

October 18, 2002

Dear Manufacturer of Covered Drugs:

Due to a recent inquiry by a pharmaceutical manufacturer, the HHS Office of Pharmacy Affairs has requested that we clarify interpretation of the October 19, 2001, "Dear Manufacturer letter" from the Department of Veterans Affairs (VA) that exempts certain Sec. 340B (Section 602 of the Veterans Healthcare Act of 1992) covered drug sales from non-FAMP calculations. Pertinent language from our 2001 letter states:

"...all sales of covered products to Section 602 covered entities at prices negotiated by the Section 602 PPV can be excluded from a manufacturer's non-FAMP calculations, even when those prices are below the Section 602 statutorily calculated price....beginning... November 15, 2001."

The drug manufacturer that requested clarification stated that it had been approached by a representative of an organization other than the HRSA Sec. 602/340B Prime Vendor, who represented his organization as "a PHS Prime Vendor" whose purchases were eligible for VA's non-FAMP exclusion on drugs sold to 340B covered entities. The representative then asked the drug company to sell 340B covered drugs at sub-340B-ceiling prices.

To dispel any misunderstanding, I wish to confirm that the only sub-340B-ceiling wholesale covered drug sales that can be excluded from a manufacturer's non-FAMP calculations are those negotiated with or listed by the single HRSA Prime Vendor, currently AmerisourceBergen. All other sub-340B ceiling priced wholesale sales must be included in the manufacturer's non-FAMP calculations.

Should you have any questions about this issue please do not hesitate to contact the undersigned at (708) 786-5167.

Sincerely yours,

Melbourne A. Noel, Jr.