

Exhibit 43

To

United States' Complaint In Intervention

No. 12cv10132-NMG

No. 12cv10631-NMG

No. 13cv10825-NMG



August 31, 2009

Mr. Howard Appel
Chief Financial Officer
Millennium Laboratories
16981 Via Tazon, Suite F
San Diego, CA 92127

Re: Millennium Sale of POC Supplies

Dear Mr. Appel:

This letter is in response to your request to analyze and assess certain issues Summit Diagnostics raised concerning Millennium Laboratories, Inc. ("Millennium") business practices in correspondence circulated in late 2008 and 2009. Specifically, the letter addresses potential compliance issues under the Federal Anti-Kickback Statute¹ ("the Anti-Kickback Law"), and the Stark Self-Referral Prohibitions² ("the Stark Law"), relating to Millennium's practice of selling point of care drug testing supplies ("POC supplies") to physician practices that refer laboratory testing to Millennium.

Section I below summarizes my conclusions. Sections II through VII set forth the analysis and reasoning upon which those conclusions are based.

I. Summary of Conclusions

1. Millennium's sale of POC supplies does not represent illegal remuneration under the Anti-Kickback Law so long as Millennium charges the recipients of these POC supplies fair market value prices, which are comparable to the prices charged by other readily available sources.
2. Likewise, Millennium's sale of POC supplies does not create the compliance risks contemplated by the Office of Inspector General, Department of Health and Human Services (OIG) in its 2003 OIG Special Advisory Bulletin titled "Contractual Joint Ventures."

¹ 42 U.S.C. § 1320a-7b

² 42 U.S.C. § 1395nn

3. For further protection from Anti-Kickback Law liability, Millennium should and can structure the POC supplies arrangements so that they fulfill as closely as possible the requirements of the Equipment Rental Safe Harbor.³ Millennium recently drafted a standard written agreement that it will use to create the POC supplies arrangements. That agreement is designed to fulfill the requirements as closely as possible of the Equipment Rental Safe Harbor.
4. Millennium should and can structure the arrangements so that they also comply with the Fair Market Value Compensation⁴ exception to the Stark Law. Millennium's standard written agreement, described above, is also designed to fulfill the requirements of the Fair Market Value Compensation exception.

II. General Discussion of Laws

Federal anti-kickback provisions prohibit anyone from either paying or being paid any form of remuneration in exchange for the referral of patients covered by federally funded health care programs, such as Medicare and Medicaid.⁵ The broad language used in the legislation potentially implicates a wide array of relationships between providers of medical services and their referring customers.

The Stark Law provides that if a physician, or an immediate family member of a physician, has a financial relationship with an entity that provides certain designated health services, which include clinical laboratory services, the physician may not refer a Medicare or Medicaid patient to the entity unless a specific exception to the self-referral provisions exists.⁶

III. Relationship between Millennium and its Referring Customers

Millennium Laboratories' primary business is the quantitative testing of drugs used in the treatment of chronic pain. Millennium's fully licensed and accredited laboratory uses High Resolution Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) methods to determine the precise levels of drugs in a patient's urine. These measurements are used to monitor patient compliance with treatment protocols and ensure that drugs are not being diverted, abused, or supplemented with drugs from other sources.

Many of Millennium's customers prefer to perform qualitative point-of-care drug screening tests in their practices utilizing in-office, CLIA licensed labs. To assist its customers in performing point of care tests, Millennium sells POC supplies to some of its customers, while other customers choose to purchase POC supplies from other suppliers unrelated to Millennium. Millennium charges these customers an amount equivalent to fair market value in exchange for the POC supplies. The POC supplies are CLIA waived

³ 42 CFR §1001.952(e)

⁴ 42 CFR 411.357(l)

⁵ 42 U.S.C. § 1320a-7b

⁶ 42 U.S.C. § 1395nn

procedures that perform multiple qualitative screenings for particular drugs. The POC supplies sold by Millennium are readily available from many other sources including manufacturers and distributors.

IV. Compliance with Anti-Kickback Law -- Fair Market Value

The key determination in whether Millennium's sale of POC supplies complies with anti-kickback provisions is whether the POC supplies represent improper remuneration. As long as Millennium charges its customers fair market value for these supplies, the practice should not implicate the Anti-Kickback Law. Millennium's customers can easily obtain the POC supplies from many other suppliers including distributors or direct from manufacturers. If Millennium's charges for the POC supplies are at fair market value and comparable to amounts charged by other manufacturers and suppliers, there is little risk that Millennium's sale of the POC supplies will be considered illegal remuneration.

V. Compliance with Anti-Kickback Law -- "Contractual Joint Ventures"

In 2003, the OIG published a Special Advisory Bulletin concerning contractual joint ventures.⁷ In that bulletin, the OIG warned of the compliance risks associated with questionable joint ventures in which the manager/supplier (in this case, the laboratory) allows the owner (in this case, the physician practice) to share in the revenue of tests and services normally performed by the manager/supplier.⁸ The OIG fears that the manager/supplier may provide illegal remuneration to the owner in the form of an opportunity to share in the revenue of tests and procedures not normally available to the owner. The OIG states:

"By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Manager/Supplier is providing the Owner with the opportunity to generate a fee and a profit."⁹

Millennium's arrangements with its customers differ from the "joint ventures" contemplated by the OIG in two ways:

1. Millennium does not perform qualitative drug screens using readily available and simple to use point-of-care devices. This type of testing is not part of Millennium's primary business model. Millennium is a fully licensed and accredited laboratory, which uses LC/MS/MS methods to provide quantitative confirmatory results of patient's drug levels. Millennium does not share the revenue from these services with physicians.
2. Millennium is not providing an opportunity to its customers, by providing the POC supplies, which is not already widely available to most physician practices.

⁷ 2003 OIG Special Advisory Bulletin "Contractual Joint Ventures"

⁸ Id.

⁹ Id.

As previously stated, the CLIA-waived tests sold by Millennium are readily available for purchase from numerous other manufactures and distributors at prices comparable to those charged by Millennium.

The above stated differences between Millennium's arrangements and those described by the OIG significantly limit the risk that either Millennium or its customers will face liability for Anti-Kickback Law violations.

VI. The Anti-Kickback Law and Safe Harbors

Federal cases interpreting the Anti-Kickback Law have broadly construed application of the statute. Even if only one purpose of the remuneration is to induce referrals of tests and services paid for by federally funded health care programs, the arrangement could implicate federal anti-kickback provisions.¹⁰ Due to the broad application of the law, the OIG developed safe harbors that protect various financial arrangements between Medicare providers and their referral sources.¹¹ If an arrangement fulfills the numerous and strict requirements of a particular safe harbor, the arrangement is protected from prosecution.

It is important to note that failure to comply with a safe harbor does not necessarily mean the arrangement is a violation of the Anti-Kickback Law. For this reason, if an arrangement does not fall squarely within the confines of a particular safe harbor, the parties to the arrangement should strive to model the arrangement as closely as possible to the applicable safe harbor.

The safe harbor that most closely resembles Millennium's arrangement is the Equipment Rental Safe Harbor.¹² That safe harbor includes numerous requirements, however, the most important factor to consider is the requirement that compensation for the equipment, (i.e. the POC supplies) is consistent with fair market value and is not determined in a manner that takes into account the volume or value of actual or anticipated referrals. By charging an amount for POC supplies that is comparable to other readily available sources, Millennium should easily satisfy the fair market value requirement. In addition, Millennium must not vary its charges based upon actual or anticipated referrals of testing from the physician customers.

If Millennium structures its POC supplies arrangements so that they fulfill as closely as possible the requirements of the above Safe Harbor, Millennium should further reduce its exposure to the risk of Anti-Kickback Law liability.

¹⁰ United States v. Kats, 871 F. 2d 105 (9th Cir 1989)

¹¹ 42 CFR §1001.952

¹² 42 CFR §1001.952(c)

VII. Compliance with Stark Law

In order to comply with the Stark Law, Millennium must structure the POC supplies arrangements so that they also fulfill the requirements of the applicable Stark exception. The Fair Market Value Compensation exception¹³ requires the following:

1. The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.
2. The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause.
3. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.
4. The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.
5. The arrangement does not violate the anti-kickback statute, or any federal or state law or regulation governing billing or claims submission.
6. The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a federal or state law.

The requirements of the above Stark exception mirror many of the requirements of the Equipment Rental Safe Harbor discussed earlier. Once again, the most important consideration is that compensation is equivalent to fair market value and not dependent upon the volume or value of actual or anticipated referrals. Millennium should have little difficulty complying with the above requirements.

If you have any further questions or concerns, please contact me.

Sincerely,

Gregory B. Root, Esq.

¹³ 42 CFR 411.357(l)