VHCA § 603

Calculating the Non-Federal Average Manufacturer Price (Non-FAMP) and the Federal Ceiling Price (FCP)

ACI’s “Big Four” Rx Pricing Boot Camp
May 19-20, 2014
Panelists

- Marci Anderson (VA OIG)
- Joy Sturm (Hogan Lovells)
Agenda

• The Basics
  ◦ Calculating the FCP
  ◦ Calculating the Non-FAMP

• Special Calculation Considerations and Current Issues

• Transferred and New Drugs

• Non-FAMP Diligence Considerations
Calculating the FCP
The FCP

- Calculated Annually
- In place for full calendar year
- Understanding the CPI-U-based additional discount and how it will affect the FCP is key
The additional discount for price increases in excess of the CPI-U

- New non-FAMP minus Old non-FAMP = change in non-FAMP (A) (*Hint*: If negative can’t compute an additional discount).

- Allowable change is Old non-FAMP times the change in CPI-U (B) (*Hint*: If no Old non-FAMP or negative Old non-FAMP can’t compute an additional discount).

- A – B equals the additional discount.
The additional discount for price increases in excess of the CPI-U

- The function of the additional discount makes projecting effects of calculation errors almost impossible. If any error affects the pivotal third quarter that would appear to cause a clear increase or decrease in the resultant FCP -- think again.
The additional discount for price increases in excess of the CPI-U

- As an example, failure to remove Government sales would arguably cause the FCP to increase except if those transactions are masking a market price increase that will trigger an additional discount.
The additional discount for price increases in excess of the CPI-U

**FCP Calculation**

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Non-FAMP</td>
<td>$ 72.63</td>
</tr>
<tr>
<td>x FCP % (76%)</td>
<td>55.20</td>
</tr>
<tr>
<td>less: Additional Discount</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>FCP Maximum</strong></td>
<td><strong>$ 54.66</strong></td>
</tr>
</tbody>
</table>

**Additional Discount**

If the increase between the benchmark 3rd quarter Non-FAMPs ("New Non-FAMP" vs. "Old Non-FAMP") is greater than the inflation adjusted Old Non-FAMP, an additional discount must be provided to the VA. In this example the CPI-U is 2.65 percent.

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Non-FAMP (3rd Quarter)</td>
<td>$ 76.50</td>
</tr>
<tr>
<td>Less: Old Non-FAMP (3rd Quarter)</td>
<td>74.00</td>
</tr>
<tr>
<td><strong>Difference</strong></td>
<td><strong>$ 2.50</strong></td>
</tr>
<tr>
<td>Old Non-FAMP x CPI-U</td>
<td>1.96</td>
</tr>
<tr>
<td><strong>Additional Discount</strong></td>
<td><strong>$ 0.54</strong></td>
</tr>
</tbody>
</table>
The FCP Calculation: 1st FSS Contract Year - 2014

- First FSS Contract Year - 2014:
  - (Annual Non-FAMP * 0.76) minus "Additional Discount"
  - Additional Discount = (New Q3 – Old Q3) – (Old Q3 * CPI-U)
    - Q3 Non-FAMP for current year minus Q3 Non-FAMP for last year
    - minus
    - Q3 Non-FAMP for last year times % increase in CPI-U (Consumer Price Index – Urban)
  - This is called the “**FCP calculated ceiling**”
  - “Dual calculation” is not performed
The FCP Calculation: 2d & Subsequent FSS Contract Yrs

- **Second & Subsequent FSS Contract Years:**
  - Lesser of:
    - The “FCP calculated ceiling,” and
    - Last year’s FSS “contract price” (price in effect on September 30, w/o the IFF) increased by the % allowable increase in CPI-U – known as the “**FSS Max Cap**”
“Exception” for Non-TAA Compliant Drugs

- For drugs that are not listed on an FSS contract because they are not TAA compliant, company must still report a non-FAMP, but they are not subject to the “FSS Max Cap”
- If such drugs are subsequently sourced in a compliant country, they must be added to the FSS within 30 days and the dual FCP calculation will then apply
- Oct. 16, 2013 DML
Calculating the Non-FAMP
Non-FAMP Defined

- [Non-FAMP] shall have the meaning set forth in Section 8126(h)(5), and shall exclude
  - (i) sales to the wholesaler for which the manufacturer processes a chargeback based on a sale to the Government; and
  - (ii) purchases (and associated chargebacks) by PHS “covered entities” (grantees, disproportionate share hospitals, etc.) [under certain conditions]
Fundamentals

- Non-FAMP is the weighted average price of a single package unit (NDC-11) of a covered drug to wholesalers.
- Takes into account all wholesaler price concessions and commercial chargebacks, but does not take into account federal government or nominal sales.
- Domestic sales only
- Innovator products only
Fundamentals

- 5 Non-FAMPs are calculated and reported for each NDC-11:
  - four quarterlies (due 45 days after the close of each calendar quarter) and
  - one annual (due on November 15)
- The annual is calculated using data from 4QY1 to 3QY2
- The Non-FAMPs used in the FCP calculation are the 3Q Non-FAMP and the annual Non-FAMP
Fundamentals

- Non-FAMP is a weighted average based on sales made to and price concessions effectuated through “merchant middlemen.” Therefore, direct sales made to and price concessions paid directly to non-wholesalers are (usually) not considered in the calculation.
The Definition of a Wholesaler

- A merchant middleman, including a prime vendor or similar distribution entity, who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale or business use.
The Non-Wholesaler Method

- Exception to the wholesaler sales only rule (as previously noted):
  - where 90% or more of total unit sales are to non-wholesalers, sales to non-wholesaler purchasers become the basis for the Non-FAMP calculation; any small number of wholesaler sales that may exist are NOT included in calculation.
The Non-Wholesaler Method

- For a manufacturer that flirts with the 90 percent benchmark the election should be made during the annual filing based on the annual period. If the annual calculation differs from the previous year, the old non-FAMP period will have to be recalculated for consistency.
Non-FAMP Ineligible Sales

- Exclusions from wholesale sales and units include:
  - Sales to the Federal Government, including Tricare.
  - Sales to PHS covered entities at the 340B statutory ceiling price, or through the PHS prime vendor at a price lower than the statutory price (a “PHS sub ceiling price”).
  - PHS inpatient sales where PHS pricing is extended generally to all covered entities under “hold harmless” arrangement. DML 7/8/04
Non-FAMP Eligible Reductions

- Wholesale sales dollars are reduced by prompt payment discount extended to wholesalers.
  - Policy rate or actual rate
  - Apply prior to or subsequent to removing Government sales
Non-FAMP Eligible Reductions

- Wholesale sales dollars are reduced by chargebacks associated with wholesaler sales to “contracted” commercial customers such as:
  - retail pharmacies
  - hospitals
  - Mail order
  - GPOs
Non-FAMP Eligible Reductions

- Wholesale sales dollars are also reduced by chargebacks and price concessions to the wholesalers from sales associated with:
  - SPAPs (if chargeback-based program)
  - Domestic wholesaler sales to entities located outside of the U.S.
    - U.S. territories are considered part of the U.S. if they are treated as domestic in the manufacturer’s financial accounting system.
Non-FAMP Eligible Reductions

- Wholesale sales dollars are further reduced by:
  - Rebates and other incentives *paid to wholesalers* resulting in a reduced price.
  - Note: rebates or other price concessions paid directly to indirect customers are not included in wholesaler sales-based Non-FAMP.
Rebates, Grants, Admin Fees, and Other Potential Adjustments to Price

- Concessions granted the wholesaler that affect the price paid should be considered in the calculation; but there is an exception for wholesaler “fees.”
- Payments not directly associated at a transactional level can be allocated to NDCs; must be consistent/apply a reasonable allocation methodology
- Bona fide fee for service arrangements do not impact Non-FAMP (VA uses reasonableness test – not CMS test)
Rebates, Grants, Admin Fees, and Other Potential Adjustments to Price

- Reductions to prices may not be called “discounts”
- When looking at a payment or allowance, consider 2 key criteria:
  - Who receives it (wholesaler or end user?)
  - Is it a reduction of price or payment for service?
Rebates/Payments to Non-Wholesalers

- Wholesaler-based Non-FAMP Calculation does not require consideration of payments to non-possession takers.
- Examples:
  - MCO rebates, fees
  - GPO fees
  - PBM rebates
- Direct Calculation – need to consider approach
Wholesaler “Fees”

- Per VA 2006 DML, “Fees” paid to wholesalers may be excluded from Non-FAMP (that is, not subtracted from wholesale sales dollars) if they are:
  - defined service charges; and
  - imposed on manufacturers generally

- VA views these as wholesaler-imposed distribution fees that should be ignored for Non-FAMP purposes.
Wholesaler “Fees” Exception

• However, per 2007 VA DML, “percent-of-sales incentive fees offered to wholesalers in order to achieve the business goals of the manufacturer” may not be excluded from Non-FAMP.

• VA sees these as product pricing/promotion discounts. If some of these fees, offered by manufacturers to prime vendors and not directly tied to product promotion, were reduced to dollar amounts (e.g., $50,000 to prepare detailed end-user reports or to prevent backorders on a drug) as opposed to percent of sales invoice payments, VA might consider those fees not to be product discounts.
Wholesaler “Fees” Exception

- Note that the VA definition of excludable service fees differs from the CMS excludable *bona fide* service fees test (e.g., itemization, FMV, no pass-through)
- CMS only permits the exclusion of fees if the services for which the fee is paid are performed “on behalf of the manufacturer” (see 42 C.F.R. §447.502)
- Reconcilable with VA requirement that fees paid to “achieve the business goals of the manufacturer” are not permitted to be excluded?
Sales to 340B Covered Entities

- Sales to covered entities under PHS 340B Program/Section 602 at the statutory ceiling price have been an allowable exclusion since September 1, 1994.
Sales to 340B Covered Entities

- Based on October 19, 2001 and October 18, 2002 Dear Manufacturer letters, however, only those sub-ceiling sales at prices set in negotiations with, or listed by, the 340B prime vendor may be excluded from the Non-FAMP calculation.

- Non-Ceiling to 340B entities (lower or higher than FCP): in error or intentional commercial sale?
Chargeback Timing

- Most manufacturers reduce their wholesale sales by those chargebacks that fall within the quarter measured by the paid or processed date.
- Though permissible, if the wholesaler invoice or sales date is used, prior period adjustments may not be captured in the calculation.
- Chargebacks are deducted after application of the prompt payment discount (if any) is applied, unless the chargebacks are adjusted to account for the prompt payment discount.
Chargeback Smoothing

- Chargebacks may be “smoothed” – i.e., they can be allocated based on a % of wholesale sales to ameliorate any effect of odd wholesaler purchasing patterns that may give rise to CPI-based additional discounts.

- Chargeback smoothing methodology must be approved by VA in advance and once employed, must be applied to all NDCs and to all reporting periods.
Chargeback Smoothing

- One methodology approved by VA for use in chargeback smoothing is the “Upjohn method:”
  - Multiply the sum of eligible chargeback dollars $Q_1$ through $Q_4$ (the annual period) by the following ratio:
    - Wholesaler sales dollars in $Q_3$ over
    - Sum of wholesaler sales dollars $Q_1$ through $Q_4$
  - To get includable chargeback dollars in $Q_3$
In addition to chargebacks, manufacturers have obtained permission from VA to smooth:

- Eligible wholesaler price concessions
- Ineligible (federal) sales — including Tricare utilization
- Non-prime vendor sub-ceiling 340B sales
Further Smoothing

- Smoothing methodology requests should be sent to NAC OGC-Vanessa Calabrese. The PL group will consider the request and provide approval.
- Once approved, prospective only. In the year of change the Old Non-FAMP (Q3 of the prior calendar year) must be recalculated to follow the new methodology.
Further Smoothing

- Smoothing cannot be expected to fix every issue.
- Identify the issue and the cause. If a manufacturer feels that they have an anomaly that is causing an unjust FCP the manufacturer needs to document the case and send a request to NAC OGC-Vanessa Calabrese for the PL group to consider.
Including or Excluding Returns

- Manufacturers are permitted to “ignore” (include) returns transactions for purposes of their Non-FAMP calculations.
- If a manufacturer chooses to exclude returns transactions from its Non-FAMP, it must:
  - maintain records of the returns and the value of those returns included in the Non-FAMP calculation as realized by the customer.
  - pay close attention to system treatment of partial unit returns.
Nominal Sales

- Nominal sales (as defined by the VA) may be excluded from Non-FAMP:
  - Any price less than 10% of the most recently calculated third quarter Non-FAMP and
  - In a sale (usually below cost) designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.
Sample Calculations

- Four Wholesaler Method sample calculations follow, any one of which is legally acceptable.
- The methods differ based on when an element is subtracted from the calculation, and how certain sales or amounts are valued when they are subtracted.
Sample Calculations

- Methods 1A and 2A result in the same Non-FAMP (in this example, $93.87).
- Methods 1B and 2B result in the same Non-FAMP (in this example, $93.97).
- Where there are government sales (as in this example), the “B” methods will result in perceptibly higher Non-FAMPs than the “A” methods.
Sample Calculations

- Method IA
  - government units are valued at the net contract price for purposes of calculating total reductions from wholesale sales, and
  - prompt payment discounts are taken as a percentage of total wholesale sales.
## Sample Calculation

### Method 1A

<table>
<thead>
<tr>
<th>Description</th>
<th>Dollars</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale Sales (WAC = $100)</td>
<td>$10,000,000.00</td>
<td>100,000</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt Pay Discount (2%)</td>
<td>$200,000.00</td>
<td></td>
</tr>
<tr>
<td>Government Sales @ $72.00</td>
<td>$360,000.00</td>
<td>5,000</td>
</tr>
<tr>
<td>PHS (@ 602 price $75.00)</td>
<td>$2,250.00</td>
<td>30</td>
</tr>
<tr>
<td>Chargebacks</td>
<td>$523,075.00</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal Reductions</strong></td>
<td><strong>$1,085,325.00</strong></td>
<td></td>
</tr>
<tr>
<td>Non-Federal Dollars &amp; Units</td>
<td><strong>$8,914,675.00</strong></td>
<td>94,970</td>
</tr>
<tr>
<td>non-FAMP</td>
<td><strong>$93.87</strong></td>
<td></td>
</tr>
</tbody>
</table>
Sample Calculations

- **Method 1B**
  - government units are valued at the net contract price for purposes of calculating total reductions from wholesale sales, and
  - prompt payment discounts are taken as a percentage of Non-FAMP eligible sales only (where government units are valued at WAC for purposes of calculating the PPD).
# Sample Calculation

## Method 1B

<table>
<thead>
<tr>
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<tbody>
<tr>
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<td></td>
</tr>
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<td></td>
</tr>
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<td></td>
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<td>Non-Federal Dollars &amp; Units</td>
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<td>94,970</td>
</tr>
<tr>
<td>non-FAMP</td>
<td>$93.97</td>
<td></td>
</tr>
</tbody>
</table>
Sample Calculations

- **Method 2A**
  - government units are valued at WAC for purposes of calculating total reductions from wholesale sales,
  - government chargebacks are removed, and
  - prompt payment discounts are taken as a percentage of total wholesale sales.
## Sample Calculation
### Method 2A

<table>
<thead>
<tr>
<th></th>
<th>Dollars</th>
<th>Units</th>
</tr>
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<tbody>
<tr>
<td>Wholesale Sales (WAC = $100)</td>
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<tr>
<td>Less:</td>
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<td></td>
</tr>
<tr>
<td>Government Sales (@ WAC)</td>
<td>$500,000.00</td>
<td>5,000</td>
</tr>
<tr>
<td>PHS (@ WAC)</td>
<td>$3,000.00</td>
<td>30</td>
</tr>
<tr>
<td>Chargebacks</td>
<td>$523,075.00</td>
<td></td>
</tr>
<tr>
<td>(Less Gov and PHS Chargebacks)</td>
<td>-$140,750.00</td>
<td></td>
</tr>
<tr>
<td>Subtotal Reductions</td>
<td>$1,085,325.00</td>
<td></td>
</tr>
<tr>
<td>Non-Federal Dollars &amp; Units</td>
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<td>94,970</td>
</tr>
<tr>
<td>non-FAMP</td>
<td>$93.87</td>
<td></td>
</tr>
</tbody>
</table>
Sample Calculations

- **Method 2B**
  - government units are valued at WAC for purposes of calculating total reductions from wholesale sales,
  - government chargebacks are removed, and
  - prompt payment discounts are taken as a percentage of Non-FAMP eligible sales only (where government units are valued at WAC for purposes of calculating the PPD).
## Sample Calculation Method 2B

<table>
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<tr>
<th>Description</th>
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<th>Units</th>
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<tbody>
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<td>Wholesale Sales (WAC = $100)</td>
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<td>100,000</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government Sales (@ WAC)</td>
<td>$500,000.00</td>
<td>5,000</td>
</tr>
<tr>
<td>PHS (@ WAC)</td>
<td>$3,000.00</td>
<td>30</td>
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<tr>
<td>Prompt Pay Discount (2%)</td>
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</tr>
<tr>
<td>Chargebacks</td>
<td>$523,075.00</td>
<td></td>
</tr>
<tr>
<td>(Less Gov and PHS Chargebacks)</td>
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<tr>
<td>non-FAMP</td>
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<td></td>
</tr>
</tbody>
</table>
Sample Calculation
Non-Wholesaler NFAMP Calculation

- 90/10 Rule Turns the Calculation
  - where 90% or more by unit volume of direct sales are made to non-wholesalers, the non-wholesalers become the basis for the calculation
  - assume no direct sales to government or 340B covered entities
## Sample Calculation
### Non-Wholesaler Non-FAMP

<table>
<thead>
<tr>
<th>Description</th>
<th>Dollars</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale Sales (WAC = $100)</td>
<td>$100,000.00</td>
<td>1,000</td>
</tr>
<tr>
<td>Non-wholesale direct @ $95</td>
<td>$855,095.00</td>
<td>9,001</td>
</tr>
<tr>
<td><strong>Less non-wholesale:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prompt pay discount (2%)</td>
<td>$17,101.90</td>
<td></td>
</tr>
<tr>
<td>Rebates to direct customers</td>
<td>$85,000.00</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal Reductions</strong></td>
<td>$102,101.90</td>
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</tr>
<tr>
<td>Non-federal non-wholesale total</td>
<td>$752,993.10</td>
<td>9,001</td>
</tr>
<tr>
<td>Non-FAMP</td>
<td>$83.66</td>
<td></td>
</tr>
</tbody>
</table>
Special Calculation Considerations and Current Issues
Penny Pricing (FCPs)

• When the additional discount is more than the annual non-FAMP times .76, the FCP is 1¢ per package (NDC-11)

• Penny pricing does not carry forward to the following year (as FSS Max Cap) for single pricers (DML 2/11/1997)

• If a manufacturer feels the penny price is unjust (because commercial price increases were not applied or did not exceed the applicable CPI-U), analysis must be performed and arguments made for relief.
Penny Pricing (FCPs)

• Caused by large increases from the old non-FAMP period to the new non-FAMP period
• Common non-market increase causes are:
  • Large deeply discounted contract that expires
  • Large volume of rebates or chargebacks that are processed in the old non-FAMP period
Negatives, False Positives

- **Negative Non-FAMP**
  - If calculated non-FAMP is negative, report the negative non-FAMP

- **False Positive Non-FAMP**
  - But when units are also negative, negative dollars divided by negative units, results in a positive number, although there weren’t positive sales
  - Report zero sales and advise the VA
TRRx Treatment

- Following DoD’s TRRx Final Rule, VA instructed industry as follows:
  - Starting with 2010 FCP calculation, wholesaler sales later ID’ed as TRICARE utilization, must be treated as Federal sales and excluded from non-FAMP computations
  - 2009 FCPs need NOT be recalculated
  - Utilization must excluded as Federal sales (using a wholesaler-based valuation methodology) from the Non-FAMP for the quarter in which the rebates are due.

- October 16, 2009 DML and related FAQs.
TRRx Calculation Issues

- Determining percentage of dispensed units sold through wholesalers
  - Develop method for allocating Tricare utilization by distribution channel

- Determining value of wholesaler units removed from non-FAMP
  - Develop method for allocating wholesaler price concessions to Tricare utilization
TRRx Treatment

- TRRx utilization claims that are formally disputed by the manufacturer should not be excluded from Non-FAMP unless and until the manufacturer loses the dispute and must pay a refund.
- Companies can smooth TRICARE utilization:
  - FAQ TRRx Sales/NFAMP
TRRx Treatment

- New invoices for TRRx utilization from 2008 and 2009 with payment dates in 2012
  - Retroactive rebate invoices due in 2012 need not be excluded from 2012 non-FAMPs and prior period NFAMPs need not be corrected to reflect additional excluded government sales
  - Oct. 16, 2012 DML

- Current issues:
  - Treatment of “late billings” – TRRx utilization
  - Quarterly calculation
  - PHS 340B “double dip” disputes (Code K)
TRRx Current Issues

- Treatment of “late billings” – TRRx utilization from one, two, or more quarters prior to invoice quarter
- Quarterly calculation – not addressed in VA letter
- PHS 340B “double dips” disputes (Code K)
Authorized Generics

- All products sold under the original NDA -- including branded \textit{and} authorized generics (AGs) -- are considered VHCA covered drugs.
- Failure to offer AGs on Master Agreements/FSS contracts at FCPs is a violation of the VHCA
- Separate Non-FAMPs (and FCPs) are calculated for branded products and AGs
Biosimilars

- All biological products identified in 21 CFR 600.3 are covered drugs
  - Statute has not been amended to carve out products licensed under 351(k) of the Public Health Service Act
Contingent Price Concessions

- “Contingent price concessions in bundled arrangements (as defined in the Medicaid/Medicare context) need not be aggregated and allocated among NDC-11s in order to calculate Non-FAMP.”

- Statement by M. Noel, Office of General Counsel, Department of Veterans Affairs, 10/09 ABA Federal Drug Pricing Program.
Free Goods Treatment

- Contingent free goods (excluding bona fide drug samples allowed by 21 USC § 353) shall be counted as a unit sale with a zero value of sales dollars.
- Free goods “contingent upon any written or verbal commercial agreements” are not exempt from Non-FAMP. VA Dr. Manuf. Ltr dated 10/7/96.
Puerto Rico/U.S. Territories Wholesalers

- Sales to Puerto Rico/U.S. Territories wholesalers are not included in the Non-FAMP if those sales are not recorded as U.S. sales in the general ledger (Dear Manufacturer letter dated June 14, 1993 and annual calculation letter dated October 19, 1993).
Transferred and New Drugs and New Package Sizes
Routine NDC # Changes

- Covered drugs subject to NDC number changes (but held by one manufacturer) are treated as one product.
- Sales for the product under the two different NDCs should be combined and the same non-FAMPs should be reported for both NDCs until stock of the first one is depleted.
New Package Sizes

• Initial FCP is based on the nearest package size among existing sizes
• The price per unit of the nearest package size is multiplied by the number of units in the new package
• This FCP will be in place until the new package size has significant sales to compute its own annual Non-FAMP (sales from launch through one full quarter) DML 9/25/2012.
New Package Sizes

- October 2011 on new package sizes:
  - A manufacturer must submit a modification to add a new package size item to its FSS contract, at a calculated FCP from an existing package FCP, to coincide with the new package size item’s launch (the first day the product is available in the commercial marketplace)
  - However, any covered drug that has a calculated FCP from an existing package’s FCP will not be included on the spreadsheet for annual calculations
  - These new package size covered items will need a separate permanent report filed with PBM after achieving a full calendar quarter of sales data. After the new package item’s permanent FCP has been established on the FSS contract, it will be included in annual calculations
  - Further clarification in DML 9/25/2012
Transferred covered drugs

- Drugs transferred with exclusivity from one Manufacturer to another maintain their originally computed FCP throughout the year.
- The new manufacturer may enter a zero in the old-Non FAMP field when calculating the FCP applicable to their first full year of ownership.
## FCPs of Drugs Transferred During Multi-Year Contract

<table>
<thead>
<tr>
<th>Date of Transfer</th>
<th>FCP Calculation in Year of Transfer</th>
<th>FCP Calculation for Next Calendar Year</th>
<th>FCP Calculation for Third Year After Transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt;, 2&lt;sup&gt;nd&lt;/sup&gt;, 3&lt;sup&gt;rd&lt;/sup&gt; Quarter (2014)</td>
<td>Transferee’s sales capped at Transferor’s FCP. (for 2014)</td>
<td>Transferee’s FCP based on statutory calculation only.</td>
<td>Transferee’s 2016 FCP calculated normally (lower of FSS Max Cap or FCP)</td>
</tr>
<tr>
<td></td>
<td>Transferee calculates and submits FCP for next year (2015) in November of 2014.</td>
<td>2015 FCP does not include additional discount based on increase over CPIU.</td>
<td></td>
</tr>
<tr>
<td>4&lt;sup&gt;th&lt;/sup&gt; Quarter (2014)</td>
<td>Transferee’s sales capped at Transferor’s FCP (2014).</td>
<td>2015 Transferee’s sales capped at Transferor’s new FCP (submitted prior November). Transferee calculates and submits FCP for next year.</td>
<td>Transferee’s 2016 FCP based on statutory calculation only. FCP does not include additional discount based on increase over CPIU.</td>
</tr>
</tbody>
</table>
Transferred Covered Drugs

- Transferee must ensure that the product is listed on its FSS contract as of the date of first sale.
- When a transferee changes the labeler code for the transferred drug, both NDC-11s must remain on contract until the original NDCs stock is depleted.
- Annual Non-FAMPs are calculated by blending the sales of both NDCs.
Transferred Covered Drugs

- It is the responsibility of the acquiring manufacturer to ensure that the old manufacturers FSS price is not used in the calculation in the year following transfer (see table).

- Transferee must obtain sales data from the transferor back to the beginning of the 4th quarter prior to the transfer

- Good idea to spell out data transfer requirement in acquisition documentation
Introduction of New Drugs*

- Provisional FCP (a means of pricing a new covered drug prior to accumulating 30 days of sales in order to add voluntarily to FSS contract). DML 10/19/2004
- Temporary FCP (based on 30 days of sales). DML 2/1993
- Permanent FCP (based on sales from launch through one full quarter of sales). DML dated 10/19/2010
- Note: flu vaccines have new NDC-11s each year; therefore they require a special approach to the FCP calculation.
Introduction of New Drugs

- A manufacturer is obligated to report Non-FAMPs for new covered drugs in a **timely** manner.
- Manufacturers will be responsible for overcharges based on late filings of Temporary or First Annual/Permanent Non-FAMPs/FCPs.
Provisional FCPs

- Provisional FCPs may be placed on the FSS upon launch to permit immediate FSS purchasing
- The CO must agree to the price
- The Provisional FCP may not exceed the wholesale list price less:
  - standard discounts to wholesalers;
  - prompt pay; and
  - 24 percent statutory discount
- Note: Direct sales product Provisional FCP is based on non-wholesaler sales
Provisional FCPs

- Beginning October 1, 2001, manufacturers employing Provisional FCPs need not tender to “Big Four” ordering activities the difference between the Provisional FCP and the temporary FCP when the latter is lower than the former. DML October 2001.

- Provisional FCPs will be the contract price for all FSS users until the CO has 90 days of sales data to negotiate a price
  - Not a written rule, just general practice
Temporary FCPs

- After the first 30 days of commercial sales, a Temporary FCP is calculated as follows: \([\text{Non-FAMP for first 30 days of sales}] \times 0.76\).
- There is no additional discount applied to the Temporary FCP.
- Temporary FCP is due 45 days after the first 30 days of sales and is in place until the effective date of Permanent FCP.
Temporary FCPs

- Temporary FCPs are not used to calculate the FSS Max.
- FSS Max is 9/30 FSS contract price that is increased by allowable CPI-U adjustment that is factored into FCP calculation for 2d & subsequent years of FSS contract.
Examples: Temporary FCP Due Dates

- Drug introduced on June 1. Temporary is due 45 days after the first 30 days of sales or by August 16th.
- Drug is introduced on August 1. Temporary is due 45 days after the first 30 days of sales or by October 16th.
Permanent Non-FAMP/FCP

- To calculate the Permanent/First Annual Non-FAMP, manufacturer must use sales from date of launch through one full quarter of experience.
- This applies no matter what calendar quarter in which the launch occurs.
- Permanent FCP is then effective for the remainder of the calendar year.
Permanent FCP timing

- The chart on next page shows due date and last effective date of Permanent FCP for products launched mid-quarter.
- Note: If product is launched on first day of quarter, then refer to the dates set forth for launch during prior quarter.
## Permanent FCP timing

<table>
<thead>
<tr>
<th>2014 Product Introduction Quarter</th>
<th>Due Date for Permanent FCP</th>
<th>Last effective date of Permanent FCP</th>
<th>1st Calendar Year for which FCP Calc. is Lesser of FCP Calc. Ceiling and FSS Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>August 14, 2014</td>
<td>12/31/14</td>
<td>2015</td>
</tr>
<tr>
<td>Q2</td>
<td>November 15, 2014</td>
<td>12/31/15</td>
<td>2016</td>
</tr>
<tr>
<td>Q3</td>
<td>February 14, 2015</td>
<td>12/31/15</td>
<td>2016</td>
</tr>
<tr>
<td>Q4</td>
<td>April 14, 2015</td>
<td>12/31/15</td>
<td>2016</td>
</tr>
</tbody>
</table>
Non-FAMP Diligence Considerations
Variance Analysis

- Due diligence can go a long way to prevent headaches in the future.
  - Compare this year's annual to last year's annual and the new to the old
    - Does the variance make sense based on your market
    - What has changed to increase or decrease the non-FAMP
  - Just because the WAC does not change does not mean the market price did not change
Variance Analysis

- Pay particular attention to the new versus old analysis
  - If the new is less than the old obviously no additional discount is incurred, but...is the new artificially low?
  - Not paying attention to the variance this year could result in a heavy additional discount next year.
  - Resources will have to be used to identify a problem that likely happened more than a year ago.
Variance Analysis

- If your (now old) non-FAMP should have been higher, you will have to restate last year’s value (and subsequent FCP).
- This action could put you at risk of owing overcharges if the restatement means last year’s FCP was overstated based on the lack of additional discount calculation.
- It could also result in undercharges/lost revenue
## A Numerical Example

### Original Calculation

<table>
<thead>
<tr>
<th>Annual</th>
<th>Old</th>
<th>New</th>
<th>Add'l Discount</th>
<th>FCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>$500.00</td>
<td>$495.00</td>
<td>$350.00</td>
<td>$0.00</td>
<td>$380.00</td>
</tr>
<tr>
<td>$505.00</td>
<td>$350.00</td>
<td>$502.00</td>
<td>$152.00</td>
<td>$234.00</td>
</tr>
</tbody>
</table>

### Corrected Calculation

<table>
<thead>
<tr>
<th>Annual</th>
<th>Old</th>
<th>New</th>
<th>Add'l Discount</th>
<th>FCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>$500.00</td>
<td>$495.00</td>
<td>$502.00</td>
<td>$7.00</td>
<td>$373.00</td>
</tr>
<tr>
<td>$505.00</td>
<td>$502.00</td>
<td>$510.00</td>
<td>$8.00</td>
<td>$376.00</td>
</tr>
</tbody>
</table>
Disclaimers to Number Example

- The CPI-U is assumed to be zero (for ease of example)
- Assume a dual pricer with the FCP Max being the lower of the two calculations
Theoretical Timeline

- Year 2 incorrect calculations are submitted and put into effect on January 1.
- In April, company identifies that Government revenue is decreasing significantly as compared with previous year.
- In June, once issue is figured out, company submits a request to correct Q3 Non-FAMP.
- Your corrected FCPs are effective September 1 after Government purchases 6,700 units.
Financial Impact

- **Y1** overcharges in the amount of $70,000 ($380-373)*10,000.
- **Y2** undercharges unrecoverable in the amount of $951,400 ($376-$234)*6,700
- **Y1** adjusted revenue $3.73 million, total **Y2** revenue $2.81 million for a total of $6.54 million
- Had the FCPs been correct the two year revenue would have been $7.49 million
Questions?

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Joy Sturm: joy.sturm@hoganlovells.com

ACI’s “Big Four” Rx Pricing Boot Camp
May 19-20, 2014