DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
Hines IL 60141

July 8, 2004

Dear Manufacturer of Covered Drugs:

This letter states the policy of the Department of Veterans Affairs (VA) regarding certain situations in which sales of inpatient covered drugs to disproportionate share hospitals (DSHs) participating in the Public Health Service 340B drug discount program may be excluded from your non-Federal Average Manufacturer Price (non-FAMP) calculations for those covered drugs. As you are probably aware, Section 1002 of the Medicare Modernization Act (MMA; P.L. 108-173), amended the Medicaid statute by adding the prices charged to 340B DSHs for inpatient drugs to the list of transactions excluded from Medicaid's "best price" reporting. However, this amendment did not refer to or directly impact the Veterans Health Care Act of 1992, P.L. 102-585, Section 603 (38 U.S.C. 8126), which requires manufacturers to report covered drug non-FAMPs to VA and accept price limits referred to as Federal Ceiling Prices (FCP). Since the enactment of MMA, VA has received many inquiries from covered drug manufacturers and the Public Hospital Pharmacy Coalition (PHPC) asking whether, as a result of Section 1002 of the MMA, VA would agree to allow manufacturers to exclude from their non-FAMP reporting all sales of inpatient covered drugs to the DSHs identified in Section 602 of P.L. 102-585 (Section 340B of the Public Health Service Act).

A similar request was addressed to VA in writing by the PHPC during June of 1998. That request was considered by the VA Federal Ceiling Price Nominal Increase Board and the VA Public Law 102-585 Policy Group during the fall of 1998. Subsequently, Assistant General Counsel Phillipa Anderson responded to the PHPC in a December 4, 1998, letter. This letter stated that, pursuant to decisions of the Board and Policy Group, VA was willing to view manufacturers' voluntary application of Section 602 (340B) computed pricing to DSH inpatient drug purchases as an extension of the statutory outpatient drug pricing that is already exempt from non-FAMP calculations. The letter went on to state, in relevant part: "The exemption is limited to sales to DSHs … and limited to those sales that are made at a 602 calculated price. Cooperating manufacturers will not be permitted to exclude from non-FAMP their sales to covered entities at low prices determined by competition in the market place rather than by Federal statute." The letter also revealed that the Executive Director of the VA National Acquisition Center concurred with the proposal that sales of inpatient covered drugs at Section 602 (340B) prices to covered entities not be used by contracting officers in determining most favored customer pricing in FSS negotiations with

cooperating drug manufacturers or in drawing conclusions concerning operation of the FSS price reduction clause. The 1998 letter concluded by stating that, after PHPC proposals for inpatient 340B pricing were accepted by a covered drug manufacturer, VA would furnish the cooperating manufacturer with a "hold harmless" letter reflecting the VA exclusion decisions.

The December 1998 letter continues to be a valid statement of VA's position regarding the exclusion of inpatient covered drug sales to DSHs from non-FAMPs. By way of fleshing out the details of the potential exclusions and the "hold harmless" letters which will authorize such exclusions, the following additional explanation of VA's policy is provided:

1. In order to qualify for the exclusion described in the 1998 letter, a covered drug manufacturer must first commit to providing all Section 602/340B DSHs with inpatient covered drugs at 602/340B calculated prices.

2. The covered drug manufacturer must offer DSHs 602/340B calculated pricing on either all of its commercially marketed inpatient covered drugs or specified covered drug product lines, but, in the latter case, the pricing must be offered on all commercially marketed NDC packages of the specified product lines.

3. The covered drug manufacturer must commit to the above pricing in a written statement to VA and the Pharmacy Affairs Branch of HRSA. If the manufacturer later decides to revoke its written commitment or to add or subtract product lines, it must inform VA and HRSA in writing within 14 days of the revocation or the change to DSH inpatient drug pricing policy.

4. The covered drug manufacturer must apply in writing to VA for a "hold harmless" letter based upon the above written commitment. "Hold harmless" letters will automatically expire if a manufacturer revokes or reneges on its commitment.

A template letter suggested by the Public Hospital Pharmacy Coalition for manufacturers to use to announce their decisions to make 340B prices available to DSHs for inpatient covered drugs and to simultaneously request "hold harmless" letters from VA is attached hereto for your convenience. However, manufacturers may use any form of letter which provides the same information. VA will consider that manufacturers that submit requests for "hold harmless" letters, by doing so, consent to publication of their 340B pricing commitment on HRSA's informational website. (Disclosure of discounted prices is not required.)

Dear Manufacturer of Covered Drugs

It must be understood that VA will not issue “hold harmless” letters to manufacturers who pick and choose which DSHs will receive the benefit of 340B pricing on inpatient drugs. In order to qualify for a VA exemption from non-FAMP, a manufacturer’s commitment must apply to all 340B DSHs. It should also be understood that VA considers that it has no authority to exclude from non-FAMP any discounted inpatient covered drugs sales to DSHs that are made at prices which were not determined according to the methodology required by Section 602 (340B) of P.L. 102-585. With regard to processing requests for “hold harmless” letters, manufacturers should allow 21 days from the day on which VA receives a request for the issuance of the exemption letter. Until an exemption letter is issued, a manufacturer is not authorized to exclude sales of inpatient drugs to DSHs from any non-FAMP calculations.

Information concerning exclusion from non-FAMP of sales through the 340B prime vendor to 340B covered entities can be found in VA’s “Dear Manufacturer” letters dated October 19, 2001, and October 18, 2002. (Currently, HRSA’s 340B prime vendor is not authorized to handle inpatient covered drugs for covered entities.)

If you have any questions concerning the above policies, please telephone the undersigned at (708) 786-5167.

Sincerely,

Melbourne A. Noel, Jr.
Senior Contract Attorney
Office of General Counsel