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April 29, 1998

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Dear Ms. Ross:

I am responding to your April 9, 1998 letter to Henry Greenberg. You ask two questions pertaining to Public Health Law (PHL) article 2 title II-D, the Health Care Practitioner Referrals Act, commonly known as the state Stark law. The facts you present, your questions, and our answers are set forth below.

Question 1

The Facts:

A medical professional corporation (PC) with more than ten primary care physician shareholders "includes a clinical laboratory which has been licensed by New York State and certified in microbiology ('POL')". It is unclear if the PC has more than one office, or whether the clinical laboratory is located at any of the office sites. It is also unclear why the clinical laboratory, which you designate as a POL, would have a permit from New York State since a physicians office laboratory, (which is the meaning usually attached to "POL"), within the meaning of PHL § 579(1) does not require a permit under PHL § 574. In order to reach your question we assume that the clinical laboratory about which you inquire, presently meets the PHL § 579(1) definition, that is, is operated by the PC, and that tests are performed by the physician shareholders or their employees, solely as an adjunct to the treatment of the patients of the PC. We further assume that the PC has obtained a laboratory permit either for purposes of Medicaid billing, or on a voluntary basis. Additionally, it is unclear what is intended by the designation "microbiology" since that is not one of the categories for which clinical laboratories receive New York State permits. Since you have not provided any identifying information regarding the laboratory, it is impossible to clarify exactly what categories of testing the laboratory is permitted

to do. If you want to obtain such clarification, I suggest you contact the Clinical Laboratory Evaluation Program (CLEP) at 518-485-5378.

You further state that the PC "has responsibility for direct supervision of its laboratory personnel" who perform the testing of specimens sent to the laboratory. It is unclear if you mean that the physician shareholders of the PC or physician employees of the PC supervise the laboratory technicians. It is also unclear if the technicians are employees of the PC.

The PC presently has an arrangement with a national laboratory (NL) pursuant to which some specimens are referred to NL. You state that NL is paid directly for such testing by the third party payor on a fee-for-service basis.

NL has asked that PC's laboratory (PCLab) perform certain tests on some of the specimens accepted by NL. It is unclear whether the laboratory permit under which PCLab presently operates would encompass the tests on the specimens forwarded from NL, or is otherwise adequate to allow the contemplated testing. You state that NL will pay the PC on a fee-for-service basis for the contemplated testing by PCLab.

Question

May the PC make referrals of specimens to NL if PC is directly compensated by NL for testing of specimens referred by NL to PCLab, or are such referrals prohibited by PHL § 238-a(1)(a)?

Answer

Under the circumstances stated, referrals by the PC to NL are prohibited by PHL § 238-a(1)(a).

Discussion

PHL § 238-a(1)(a) prohibits a physician from making a referral for clinical laboratory services to a provider of such services if there is a financial relationship between the physician and the provider.

Under the circumstances you present, the PC is compensated for the testing referred by NL and performed by PCLab. Under the broad statutory definitions of financial relationship and compensation relationship [see PHL § 238(3) and § 238-a(5)], there is a financial relationship between the PC and NL, and the physicians of the PC may not refer specimens to NL.

You urge that the department find that referrals by PC to NL are permissible under 238-a(1)(a) even if there is a compensation arrangement between the PC and NL, and even if there is no statutory exception to the compensation arrangement, arguing that the arrangement

"fits within the intent of the Referral Law"..., and that "...there is no inducement for POL to increase the volume" of referred tests "and it will be paid fair market value only for the tests it actually performs."

We do not agree with the arguments you present. First, the state self-referral prohibition is a strict liability statute; intent to violate the law or the occurrence of the harm intended to be curbed, is not necessary to support a finding that the statute is violated. In enacting the law, the legislature has already determined that the statutory situations which invoke the prohibition are sufficiently likely to lead to the harm which the law seeks to curb, independent of whether the parties intend the harm or whether the harm will occur. Second, it is not clear that the PC will have no inducement to overorder tests. Under the circumstances stated, the more tests ordered by the PC, the greater the benefit to NL, which may then refer more specimens to PCLab. The referring physicians of the PC, who own PCLab, receive financial gain from the tests performed.

Additionally, please note that if PCLab accepts specimens from NL, then clearly PCLab is not a POL within the meaning of PHL § 579(1), and its New York State permit would have to reflect that it is functioning as an independent clinical laboratory.

You should also note that in order for the PC to make referrals to its own laboratory (PCLab), the requirements of PHL § 238-a(2)(b) would have to be met in their entirety.

Further, in reviewing contemplated situations pertaining to the provision of clinical laboratory services, you should consult PHL article 5 title VI, in particular §§ 586 and 587. Note by way of example only, that if PCLab were to function as an independent clinical laboratory appropriately permitted, then under PHL §§ 587(1)(d),(2)(d), the laboratory could not be located in the offices of the PC.

We take no position as to whether the facts you present constitute a violation of federal fraud and abuse statutes, including but not limited to, Stark II codified at 42 USC § 1395nn.

Question 2

The Facts:

An independent practice association (IPA) has been duly formed. The physicians of the PC "are participating physicians in the IPA". The IPA will have "a full-risk capitation contract" with NL, and NL will have "a full-risk capitation contract" with PCLab. You state that "As the IPA grows, the percentage of patients served by this arrangement which are PC patients would decrease....The overall intent of this scenario is to provide patients of the IPA with quality laboratory services and control costs in the marketplace..."

Question

You ask whether, under the above-stated facts, there is a violation of PHL § 238-a(1)(a).

Answer

We cannot answer your question since the facts are unclear and are worded in a manner which appears to conflict with applicable law. However, PHL § 238-a(2)(c) exempts from the provisions of the self-referral prohibition, "services furnished to subscribers of a health maintenance organization operating pursuant to article forty-three of the insurance law or article forty-four of this chapter..."

Discussion

Under New York law, a health maintenance organization (HMO), may only contract with an IPA whose powers and purposes are limited to arranging for the delivery of health care services by means of contracting with providers. See 10 NYCRR § 98.5. An IPA has no patients, contrary to your representation; the persons enrolled in the HMO which has contracted with the IPA are enrollees of the HMO and are the patients of the direct providers of health care, and those providers are in the IPA's network. The department has the responsibility to review model contracts between the HMO and an IPA, and the IPA and direct providers, including financial arrangements and risk arrangements between HMO, IPA, and providers.

If we assume that:(1) the IPA to which you refer, is under contract with an HMO, which has a PHL article 44 operating certificate, to arrange for the delivery of clinical laboratory services to the HMO's enrollees; (2) the enrollees include the patients of the PC; (3) the IPA has chosen to contract with NL for the delivery of laboratory services; (4) NL intends to subcontract with PCLab; and (5) the department has reviewed model contracts pertaining to the intended arrangements, including proposed financial arrangements, and found them acceptable, then the provisions of PHL § 238-a(2)(c) would apply, and the referral would not be prohibited.

If you have any questions regarding the above, feel free to contact me at 518-486-1336.

Sincerely,

Harriet S. Bougen
Senior Attorney