July 17, 2000

[Name and Address redacted]

Re: "Up-front Rebates," "Prebates," and "Signing Bonus" Payments

Dear [Name redacted]:

We are writing in response to your letter requesting clarification regarding the legality of up-front and percentage payments in connection with medical supply contracts. Specifically, you have asked whether arrangements involving advance contractual payments, variously described as (i) "up-front rebates", (ii) "signing bonuses", and (iii) "prebates", implicate the Medicare and Medicaid anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

You described the following situation. A manufacturer or distributor of various medical products and services (the "Seller") enters into contracts with group purchasing organizations and end-users of those products (the "Purchasers"). The Seller agrees to pay substantial up-front payments to the Purchasers upon execution of the contract and may provide for additional advance payments to be made at various times during the terms of the contracts. The contracts would not provide for any refund to the Seller upon failure of the Purchasers to satisfy any minimum purchase requirements and may establish an exclusive purchasing relationship between the parties.

As you have not requested a formal advisory opinion, we cannot opine on the legality of the particular arrangements described in your letter. However, we can make some general observations regarding the anti-kickback statute's applicability to the payment arrangements described.

In general, the practices described in your letter raise issues under the anti-kickback statute, because the payments (i.e., remuneration) are obviously incentives to induce the purchase of items or services, some of which are Federally reimbursable. The payments would not be covered by the discount safe harbor, which applies to certain discounts and rebates (42 C.F.R. §1001.952(h)), because they are made prior to any purchase and are not attributable to identifiable purchases of items or services. Simply put, discounts are price reductions at the time of sale of goods, and rebates are discounts subsequent to the sale. Moreover, these practices appear to pose a significant risk of fraud and abuse. Not only are such payments difficult to trace to ensure proper disclosure, but they also have the practical effects of "locking in" the purchasers for an extended period of time, increasing the potential for overutilization and interfering with a purchaser's normal cost/quality considerations in ordering specific goods or services. Accordingly, up-front rebates, prebates, signing bonuses, and similar payments are suspect under the anti-kickback statute, placing persons offering or receiving them potentially at risk.

For advice concerning the application of the anti-kickback statute to a specific arrangement that either is in existence or is one the requestor in good faith plans to undertake, this office has established a formal advisory opinion procedure. <u>See</u> 42 C.F.R. Part 1008.

We hope this information is helpful. I appreciate your bringing the practices described in your letter to our attention.

Sincerely,

/s/

D. McCarty Thornton Chief Counsel to the Inspector General