.

Sincerely,

Jennifer Zacher, Pharm.D.
Associate Chief Consultant
Pharmacy Benefits Management Services
VACO Pharmacy Service
VII. ATTACHMENTS

A. METHODOLOGY CHANGE REQUEST

Purpose: Allows the company to request approval from VA of a change in their methodology used to calculate NFAMP data for the 2018 annual reporting year, and to request approval of restated 3Q2017 (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 VA of pending and approved requests. Upon receipt, the VA Office of Inspector General (OIG), in coordination with the VA Office of General Counsel (OGC), will analyze methodology change requests. At this point, and to reduce e-mail traffic, a corrected workbook with revised data values will not be re-issued. The corrected values will be used in calculations and will reflect in the final FCP report to the company.

NOTE: This format is to request NFAMP methodology changes in advance of the due date (Oct 23, 2018).

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 2017 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 2017 values in “rev_nfamp_old” fields; include documented OIG approval and update the subject line with the manufacturer’s name + FSS contract number and “Methodology Change Approved”
5. For options 4(a) & (b) above, subject line should include the full manufacturer’s name + FSS contract number, 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 the manufacturer that the change and revised Q3 2017 NFAMPs are approved
7. Upon approval, PBM will use the updated methodology (revised 3Q OLD values) to calculate 2018 FCPs

Example:
B. WORKBOOK VERIFICATION DISPUTES

RETURN DATE: 10/30/2018

Purpose: For the manufacturer to notify the VA of any disputes concerning the accuracy of the annual workbook contents provided for verification. Disputes can be a September 30 FSS price, and/or a 3Q CY 2017 (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 the due date (October 30, 2018). After October 30, disputes should be reported with the annual filing due no later than November 14, 2018.

Instructions: How to Submit FSS price disputes and/or 3Q CY 2017 disputes unrelated to methodology changes and/or a potentially omitted covered item(s). NOTE: Items introduced after 4/1/2018 may not be included in this year’s annual workbook for 2019 FCP calculations (exceptions are covered drug NDC changes of existing item(s) and divested/acquired items).

1. Upon receipt of your company’s Excel workbook, review the covered items where potential disputes exist. Multiple disputes may exist in the Excel workbook.

2. To dispute the FSS price and/or 3Q CY 2017 price: Mark column W (Dispute_fss) with a “Y” in the Excel workbook; to dispute the 3Q CY 2017, mark column X (Dispute_nfamp_old) with a “Y” in the Excel workbook. See example below.

<table>
<thead>
<tr>
<th>Q</th>
<th>U</th>
<th>W</th>
<th>Y</th>
<th>Z</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.02</td>
<td>35.67</td>
<td>Y</td>
<td>IFF</td>
<td>Z</td>
</tr>
<tr>
<td>3.03</td>
<td>35.67</td>
<td>Y</td>
<td>FET</td>
<td>Z</td>
</tr>
<tr>
<td>3.04</td>
<td>35.67</td>
<td>Y</td>
<td>IFF/FET</td>
<td>Z</td>
</tr>
<tr>
<td>3.05</td>
<td>35.67</td>
<td>Y</td>
<td>IFF/FET</td>
<td>Z</td>
</tr>
<tr>
<td>3.06</td>
<td>35.67</td>
<td>Y</td>
<td>IFF/FET</td>
<td>Z</td>
</tr>
<tr>
<td>3.07</td>
<td>35.67</td>
<td>Y</td>
<td>IFF/FET</td>
<td>Z</td>
</tr>
</tbody>
</table>

Note that for one of these NDCs, there is more than one type of dispute (FSS dispute and 3Q CY 2017 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 2017 VALUES, input the revised 3Q 2017 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 or contract award documents 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 2017 value(s)

6. Subject heading should include the full contract number and the words “Dispute Notification”

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 2017 (nfamp_old) Dispute
- Omitted Item

As instructed in the DML, the original workbook and supporting documents have been submitted for consideration.
B. WORKBOOK VERIFICATION DISPUTES (cont’d)  RETURN DATE:  10/30/2018

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
   - Proposed 9/30 FSS price (without IFF/FET)
   - 2018 annual NFAMP value (10/1/2017 to 9/30/2018)
   - 3Q Calendar Year 2017 (NFAMP OLD) value (7/1/2017 to 9/30/2017), if applicable
   - 3Q Calendar Year 2018 (NFAMP NEW) value (7/1/2018 to 9/30/2018), 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

Dear PBM:

Company Name + FSS contract number [insert full or pending contract number here], believes the item(s) listed below should have been included in this year's workbook for the following reason(s):

<table>
<thead>
<tr>
<th>NDC11</th>
<th>Date of Market Entry</th>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Annual NFAMP Value</th>
<th>3Q NFAMP OLD Value</th>
<th>3Q NFAMP NEW Value</th>
<th>42-2A NDC Change (Y/N)?</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>0001122223</td>
<td>3/18/2017</td>
<td>DRUG BRAND CREAM</td>
<td>GENERIC CREAM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1111122223</td>
<td>3/28/2017</td>
<td>DRUG BRAND BOTTLE</td>
<td>GENERIC BOTTLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Subject heading should include the Manufacturer's name, full contract number and the words “Dispute Notification”

10. The original Excel workbook received should be returned via e-mail to AMMHIN.PL102585@va.gov.

11. Attach copies of modifications or contract award documents to support manufacturer’s FSS price dispute.

12. PBM, FSS and OIG will work to resolve issues. Similar to the 2017 reporting year and to reduce e-mail traffic, a corrected workbook will not be re-issued. Omitted item(s) will be included in the final FCP report to the company.

13. PBM will only process the data after all disputes have been resolved. All corrected information will be included in the final 2019 FCP calculation workbook.

14. Unresolved item(s) will be tagged for follow-up in the 1Q 2019 CY, on a case by case basis.
C. COMPLIANCE REMINDERS

**Rounding** - Annual NFAMP data includes sales from 10/1/2017 to 09/30/2018 (“nfamp” column “R” in Excel workbook) and 3Q NFAMP NEW data includes sales from 7/1/2018 to 9/30/2018 (“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.

*Rounding Examples:*
- value of 2.1462 rounds to 2.15
- value of 2.1449 rounds to 2.14

**Discontinuations** - Covered drug items that are contained in the annual workbook received from PBM but have a pending FSS discontinuation modification should still have a 2018 annual NFAMP report filed to calculate a 2019 FCP; there is no need for a price-changing FSS Request for Modification (RFM) for 2019, if the stock of the discontinued drug at wholesalers is exhausted by about Dec. 1, 2018. (In such a case, a proper deletion FSS RFM would be filed before Jan. 1, 2018.) However, if sales of wholesaler stock will continue into 2019, the company must follow all the usual steps to have statutory pricing in place for 2019.

**Flu Vaccines** - The VA has established specific guidelines for reporting the provisional and permanent FCP data for influenza vaccines and are excluded from the workbook. However, companies are expected to comply with the reporting requirements as outlined in the March 31, 2014 DML.

**Eligibility** - Annual NFAMP data will not be required to be reported for a new covered drug that was introduced into the commercial market after 4/1/2018, and has not experienced at least one full calendar quarter of sales by September 30th, 2018. In addition, the item will not appear in the annual workbook for FCP calculations. (NDC changes are the exception to this rule).

**Permanent FCP establishment** - All new covered drugs that reach Permanent FCP stage after September 30, 2018 (that is, any product with a date of market entry after 4/1/2018) must be reported under separate e-mail from the 2018 annual report. These permanent FCPs will remain in effect for the 2018 calendar year and through the 2019 calendar year until the next annual filing due in November of 2019.


**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 omitted items (page 11). The new NDC(s) will be included in the final 2019 FCP workbook.

**Excel workbook** – Several of the cells in PBM’s Excel workbooks 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 further guidance to manufacturers on how to treat sales which become the basis for TRICARE Retail Pharmacy Program (TRRx) rebates (page 8). Additional guidance can be found at: [https://health.mil/About-MHS/Defense-Health-Agency/Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers/Contact-the-TRICARE-Retail-Refund-Team](https://health.mil/About-MHS/Defense-Health-Agency/Operations/Pharmacy-Division/Information-for-Pharmaceutical-Manufacturers/Contact-the-TRICARE-Retail-Refund-Team).

**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. The newly awarded contract number will be used for the final 2019 FCP workbook.
D. 2019 FCP DISPUTE PROCESS

Instructions: How to Submit a Dispute of the 2019 calculated FCPs for annual reporting year 2018

Purpose: Company is to use this format to dispute or resubmit data for 2019 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 F rather than an FCP Dispute e-mail.

1. In the report, identify all covered items where the 2019 FCP is being disputed due to a database error.

2. In the body of the e-mail, provide the values for the following fields:
   - NDC_11 and TRADE_NAME
   - Calculated FCP and Revised FCP
   - Revised 2018 NFAMP value (10/1/2017 to 9/30/2018)
   - Revised 3Q Calendar Year 2018 NFAMP value (7/1/2018 to 9/30/2018)
   - Reason for dispute

3. Include all documentation that would support the dispute or resubmission, as necessary.

4. Subject heading should include the full contract number and title “Dispute FCP Report”

   NOTE: Resubmissions are limited to disputes resulting from database errors only and reports should be submitted via e-mail to nonfamp@va.gov.

Example:

```
To whom it may concern:

FSS contract VY97-X-XXXX is disputing the 2019 calculated FCP data for the following NDCs:

<table>
<thead>
<tr>
<th>NDC_11</th>
<th>TRADE_NAME</th>
<th>Calculated FCP</th>
<th>Revised FCP</th>
<th>Revised ANNUAL NFAMP</th>
<th>Revised 3Q NEW NFAMP</th>
<th>Reason for Dispute</th>
</tr>
</thead>
<tbody>
<tr>
<td>1111122233</td>
<td>DRUG BRAND NAME</td>
<td>82.79</td>
<td>85.92</td>
<td>75.8</td>
<td>N/A</td>
<td>Data entry error for ANNUAL NFAMP</td>
</tr>
<tr>
<td>00131234567</td>
<td>DRUG BRAND BOTTLE</td>
<td>24.98</td>
<td>18.32</td>
<td>16.51</td>
<td>18.2</td>
<td>Data entry error for 3Q NEW NFAMP</td>
</tr>
</tbody>
</table>

The attached document(s) support the disputed calculated FCPs.

Sincerely,

Pharmaceutical Vendor

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

- Revised 3Q 2017 value(s) approved, but not used for the 2019 FCP calculations
- Revised Sep 30 FSS price was approved, but not used for the 2019 FCP calculations
- Omitted item(s) had incorrect 3Q 2017 value applied for the 2019 FCP calculations

Scrivener’s errors during entry (e.g., 3Q values were entered into the annual fields)

NOTE: Due to the time constraints and review processes involved, 2019 calculated FCPs unrelated to database errors may be delayed.
E. SELF-DISCLOSURE

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 [insert e-mail AMMHIN.PL102585@va.gov ].
4. Subject should include the manufacturer’s name, full FSS contract number, and the words: “Self Disclosure”.

Example:

<table>
<thead>
<tr>
<th>Subject:</th>
<th>V797P-XXXXX Manufacturer Name - Self-disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attached:</td>
<td>Provide all supporting documents</td>
</tr>
</tbody>
</table>

Dear OIG/OIG:

FSS contract V797P-XXXXX 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 documentation and contact phone numbers.

Sincerely,

Pharmaceutical Vendor