



DEPARTMENT OF VETERANS AFFAIRS  
Drug & Pharmaceutical Product Management Section  
VACO Pharmacy Service  
PO Box 126  
Hines, IL 60141

RECEIVED  
10/20/93

FCPs effective 1/94

October 19, 1993

In Reply Refer To: 578/119D

Dear Manufacturer:

The following information is provided to assist your company in reporting the data mandated by Section 603 of Public Law 102-585 (Veterans Health Care Act of 1992). Annual non-Federal Average Manufacturers Price (non-FAMP) calculations with 1994 Federal Ceiling Prices (FCP) for covered drugs are due to be reported to Chief, Drugs & Pharmaceutical Products Management (D&PPM) on or before November 15, 1993.

Each covered drugs's mandated FCP for 1994 (the second year of FSS multiyear contracts) will be determined by adopting the lower of two calculations' results. These two calculations are described in <sup>(1)</sup> 38 U.S.C. 8126 (d) (1) and <sup>(2)</sup> 38 U.S.C. 8126 (d) (2) & (a) (2). The same percent change in Consumer Price Index - Urban (CPIU) will be utilized in performing both calculations. This change in CPIU is identified as the percent change from September 1992 to September 1993 which is 2.69 percent.

The Section 8126 (d) (1) calculation will begin with the Federal Supply Schedule (FSS) price of a covered drug in effect on September 30, 1993, for manufacturers that elected a single FSS pricing schedule. For those manufacturers that elected dual FSS pricing, the Section 8126 (d) (1) calculation will begin with the first FSS price in effect after dual price election negotiations are completed, but no later than October 30, 1993. The appropriate FSS price will then be increased by the above percent change in CPIU to arrive at the 1994 FSS price cap. (This cap applies to all "other user" FSS prices in 1994.)

The Section 8126 (d) (2) & (a) (2) calculation will begin with the 1993 non-FAMP computation; it will continue by multiplying that number by .76 and then subtracting out any additional discount calculated based on a difference between "old" and "new" non-FAMPs. (This calculation involves the same steps as were performed in December 1992 to arrive at the 1993 FCPs.) The lower of the above two calculated numbers will become the 1994 FCP.

Nominal prices for exclusion from non-FAMPs for 1994 calculations are identified as prices that do not exceed 10 percent of that particular item's non-FAMP during the third quarter of 1992 (7/1/92 through 9/30/92).

After reviewing the effect of U.S. island territories' covered drug sales on non-FAMP calculations, the Department of Veterans Affairs (VA) has determined that the impact

of including them was negligible. It has been determined that the inclusion or exclusion of U.S. island territories' sales will be left to the discretion of the manufacturer and their customary accounting practices (i.e., if these sales are normally included by the manufacturer in U.S. sales data, they should be included in the non-FAMP calculations). However, wholesalers in Puerto Rico may not be used to artificially lessen the impact of FCP. Auditing will be conducted to assure that this does not occur.

All correspondence related to non-FAMP calculations, FCP calculations, quarterly non-FAMP reports, annual FCP reports, FCP reports for new products, FCP recalculations for new products, corrections to quarterly non-FAMP reports and correction to annual FCP reports should be forwarded to:

Albert A. Patterson, R.Ph.  
Chief, Drugs & Pharmaceutical Products (119D)  
Building 1 Room A148  
5th Ave. and Roosevelt Road  
Hines, Illinois 60141

or

P.O. Box 126  
Hines, Illinois 60141

The quarterly non-FAMP report for the third quarter of 1993 would consist of the same data as the "new non-FAMP" (7/1/93-9/30/93) reported on the annual calculation form for 1994 FCPs which is due November 15, 1993. Consequently, it will not be necessary to submit the Non-FAMP Third Quarter 1993 Report separately. However, manufacturers that do not meet the November 15, 1993 annual reporting deadline will be subject to penalties as described in the Master Agreement for late data reporting.


Section 8126 (e) of the Law states that quarterly non-FAMP reports are due 30 days after the end of the quarter. These figures should be as accurate as possible, since they serve as an indicator of pricing trends and will be used during Inspector General (IG) audits. Nevertheless, to assist manufacturers in providing the most accurate quarterly non-FAMP calculations possible, the Drug & Pharmaceutical Product Management Section (D&PPM) will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. Again, please note that each year the non-FAMP third quarter data may be submitted as part of the Annual Report (which is due 45 days after the end of the third quarter).

Pursuant to Section 8126 (i) of the Law, "the first year for which the contract is in effect" for new drugs means whatever portion of 1993 that a new covered item was on a Government contract or schedule. The "next contract year" will begin on January 1, 1994. The "first year" for any new product introduced during the year will be that

portion of the year from the time of introduction through December 31 of the same year. This is also true of new FSS contracts first negotiated during 1993. The second year for these contracts begins on January 1, 1994, and their annual report of data and new Pharmaceutical Pricing Agreement (PPA) addendum are due on the same schedule as all pre-1993 FSS contracts. If there are "no sales" in a benchmark third quarter of a year that is used to derive the new non-FAMP or old non-FAMP, there can be no additional discount calculation for that particular item. In those cases, the additional discount will be entered as zero (0).

After your company reports its 1993 data in the format illustrated on the enclosed sheets, the authorized official who signed your company's PPA in 1992 (or an authorized successor) must draw up and sign a new addendum to the PPA, listing each covered drug and its 1994 FCP. This addendum must then be forwarded before January 1, 1994 to the VA National Acquisition Center (90N-E), P.O. Box 76, Hines, Illinois 60141. Once these steps have been completed, VA National Acquisition Center contracting officers will work with your company's representative to make any FSS modifications and price list adjustments necessitated by the new FCPs.

Sincerely,

  
Albert A. Patterson, R.Ph.  
Chief, Drug Products Management  
VACO Pharmacy

Enclosures: 4

Instructions for 1994 Data Sheets Completion  
Data Sheet  
FCP Calculations for New Drugs  
Public Health Service Memo