

IN THE MATTER OF
SANFORD J. SIEGEL , M.D

Respondent

License Number: D32029

* BEFORE THE
* MARYLAND STATE
* BOARD OF PHYSICIANS
* Case Number: SR 0-9911-0141

* * * * *

CONSENT AGREEMENT

Based upon information received by the Maryland State Board of Physicians (the "Board"), pursuant to its authority under the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("Health Occ.") §§ 14-101 *et seq.* (2009 Repl. Vol.) and the Maryland Patient Referral Law ("MPRL"), Health Occ. §§ 1-301 *et seq.*, the Board conducted an investigation of Sanford J. Siegel, M.D. (the "Respondent"), License Number D32029, in his capacity as a licensee and as President and Chief Executive Officer of Chesapeake Urology Associates, PA ("CUA").

The pertinent provisions of the MPRL provide the following:

§ 1-302. Prohibited referrals; exceptions; disclosures.

(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 or the practitioner in combination with the practitioner's immediate family owns a beneficial interest;

* * *

(c) *Applicability of subsection (a).* – Subsection (a) of this section applies to any arrangement or scheme, including a cross-referral arrangement, which the health care practitioner knows or should know has a principal purpose of assuring indirect referrals that would be in violation of subsection (a) of this section if made directly.

The State and the Respondent jointly submitted this Consent Agreement for consideration by the Board. The Consent Agreement memorializes an agreement between the Board and the Respondent that resolves the Board's investigation. By its terms, CUA agrees to the monitoring and reporting requirements set forth herein. In consideration for CUA's agreement to comply with these obligations, the Board hereby closes its investigation effective as of the date of this Consent Agreement. The Board voted to adopt this Consent Agreement.

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent was licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on March 5, 1985, and his license is presently active.

2. The Respondent is President and CEO of Chesapeake Urology Associates ("CUA"), a urology practice with offices located throughout the State of Maryland. The Board's investigation of the Respondent was undertaken in his capacity as a licensee and as President and CEO of CUA.

3. The Board's investigation in this matter did not relate to Respondent's or any other CUA physician's clinical judgments or treatment of patients, but related instead to a particular aspect of CUA's compliance with the MPRL.

4. The Board's investigation commenced in June 2011 and focused on whether the structure of referrals made by CUA physicians for the furnishing of radiation therapy services at CUA's Prostate Center is legally permissible in light of the Board's decision in Declaratory Ruling 2006-1 ("DR 2006-1") and the MPRL. CUA has maintained throughout the investigation that its referral practices associated with the

delivery of radiation therapy services at its Prostate Center are legal and comply fully with DR 2006-1 as well as the MPRL.

5. As of the date of this Consent Agreement, CUA has 53 physicians -- 46 urologists, four radiation oncologists, and three pathologists. Of the 46 urologists, 34 are owners, each holding an equal 100 shares of stock in CUA, and 12 are salaried employees. CUA's four radiation oncologists and two of the three pathologists are salaried employees. The third pathologist is an independent contractor.

6. As President and CEO of CUA, the Respondent spends approximately ten percent of his time as a practicing urologist and 90 percent of his time presiding over the administration of CUA. He is responsible for overseeing the running of CUA, including its approximately 400 employees. In 2006, the executive committee of CUA voted to build a new medical office as part of its group practice that would be dedicated to the treatment of men with prostate cancer. CUA's medical office, also known as the Prostate Center, would offer radiation oncology consultation services and radiation therapy treatment to prostate cancer patients, including intensity-modulated radiation therapy ("IMRT").

7. Prostate cancer starts in the prostate gland, which is a small, walnut-sized structure within the male urogenital system. Prostate cancer is the second leading cause of cancer death in American men. IMRT is a type of external beam radiation therapy that uses multiple small radiation beams of varying intensities to precisely radiate a tumor. For the treatment of prostate cancer with external beam radiation therapy, IMRT delivers high doses of radiation precisely to the prostate while minimizing risk of collateral damage to adjacent structures.

8. In building the Prostate Center, CUA sought to integrate radiation therapy using IMRT into its medical practice. CUA's leadership viewed the building of the Prostate Center as an opportunity to create a cancer treatment center that specialized in the treatment of prostate cancer and that offered men with prostate cancer an alternative setting to hospitals and radiation oncology centers that treat patients with various forms of cancer.

9. At the time that CUA decided to build and operate the Prostate Center, it performed a financial analysis to determine the economic feasibility of the project. This analysis included a projection of revenue using estimated rates of reimbursement along with estimated patient volume based upon historical utilization of IMRT. Based upon its financial analysis, CUA projected that, with an initial investment in the construction of the Center and the purchase of equipment, it would ultimately be able to realize a profit from the delivery of IMRT at the Prostate Center.

10. CUA's financial analysis assumed that a certain number of CUA patients diagnosed with prostate cancer by a CUA urologist would ultimately choose to receive IMRT at the Prostate Center, after a consultation with a CUA radiation oncologist, who would make an independent, professional judgment about the full range of treatment options for the patient, including whether the patient was an appropriate candidate to receive IMRT. CUA's leadership believed that patients choosing IMRT would prefer the continuity of care and specialization that the Prostate Center offered.

11. In early 2007, CUA's executive committee of which the Respondent was a participant held a series of meetings to discuss, among other things, the status of the

construction of the Prostate Center and CUA's plan, after the Prostate Center became operational, to retain a group of radiation oncologists as employees of CUA.

12. As CUA conceptualized the development of the Prostate Center's operational protocols, it was determined that CUA's urologists would discuss various treatment options with their patients diagnosed with prostate cancer and, when appropriate, refer patients for a radiation oncology consultation with one of the radiation oncologists employed by CUA. The radiation oncologist employee would review the patient's records, conduct an independent medical examination of the patient, and then discuss with the patient the radiation oncologist's recommendations of appropriate treatment options. The radiation oncologist employee would then document the consultation and discussion in CUA's electronic medical record system.

13. Since June 2007, CUA has continuously owned and operated the Prostate Center as one of CUA's medical offices located in Owings Mills, Maryland. The Prostate Center is not a distinct legal entity, but rather is part of CUA.

14. CUA employs four radiation oncologists. The radiation oncologists are salaried employees of CUA and do not have, nor have they ever had, any ownership interests in CUA. The salaries of the radiation oncologists are fixed by the terms of the radiation oncologists' employment contracts and are not dependent upon the number of patients who receive radiation therapy at the Prostate Center. The radiation oncologists do not receive any kind of bonus, distribution, or other incentive-based compensation from CUA for referring or treating patients with radiation therapy at the Prostate Center.

15. The radiation oncologists provide consultations for patients with prostate cancer and prescribe, manage, and supervise the care of those patients who choose to be treated with IMRT at the Prostate Center.

16. In certain circumstances, when a CUA patient is diagnosed with prostate cancer by a CUA urologist, the patient is referred to one of CUA's radiation oncologists for a consultation to evaluate the full range of appropriate treatment options for the patient, including IMRT. When the radiation oncologist meets the patient for the consultation, no other CUA physician has already ordered radiation therapy or any other type of treatment.

17. As part of the consultation, the radiation oncologists conduct an extensive medical examination that includes a review of the patient's medical chart and pathology reports related to the patient's cancer diagnosis, a complete physical examination, and an interview with the patient to learn of the patient's family and medical history. The radiation oncologists make an independent, professional judgment about the full range of appropriate treatment options for the patient and discuss those options with the patient.

18. When the radiation oncologists recommend IMRT as a treatment option for patients, the radiation oncologists routinely offer alternative locations where the patients can choose to obtain treatment. If a patient chooses to receive IMRT at the Prostate Center, the radiation oncologists take on the professional responsibility for that patient's continued care throughout the course of the patient's IMRT treatment.

19. Consistent with the plan for the operation of the Prostate Center, the Respondent as well as other CUA urologists – both owners and employees of the group

practice – have referred many prostate cancer patients to CUA’s radiation oncologist employees for radiation oncology consultations and certain of those patients received a recommendation of IMRT from the radiation oncologist employees of CUA. Some of those patients have chosen to receive IMRT at the Prostate Center. Other of those patients who are seen by a CUA radiation oncologist for a consultation either choose a different therapy (such as brachytherapy or surgery), active surveillance, or choose to have IMRT at a location other than CUA’s Prostate Center.

DISCUSSION

The Board’s investigation focused on concerns that the manner in which CUA patients are referred for IMRT at the Prostate Center violates the MPRL by “directing an employee” – the radiation oncologist employees of CUA – “to refer a patient to a health care entity . . . in which [the urologist owners of CUA] . . . own[] a beneficial interest.” See Health Occ. § 1-302(a). The investigation also focused on whether CUA had an “arrangement” with its radiation oncologist employees that CUA’s urologist owners “know or should know has a principal purpose of assuring indirect referrals that would be in violation of [the MPRL] if made directly.” Health Occ. § 1-302(c).

The Respondent and CUA’s other urologists deny ever having “direct[ed]” a radiation oncologist employee to make any referral to the Prostate Center. The Respondent, on behalf of CUA, as well as CUA’s radiation oncologist employees, attested that no CUA urologist has ever directed or pressured any one of the radiation oncologist employees to recommend external beam radiation therapy or any other form of treatment to any patient, to increase the number of radiation therapy treatments the radiation oncologists administer, or to convince patients to choose to receive radiation

therapy at the Prostate Center instead of at another location. The Respondent, on behalf of CUA, further denies that CUA's arrangement with its radiation oncologist employees has a "principal purpose of assuring indirect referrals" that would violate the MPRL if made directly.

This Board has previously construed the relevant provisions of the MPRL. In Declaratory Ruling 2006-1, which principally concerned referrals by orthopaedic surgeon owners of medical group practices for performance of magnetic resonance imaging ("MRI") scans within the physicians' medical offices, the Board ruled that, under several fact patterns, "[a] referral by an orthopedic physician for an MRI to be performed on or by an MRI machine owned or leased by the orthopedic practice . . . is an illegal self-referral within the meaning of the Maryland [Patient] Referral Law."

The Board further addressed a fact pattern labeled in the Declaratory Ruling as "Variation 3," in which "a physician who is an *employee* of the medical practice that provides the MRI scan evaluates the patient and orders the MRI to be done by that practice," and in which "[t]he physician-employee does not have any beneficial interest in the medical practice." (Emphasis added.) The Board stated, with respect to Variation 3, that it was "unable to make an all-encompassing ruling on all cases in which the referring physician is an employee of the practice" and that referrals for MRI scans by employee physicians "may or may not violate the [Patient] Referral Law, depending on the circumstances."

The Board identified two circumstances in which a referral under Variation 3 would violate the MPRL. The Board ruled that the referral by the employee physician would be "an illegal self-referral" within the meaning of the statute if the employee is

“directed’ by an employer who is a beneficial owner to make the referral to the health care entity owned by the employer....” The Board also ruled that “if the referral is made according to an ‘arrangement’ or ‘scheme’ by which prohibited referrals are made indirectly,” then the referral would violate the MPRL.

The Board made clear in DR 2006-1, however, that not all referrals by employee physicians violate the MPRL. Specifically, the Board ruled that if “an employee physician (1) is not directed to make the referral; (2) there is no arrangement or scheme by which self-referrals are accomplished; and (3) the employee physician is employed under a ‘bona fide employment agreement,’ then a referral to the employer’s MRI facility under Variation 3 does not violate the Maryland [Patient] Referral Law.” The Board further explained in its ruling that a “bona fide employment agreement” is “an otherwise valid employment agreement which by its terms does not require referrals to the employer’s health care entity, which in practice does not require referrals to the employer’s health care entity and under which no form of remuneration or compensation or favorable treatment is directly or indirectly tied to referrals to the employer’s health care entity.”

On judicial review, the Court of Appeals upheld Declaratory Ruling 2006-1 in its entirety. See *Potomac Valley Orthopaedic Associates, et al. v. Maryland State Board of Physicians, et al.*, 417 Md. 622 (2011). CUA was a party to the *Potomac Valley* case.

Shortly after the Court of Appeals issued its decision in *Potomac Valley*, the Board posted a document on its website entitled “Self Referral Law - Educational Update” with historical background about the MPRL and details about the Court of Appeals’ ruling. The Board explained that a referral for an MRI made by an orthopaedic

physician who has a “beneficial financial interest” in the orthopaedic practice violates the law. Under a separate heading, entitled “Physician-Employees,” the Board explained, consistent with its analysis in Variation 3 set forth in DR 2006-1, that “where a physician who is an employee of the medical practice (but who does not have any beneficial interest in the medical practice that provides the MRI scan) evaluates the patient and orders the MRI to be done by that practice, the referral does not violate the law,” as long as certain requirements are satisfied, namely that (i) the physician works under a valid employment contract; (ii) the employment contract by its terms does not require referrals to the employer’s health care entity, (iii) the employment relation does not in practice require referrals to be made to the employer’s health care entity, (iv) no form of remuneration or compensation or favorable treatment is directly or indirectly tied to referrals to the employer’s health care entity, (v) the employee is not directed to make a referral to the employer’s health care entity, and (vi) there is no arrangement or scheme by which the prohibited referrals are made indirectly, which the referring physician knows or should know has as a principal purpose the making of otherwise prohibited referrals.

This case presents the same basic facts as “Variation 3” in Declaratory Ruling 2006-1. Physicians who are employees of CUA, the radiation oncologists, evaluate patients, recommend appropriate treatment options and, when chosen by the patient, prescribe, manage and supervise the furnishing of IMRT at CUA’s Prostate Center. The radiation oncologist-employees of CUA do not have a beneficial interest in CUA.

With regard to subsection (a) of § 1-302, the Board finds that a health care practitioner with a beneficial interest in a health care entity could give prohibited

“direct[ion]” to an employee to make a referral either expressly or by implication. Thus, the Board would have been required to find a violation of § 1-302(a) in this case if the State had demonstrated that the Respondent or other CUA urologist owners expressly or impliedly directed CUA-employed radiation oncologists to refer patients for performance of IMRT at CUA’s Prostate Center.

In subsection (c) of § 1-302, the MPRL requires the Board to resolve questions of intent. That provision prohibits any “arrangement or scheme” that has “a *principal purpose* of assuring indirect referrals that would be in violation of subsection (a) of this section if made directly.” (Emphasis added.) Thus, the Board would have been required to find a violation § 1-302(c) in this case if the State had demonstrated that the Respondent or other CUA urologist owners had an arrangement or scheme in place the principal purpose of which was to assure indirect referrals that would have violated § 1-302(a) if such referrals had been made directly.

In evaluating possible violations of § 1-302(a) or § 1-302(c), the State could rely on statements or other evidence directly tending to show that a physician-owner “directed” an employee to make a referral, or that an arrangement has a “principal purpose” to assure indirect referrals that would be prohibited if made directly. Evidence of a pattern of overutilization of a particular procedure associated with referrals by a physician-employee could imply an intent that an employment relationship, in practice, required referrals to be made to the employer’s health care entity.

ORDER

Based on the foregoing Findings of Fact and without any finding that the Respondent or any other CUA physician violated the Maryland Patient Referral Law, it is this 20th day of March, 2013, by a majority of a quorum of the Board considering this case:

ORDERED that beginning April 1, 2013, and through October 1, 2014, the Respondent, in his capacity as a licensee and as President and CEO of CUA, shall fully and satisfactorily comply with the following terms and conditions:

1. The Respondent shall ensure that during the above-referenced time period CUA employs no more than four (4) radiation oncologists at any one time;
2. The Respondent shall ensure that CUA through its Prostate Center performs IMRT procedures on no more than 45% of those patients who are newly diagnosed with prostate cancer by CUA urologists during the time period April 1, 2013 through October 1, 2014;¹
3. The Respondent shall be responsible for ensuring that CUA submits written reports to the Board on a quarterly basis detailing the information listed in subparagraphs (i) through (v) below. The written reports shall be submitted to the Board no later than 30 days following the end of the preceding quarter, so that the first written report shall be submitted on or before August 1, 2013 reporting on the period April 1, 2013 through June 30, 2013, the second written report shall be submitted on or before November 1, 2013 reporting on the period July 1, 2013 through September 30, 2013, and so forth. The last of the six written reports shall be submitted on or before November 1, 2014. Each written report shall detail the following:
 - (i) the number of patients newly diagnosed with prostate cancer by CUA urologists during the preceding quarter;
 - (ii) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who were referred to or seen by any radiation oncologist employed by CUA for a radiation oncology consultation;

¹ The Board takes no position as to the appropriateness of any particular utilization rate for IMRT outside the facts and circumstances of this Consent Agreement.

- (iii) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who were advised by any radiation oncologist employed by CUA who furnished a radiation oncology consultation that IMRT was a viable treatment option for that patient's cancer;
 - (iv) the total number of patients newly diagnosed with prostate cancer by CUA urologists from April 1, 2013 through the end of the quarter for which the report is being submitted who, following a consultation with any CUA radiation oncologist, chose to receive IMRT at a facility owned by CUA; and
 - (v) the total number of patients newly diagnosed with prostate cancer by CUA physicians from April 1, 2013 through the end of the quarter for which the report is being submitted who, to the best of CUA's knowledge, following a consultation with any CUA radiation oncologist, chose to receive IMRT at a facility other than one owned by CUA.
4. The Respondent shall provide to the Board any CUA medical or billing records that the Board staff requests in order to verify the data reported by CUA in response to Paragraph 3(i)-(v).
5. The Respondent shall ensure that all patients newly diagnosed with prostate cancer by CUA urologists are provided with materials describing the full range of treatment options for prostate cancer and that all such patients who choose to receive a radiation oncology consultation from a radiation oncologist employed by CUA and who are deemed appropriate candidates for IMRT are informed that there are alternative locations available at which they can receive IMRT.

ORDERED that in the event that the Respondent, at any time during the period April 1, 2013 through October 1, 2014, is unable to ensure adherence by CUA to the requirements set forth in paragraphs 1 through 5 above, the Respondent shall immediately notify the Board as to the reasons why compliance with the requirements is not possible; and be it further

ORDERED that the Board's investigation of Case Number SR 0-9911-1041 is hereby closed; and be it further

ORDERED that, subject to (a) Respondent fulfilling the requirements set forth in paragraphs 1 through 5 above for the period April 1, 2013 through October 1, 2014, and (b) Respondent ensuring that any radiation oncologists employed by CUA continue to work under valid employment contracts that by their terms or in practice do not require referrals to CUA, that no form of remuneration or compensation to the radiation oncologists is directly or indirectly tied to referrals to CUA, and that the radiation oncologists are not directed to make referrals to CUA, the Board will not reconsider the legal question of whether CUA physicians' referrals of patients for radiation oncology consultations and the provision of IMRT at a facility owned by CUA complies with the MPRL; and be it further

ORDERED that subject to the terms of this Consent Agreement the Board reserves all rights it is granted under Maryland law to conduct future investigations ; and be it further

ORDERED that this Consent Agreement is a public document pursuant to Md. St. Govt. Code Ann. §§ 10-611 *et seq.*

3/27/13
Date


Andrea Mathias, M.D.
Chair
Maryland Board of Physicians

CONSENT

I, Sanford Siegel, M.D., acknowledge that I am represented by counsel and have consulted with counsel before entering into this Consent Agreement. By this Consent Agreement and for the sole purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Agreement and its conditions.

I acknowledge the validity of this Consent Agreement. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Agreement.

I sign this Consent Agreement after having an opportunity to consult with counsel, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of the Consent Agreement.

3/27/2013
Date

Sanford Siegel MD
Sanford Siegel, M.D.

Reviewed and Approved by:

HRU
Howard R. Rubin, Esquire

STATE OF: Maryland

CITY/COUNTY OF Baltimore

I HEREBY CERTIFY that on this 27th day of March, ~~2012~~,
2013

before me, a Notary Public of the foregoing State and City/County personally appeared Sanford Siegel, M.D, License Number D32029, and made oath in due form of law that signing the foregoing Consent Agreement was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.



Commission expires:

A handwritten signature in cursive script, reading "Ann M. Lesini", is written over a horizontal line.

Notary Public

ANN M. LESINI
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires 8/13/2015