

MARYLAND STATE BOARD OF PHYSICIANS
IN THE MATTER OF PETITION FOR DECLARATORY RULING

Petitioner:

**Maryland Society of Pathologists,
Inc.**

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Declaratory Ruling No. 2006-2

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DECLARATORY RULING

INTRODUCTION

This Declaratory Ruling arises out of a formal petition filed on August 25, 2006, by Maryland Society of Pathologists, Inc. ("Petitioner"). Petitioner requests a ruling from the Board regarding the propriety under the Maryland Self-Referral Law of certain referrals made by urologists for pathological services when the urologist obtains a financial benefit from the performance of the referred service. Enclosed with the petition were letters setting out in more detail the factual scenarios that are being questioned.

On September 27, 2006, the Board voted to grant petitioner's request for a Declaratory Ruling under COMAR 10.32.16.03A. The Board has met and considered the petition and hereby sets out its Declaratory Ruling.

QUESTIONS PRESENTED

Petitioner asks whether referrals made under two specific factual scenarios violate the Maryland Self-Referral Law, as codified in Md. Health Occ.

Code Ann §1-301 *et. seq.* (1993).¹ Petitioner's factual scenarios are set out below and individually analyzed.

Scenario 1

A urology group sets up a small histology laboratory within its office. The urology group either directly owns the laboratory or has a financial interest in its operation. The urology group, however, contracts with an independent pathology group to staff the laboratory and perform the pathology services. Members of the urology group refer patients (or specimens from patients) to the lab. The urology group then pays the pathology group a set fee for each slide prepared. The preparing of the slides is called the "technical component" of the pathology services. The independent, contracting pathology group performs and supervises this technical component. The urology group, however, bills the patient for this component (the technical component) of the pathology examination.

In addition to supervising the laboratory, the independent pathology group provides a pathologic diagnosis on the prepared slides. Providing the pathologic diagnosis is called the "professional component" of the pathology services. The independent pathology group directly charges the patient for this professional component of the pathology examination.

Analysis

The question raised by this fact pattern is whether the referral of patients (or specimens from patients) by members of this urology group to the described histology laboratory violates the Maryland Self Referral Law. First, the transaction described above is a "referral" because it is the "establishment of a plan of care," which includes a pathologic diagnosis performed by an "outside" entity, the pathology group. Thus, it meets the definition of "referral" in § 1-301 (l) (2) (ii).

¹ Unless otherwise noted, all citations within this Declaratory Ruling refer to §1-301 *et. seq.* of the Health Occupations Article of the Annotated Code Maryland.

The next step is to determine whether or not the referral is a “prohibited referral” under §1-302(a). If the referral is included within §1-302(a), it is a prohibited referral unless an exception contained in §1-302(d) applies. Section 1-302(a) states:

(a) *Prohibited Referrals* – Except as provided in subsection (d) of this section, a health care practitioner may not refer a patient, or direct an employee of or person under contract with the health care practitioner to refer a patient to a health care entity:

(1) In which the health care practitioner, the practitioner’s immediate family, or the practitioner in combination with the practitioner’s immediate family owns a beneficial interest; or

(2) With which the health care practitioner, the practitioner’s immediate family, or the practitioner in combination with the practitioner’s immediate family has a compensation agreement.

§1-302(a)(2). (Emphasis added)

The urologist’s referral under this scenario is a prohibited referral because the urologist holds a beneficial interest in the histology lab that will perform the referred examination. A beneficial interest is defined as an ownership interest. Section 1-301(b). This referral thus violates the Self-Referral Law unless one of the exceptions contained in §1-302(d) applies.

The urologist’s referral is not exempt from the Self-Referral Law under any of the §1-302(d) exceptions. Section 1-302(d)(2), the "group practice" exception does not apply. By the terms of this scenario, the pathology group that contracts to run the in-office histology laboratory is independent and not a member of the same group practice.”²

² There may be additional limitations on referrals under the (d)(2) exception. See *Injured Workers' Insurance Fund, et. al*, Declaratory Ruling No. 2006-1. The Board, however, does not have to discuss these issues in order to decide this case, since the pathology group by definition is not part of the urology group's group practice.

The exception in § 1-302(d)(3) applies only if the referral is personally performed by or directly supervised by the referring physician. The urologist in this scenario is not performing the preparation of the histology slides. The independent, contracting pathology group is performing and supervising the preparation of the histology slides. "Direct supervision," by definition, requires the referring physician to be "present on the premises" and "available for consultation within the treatment area." §1-301(d). Direct supervision is a form of supervision; the "present on the premises" requirement in § 1-301(d)(3) is in addition to, and not a substitute for, the requirement of supervision. Because neither the referring urologist, nor a practitioner within his or her group practice, is in any medical sense supervising the preparation of the histology slides (the slides are being prepared under the supervision of the outside, independent, contracting pathology group), there is no "supervision" within the meaning of §1-301(d). This principle holds regardless of the location of the urologists vis-à-vis the histology laboratory. Because there is no supervision, §1-302(d)(3) does not apply to the urologist's referral.

The exception in (d)(3) does not apply for an additional reason. Exception (d)(3) applies only to referrals to *outside* entities in which the referring physician has a beneficial interest.³ Because the histology laboratory is set up within the office of the referring urologist, it is not an outside entity; exception (d)(3), therefore, would not apply even if the urologist were "supervising" the preparation of the histology slides.

³ The legislative documentary history and textual analysis supporting this statement is not set out here, but was discussed thoroughly in *Injured Workers' Insurance Fund, et. al*, Declaratory Ruling No. 2006-1.

The urologist's referral is not exempt from the Self-Referral Law under §1-302(d)(4) because it fails to meet all of the requirements of that exception.

Section 1-302(d)(4) states:

(d) *Exemptions from section.* – The provisions of this section do not apply to:

(4) A health care practitioner who refers in-office ancillary services or tests that are:

(i) Personally furnished by:

1. The referring health care practitioner;
2. A health care practitioner in the same group practice as the referring health care practitioner; or
3. An individual who is employed and personally supervised by the qualified referring health care practitioner or a health care practitioner in the same group practice as the referring health care practitioner.

(ii) Provided in the same building where the referring health care practitioner or a health care practitioner in the same group practice as the referring healthcare practitioner furnishes services; and

(iii) Billed by:

1. The health care practitioner performing or supervising the services; or
2. A group practice of which the health care practitioner performing or supervising the service is a member.

Md. Health Occ. §1-302(d)(4) Code Ann. (1993). (Emphasis added)

To meet the requirements of this (d)(4) exception, three general criteria must be met: (i) the pathological examination has to be *personally furnished by or personally supervised by the referring practitioner or a member of the referring practitioner's group*; (ii) it must be provided within the referring practitioner's office; and (iii) it has to be billed by the referring practitioner or his or her group practice.⁴

The urologist in this scenario fails to meet the first requirement. The scenario describes a histology lab that is owned by the urology group. The

⁴ In addition, the services referred must be "basic" and "routinely performed." § 1-301(k).

histology lab, however, is managed, supervised, staffed and operated by a subcontracting pathology group. The employees who staff the laboratory are employees of the pathology group, not the urology group. Thus, the urologist is not involved in either the performance or the supervision of the pathological examination at all, nor is any other practitioner in the urologist's group involved. Therefore, this arrangement does not meet the requirement of §1-302(d)(4)(i), and this exception is not available.

No other exception applies to this factual scenario. This does not mean that additional facts might not justify a finding that another exception applies. For example, if additional facts were added to Scenario 1 that showed that patients would be deprived of needed care if the prohibition on self-referrals applied, the exception in § 1-302 (d)(5) might apply.

For these reasons, a referral for pathology services as set out in Scenario 1 violates the Maryland Self-Referral Law.

Scenario 2

A urology group submits a biopsy specimen to an independent commercial laboratory. The laboratory prepares the slides and bills the patient directly for this technical component of the pathology examination. The prepared slides are then sent to the urology group's office.

The urology group contracts with a pathologist to perform a pathologic diagnosis (the "professional component") on the prepared slides. The urology group pays the pathologist a set fee that is below the market rate for this professional component. The urology group then bills the patient at the market rate for the professional component.

The pathologist discounts his or her rate below the market rate to the urology group. This discount (and the subsequent markup by the urology group) provides a financial incentive for the

urology group to refer specimens to this pathologist. Each referral to this pathologist results in additional financial gain to the urologist (through the discount-and-markup procedure).

Analysis

This analysis is not concerned with the relationship between the urology group and the independent commercial laboratory. The Board is concerned with, and sets out in its analysis below, the legality of the referrals between the urology group and the pathologist.

The referral in this scenario falls within §1-302(a) because the urology group has a "compensation arrangement" with the pathologist who performs the professional component of the examination. §1-302(a)(2). A "compensation arrangement" is defined in the Self-Referral Law as:

[A]ny agreement or system involving any remuneration between a health care practitioner ... and a health care entity.

Md. Health Occ. §1-302(c)(1) Code Ann. (1993).

The urology group in this scenario has a compensation arrangement with the pathologist because there is an "agreement or system" by which the pathologist performs the professional component for remuneration, and the urology group receives remuneration for each referral (in the form of the discount and subsequent markup).⁵

While certain compensation arrangements with independent contractors are excluded from the Self-Referral Law, this particular compensation arrangement is not excluded:

⁵ By statute, "compensation arrangement" is defined (with many exceptions) as any "system involving any remuneration." The remuneration does not have to be paid for *health care services* in order for the system to be a "compensation arrangement." Nevertheless, that is the situation in this case, since the remuneration is being paid for the professional component.

(c)(2) "Compensation arrangement" does not include:

* * *

- (iii) An arrangement between a health care entity and a health care practitioner or the immediate family member of a health care practitioner for the provision of any services, as an independent contractor, if:
1. The arrangement is for identifiable services.
 2. The amount of the remuneration under the arrangement is consistent with the fair market value of the services and is not determined in a manner that takes into account, directly or indirectly, the volume or value of any referrals by the referring health care practitioner; and
 3. The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the health care practitioner.

Md. Health Occ. §1-302(c)(1) Code Ann. (1993). (Emphasis added)

The Board concludes that the exception from the term "compensation arrangement" in §1-302(c)(2)(iii) does not apply. The exclusion applies only to arrangements in which the goods or services are purchased at "fair market value." *Id.* Since, according to the terms of the scenario, the payment by the urologist to the pathologist for the professional component is below fair market value, the exclusion for independent contactors does not apply. In addition, although there are many other exclusions from the term "compensation arrangement" in § 1-301(c)(2), none of these other exclusions applies to this scenario.

Because the urology group has a "compensation arrangement" with the pathology group, the urology group's referral of specimens to the pathology group is a "prohibited referral" and a violation of the Self-Referral Law unless an exception in §1-302(d) applies.

None of the exceptions to §1-302(d) apply. First, exception (d)(2) deals only with referrals to another practitioner in the "same group practice." In this

scenario, however, the pathologist is not a member of the urology group's group practice. Thus, exception (d)(2) plainly does not apply.⁶

Second, exception (d)(4) does not apply. This exception deals with "in-office" ancillary services. In this scenario, however, the professional component of the pathology examination is rendered by a contractor outside of the referring urologist's office, and therefore beyond the scope of (d)(4). And in any case, exception (d)(4) requires that the referring physician (or a physician in that group) personally perform or supervise the service – and in this scenario neither the referring urologist nor a member of the referring urologist's group either performs or supervises the professional component in this scenario. For both of these reasons, exception (d)(4) does not apply.

A third exception that needs to be considered in this scenario is the "direct supervision exception" contained in §1-302(d)(3), which permits referrals to entities in which the referring physician has a beneficial interest, provided that the referring physician personally performs or directly supervises the service.

Section 1-302(d)(3) states:

- (d) *Exemptions from section.* – The provisions of this section do not apply to:
 - * * *
 - (3) A health care practitioner with a beneficial interest in a health care entity who refers a patient to that health care entity for health care services or tests, if the services or tests are personally performed by or under the direct supervision of the referring health care practitioner.

Md. Health Occ. §1-302(d)(3) Code Ann. (1993) (Emphasis added.)

⁶ There are additional limitations on referrals under the (d)(2) exception, see *Injured Worker's Insurance Fund, et. al.*, Declaratory Ruling No. 2006-1, but the Board does not have to consider these additional limitations in this case.

The referral in this scenario, however, fails to meet either of the two requirements emphasized above. First, the urology group member does not have a beneficial interest in the practice of the pathologist to which the referral was made. In this scenario, the urologist merely has a contractual relationship with the pathologist; this is not a beneficial interest. Thus, the referral fails to meet the requirements of the exception in §1-302(d)(3) for this reason alone.

Second, the referring urologist does not perform or supervise any part of the examination. Under the “direct supervision requirement” of this exception, the referring physician must either directly supervise or personally perform the referred service or test. The urologist in this scenario does not in any sense either perform or supervise any part of the pathologic examination. Both components of the pathology exam are performed outside of the urologist’s office by outside contractors who are not members of the urology group. The urologist acts simply as a purchaser and reseller to the patient. Therefore, because the urologist does not perform or supervise any part of the pathology examination, §1-302(d)(3) does not exempt the urologist’s referral.

Since none of the exceptions apply, a referral made under this scenario violates the Maryland Self-Referral Law.⁷

Conclusion

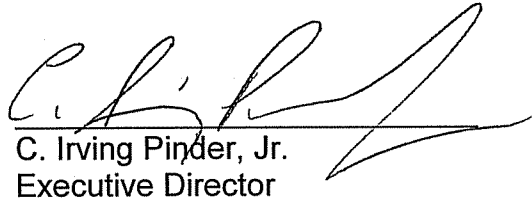
The referrals described above in both Scenario One and Scenario Two violate the Maryland Self-Referral Law, as codified in §1-301 *et seq.* This ruling

⁷ This Declaratory Ruling is limited to the general rule and the exceptions found in (d)(2), (d)(3) and (d)(4). The scenarios dealt with here did not bring into play the other exceptions found at (d)(1) and at (d)(5) through (11). Additional facts altering the scenarios could result in a finding that an exception found in (d)(1) or (d)(5) through (d)(11) applies.

is binding on the Board and the Petitioner with regard to these specific factual scenarios.

12/29/06

Date



C. Irving Pinder, Jr.
Executive Director

NOTICE OF RIGHT TO APPEAL TO COURT

Petitioner Maryland Society of Pathologists, Inc., if dissatisfied with this Declaratory Ruling, is entitled to appeal the ruling to the circuit court under Md. State Gov't Code Ann. § 10-305 (c).