Department of Veterans Affairs

Memorandum

Date: May 8, 1998

From: Office of General Counsel (025NAC)

Subj: Calculating FCPs for Flu Vaccines

To: Assistant General Counsel (025)
P.L. 102-585 Policy Group

1. Influenza vaccines produced by a handful of manufacturers are covered biologicals under 38 U.S.C 8126(h)(2)(C). As such, they must have non-Federal Average Manufacturer Prices (non-FAMP) and Federal ceiling prices (FCP) calculated for them annually and reported to the Department of Veterans Affairs' (VA) Pharmacy Benefits Management (PBM) at Hines, Illinois. However, flu vaccines are unlike pharmaceuticals and other biological products in that their formulation must change each year in order to be effective against the strains of influenza that are expected to be prevalent in the coming flu season. Consequently, the NDC numbers of flu vaccines change each year, and the costs of production and commercial wholesale prices are not known until the required vaccine strains are produced. Additionally, flu vaccines have relatively short product lives and are marketed for only about seven months each year, i.e., July through January of the following year.

2. Because of the unique production and marketing attributes of flu vaccines described above, it is not feasible to calculate non-FAMPs and FCPs for them in the standard fashion prescribed by the Statute for pharmaceuticals and other biological products. In many ways, each year's new flu vaccine is a new product that never accumulates 12 months of wholesales sales data and cannot be compared with the previous year's product for purposes of calculating an additional discount.

3. For the above reasons, the VA policy group responsible for administering the Veterans Health Care Act of 1992, Section 603 (38 U.S.C. 8126) has decided that flu vaccines should have their non-FAMPs and FCPs calculated according

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to a modified version of the "new drug policy" issued on September 23, 1993. Using that guideline, flu vaccine manufacturers will report a "temporary" non-FAMP and FCP to PBM for the vaccines as they come to market during the summer, starting with the first 30 days of wholesale sales or backorders to determine the per unit non-FAMP and then multiplying by .76 to obtain the FCP. After a full calendar quarter of vaccine sales, the manufacturers will recalculate the non-FAMPs and FCPs using all the wholesale sales data (or direct sales data, if no wholesale sales were involved), from the date that the vaccine came on the market through the end of the full calendar quarter. The practical effect of this procedure will be that almost all flu vaccine sales to Public Law beneficiaries will be made at a temporary FCP because they will occur prior to the final calculation. This approach should allow the Government to take the benefit of the statutory 24 percent discount, while at the same time having a simple, easily administered way of calculating and reporting flu vaccine FCPs.

Sincerely yours,

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cc: Director Contract Review & Evaluation (53C)
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