Reporting New Covered Drug Federal Ceiling Price subject to PL 102-585

Updated guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585

Background:

Public Law 102-585, also known as the Veteran's Healthcare Act, was established in 1992, and promulgated January 1, 1993. The statute requires all manufacturers of 'covered drugs' to enter into a Pharmaceutical Pricing Agreement (PPA) for each 'covered drug' and make them available for procurement on the Federal Supply Schedule (FSS). A covered drug as defined by the statute is any legend drug that is FDA approved under a New Drug Application (NDA) or Biological Licensing Agreement (BLA).

Overview:

Manufacturers are required to establish FCPs for new covered drugs that are introduced to the commercial marketplace. In order to establish an FCP, manufacturers are required to submit a report that contains the non-Federal Average Manufacturer's price (NFAMP) report to Pharmacy Benefits Management (PBM). The calculated FCPs will potentially experience four different phases which are described below; also provided are examples of the basic calculation methodology used to determine FCPs with Dear Manufacturer's Letter (DML) referenced.

I. Provisional FCP:

- Introductory stage prior to accumulating 30 days of sales (DML 10/19/2004)
- Predicated upon a statutory discount off of the wholesale acquisition cost (WAC) price at time of market launch
- Covered drugs do not have to establish FCPs at this phase nor be added to FSS contracts

Basic calculation: ***PROV FCP calculation = WAC price (less discounts) less 24%***

II. Temporary FCP:

- Predicated upon first 30 days of commercial sales data (DML 2/1993)
- Covered drugs are required to establish FCP and be offered on FSS contract at this stage
- After the first 30 days of commercial sales, vendors are given 45 additional days to submit temporary NFAMP pricing calculation data to PBM, to establish a temporary FCP

Basic calculation: ***TEMP FCP calculation = non-FAMP less 24%***

III. Permanent FCP:

- Predicated upon the data from launch (DML 2/1993) through the first full quarter of sales (DML 10/19/2010)
- After the end of the first full calendar quarter of sales, vendors must submit permanent NFAMP pricing calculation data to PBM and establish a permanent FCP
- If the permanent FCP is lower than the then-current FSS price, then the price must be reduced accordingly

Basic calculation: ***PERM FCP calculation = non-FAMP less 24%***

IV. New Package Size (NPS):

- New Package Size FCPs are derived from an existing covered drug FCP(DML 10/19/2010)
- The initial FCP of a new package size of an existing covered drug is to be based on the FCP for the nearest package size among the existing FSS contract package sizes of the same covered drug

Basic calculation: ***NPS FCP calculation***

1. ***Calculate existing covered drug FCP per unit (tablet,gram,ml,etc.)***
2. ***Multiply the price per unit (from #1) by the number of units in the new covered drug package size***

V. Flu Vaccines:

- Flu Vaccines are considered new products every year (DML 3/31/2004)
- No Temporary FCP report is required
- Because flu vaccine is a seasonal product, no FSS tracking customer needs to be established

PBM Compliance Reminders:

- Public Law related documents available here: http://www.va.gov/oal/business/fss/publicLaw.asp
- Submit completed templates via e-mail to nonfamp@va.gov
- Reports are processed within 5 business days, based on workload

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New Product non-FAMP template Data Definitions for Public Law 102-585

Column	Field Name	Definition	Notes
A	Preparation date	Date the report is prepared by manufacturer; format = "mm/dd/yyyy"	
B	Ndc_1	FDA Assigned Labeler Code	5 digits
C	Ndc_2	Product code	4 digits
D	Ndc_3	Package code	2 digits
E	Unt_pkg	Number of units per package per NDC; Examples: -bottle of 1000 tablets/capsules would be "1000" -liquid bottles of 473ml would be "473" -ointments/creams/lotions of (30gm or 30ml) would be "30" -Aerosol containers of 17.5gm would be "17.5" -injectables, vials, patches, IV bags would be the number of each per package -birth control would be the number of cycles (6x28 or 3x91) *exceptions: blood products; preference is to report FCP per unit	report the units per package in a like manner of wholesaler sales; **Ask**: would the wholesaler break up the packaging when selling?
F	Date_enter	Date the NDC was reported as first commercially available for sale	
G	Dose_form	Dosage form of the NDC	Examples: Cap,Sol,Vial,etc.
H	Strength	NDC strength	Examples: 250mg, 5mg/5ml
I	FDA_name	Product name listed on FDA application	
J	Trade_name	Brand/Trade name proprietary to manufacturer	
K	Generic_name	Generic name	
L	New Product non-FAMP	Non-FAMP is the weighted average manufacturers' sales price for the NDC. As described by paragraphs I., J., N., O., and II.B.5.of the Master Agreement, nonFAMP is total non-Federal dollar sales for the specified time frame (sales through 30 days if TEMPORARY; sales through first full quarter if PERMANENT) 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 2nd decimal is >=5. NOTE: See notes for Provisional status.	*PROVISIONAL FCP will be determined with statutory discount off of WAC
M	FCP	New product Federal Ceiling Price; calculated as the product of the nonFAMP and 0.76 (as defined in the statute). This number is expressed in dollars and cents. **Calculation is rounded to two decimal places**; rounding up if 2nd decimal is >=5.	
N	Status	Status of calculated FCP; selections include PROV (Provisonal), TEMP (Temporary), PERM (Permanent) or *NPS (New Package Size)	*please submit the NPS FCP report to PBM
O	Cnt_no	FSS contract number assigned by the National Acquisition Center (NAC) as of 9/30/2012	V797P-xxxxx format
P	Vendor	Name of drug manufacturer submitting data	
Q	Company_of	Name of the manufacturer's official authorizing and certifying that the data provided in this workbook is correct	
R	nonTAA	non-Trade Agreements Act indicator; mark "Y" if product is not compliant with the Trade Agreements Act; if compliant, please leave blank	

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PBM PERMANENT FCP Recalculation Guidance Sheet

IF DRUG IS LAUNCHED:	Between date range:	Use Sales from launch through	Then PERM FCP is due:
1 Calendar Quarter	**1/1/20XX	3/31/20XX	5/15/20XX
1 Calendar Quarter	1/2/20xx- 3/31/20XX	6/30/20XX	8/15/20XX
2 Calendar Quarter	**4/1/20XX	6/30/20XX	8/15/20XX
2 Calendar Quarter	4/2/20xx – 6/30/20XX	9/30/20xx	11/15/20XX
3 Calendar Quarter	**7/1/20XX	9/30/20XX	11/15/20XX
3 Calendar Quarter	7/2/20xx – 9/30/20XX	12/31/20XX	2/15/20XX
4 Calendar Quarter	**10/1/20XX	12/31/20XX	2/15/20XX
4 Calendar Quarter	10/2/20xx – 12/31/20XX	3/31/20XX	5/15/20XX

**Drug launches that occur on the first day of the quarter, will utilize only that quarter's sales.