[Date Issued -- September 22, 1999]

By Facsimile and Regular Mail

[Name and address redacted]

Re: Discount Arrangements Between Clinical Laboratories and SNFs

Dear [Name redacted]:

I write in response to your letter dated September 14, 1999, in which you asked several questions regarding certain arrangements between clinical laboratories and skilled nursing facilities ("SNFs") paid under the Prospective Payment System ("PPS") for patients covered under Medicare Part A. In particular, you have inquired about the applicability of OIG Advisory Opinion 99-2 (Feb. 26, 1999), which addressed a discount arrangement involving ambulance services, to similar arrangements involving laboratories, and you seek clarification with respect to the kinds of discounts that are prohibited under the anti-kickback statute.

An advisory opinion applies only to the specific arrangement about which the opinion is sought and is only binding on the party or parties requesting the opinion. We do not provide formal legal guidance about such arrangements outside the scope of the advisory opinion process. We issue advisory opinions regarding the anti-kickback statute's application to specific arrangements pursuant to procedures set forth in regulations at 42 C.F.R. Part 1008. The regulations are also available on our web page at https://www.hhs.gov/oig. Requests must be submitted by parties actually participating in the arrangement or by parties who certify a good faith intent to enter into the arrangement if a favorable advisory opinion is issued.

Notwithstanding, we can make some general observations about Advisory Opinion 99-2. In general, the analytical framework set forth in Advisory Opinion 99-2 would apply to arrangements between SNFs and any ancillary services provider, including, but not limited to, clinical laboratories. At issue in Advisory Opinion 99-2 were ambulance service contracts that joined discounts to the SNFs for ambulance services for PPS-covered patients with referrals of lucrative Part B business that the ambulance company could bill directly to Medicare at an undiscounted rate. The arrangements fell squarely within the anti-kickback statute: the ambulance provider was giving something of value to the SNF (a discount on PPS-covered business) that was tied to referrals of the SNF's Part B ambulance business. In such circumstances, an unscrupulous provider may have an incentive to overutilize services or to increase Federal costs by improper billing (such as, in the case of ambulances, billing for more expensive forms of transport than are necessary) to make up potential losses on the discounted PPS business. These are some of the very evils that the anti-kickback statute is designed to prevent.

As explained in the opinion, a key inquiry under the anti-kickback statute is whether the discount on the PPS-covered business is intended to induce the referral of Part B business. Neither the size nor structure of the discount is determinative of an anti-kickback violation. Rather, the appropriate question to ask is whether the discount -- regardless of its size or structure -- is tied or linked directly or indirectly to referrals of other Federal health care program business.

When evaluating whether an improper connection exists between a discount on PPS-covered business and referrals of Part B business, we look for indicia that the discount on the PPS-covered business is not commercially reasonable in the absence of other, non-discounted business. In other words, we look to see whether the discount on the PPS-covered services makes business sense "standing alone" without reference to any other business the provider may receive from the SNF.

Advisory Opinion 99-2 identified two examples of discounts that are suspect:

1. discounts that are below the supplier's fully loaded costs, and

2. discounts that are lower than the prices that the supplier offers to a buyer that (i) generates a volume of business for the supplier that is the same or greater than the volume of Part A business generated by the PPS SNF, but (ii) does not have any potentially available Part B or other Federal health care program business.

In the absence of other facts to the contrary, these kinds of discounts suggest that the supplier and the SNF may be "swapping" discounts on PPS-covered business in exchange for profitable non-discounted Part B business, from which the supplier can recoup losses incurred on the discounted business, potentially through overutilization or abusive billing practices. These two discount arrangements were intended as examples of suspect discounts. Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes (such as capitation arrangements) made in conjunction with explicit or implicit agreements to refer other facility business. In sum, if any direct or indirect link exists between a price offered to a SNF for PPS-covered services and referrals of Part B business, the anti-kickback statute would be implicated.

Finally, you asked whether a laboratory may pass along to a SNF cost savings (if any) resulting from billing a SNF directly under the PPS system if the intent of providing this cost savings discount is to induce the referral of Part B services. In general, the anti-kickback statute, 42 U.S.C. ï¿½ 1320a-7b(b), makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration (i.e., anything of value) to induce, or in return for, the referral of items or services for which payment may be made in whole or in part by a Federal health care program. In other words, the statute prohibits payments made purposefully to induce referrals of business paid for by a Federal health care program, including Medicare and Medicaid. The statute has been interpreted by courts to cover any arrangement where one purpose of the remuneration is to induce referrals. Because the anti-kickback statute is an intent-based statute, the determination whether a particular payment practice violates the statute can only be made on a case-by-case basis after reviewing all potentially relevant facts to determine the intent of the parties.

We are continuing to monitor the situation with respect to potentially unlawful contracts between SNFs and services providers, as well as the potential ramifications of these arrangements under the prohibition on charging Medicare or Medicaid amounts substantially in excess of a provider's usual charge (section 1128(b)(6) of the Social Security Act).

I hope this information is helpful. If you have further questions or comments, please feel free to contact me at 202-619-0335.

Sincerely,

/s/

Kevin G. McAnaney
Chief, Industry Guidance Branch