

**VIRGINIA BOARD OF HEALTH PROFESSIONS
PRACTITIONER SELF-REFERRAL COMMITTEE
INFORMAL CONFERENCE ON REQUEST FOR ADVISORY OPINIONS
AUGUST 29, 2006**

- TIME AND PLACE:** The meeting was called to order at 8:50 a.m. on Tuesday, August 29, 2006 in Conference Room 4 of the Department of Health Professions, 6603 West Broad Street, Richmond, VA.
- MEMBERS PRESENT:** David H. Hettler, O.D., Chair
Juan M. Montero, II, M.D.
- STAFF PRESENT:** Elizabeth A. Carter, Ph.D., Director for the Board
Jim Banning, Executive Director, Administrative Proceedings Division
Ann Joseph, Administrative Proceedings Division
Carol Stamey, Administrative Assistant
- OTHERS PRESENT:** Walter Rabhan, Tuckahoe Orthopaedic Association
Steve McCoy, Esq., Williams Mullen
Wyatt Beazley, IV, Esq., Williams Mullen
Pat Devine, Winchester Orthopaedic Associates and Winchester Neurological Consultants
Jim Daniel, Winchester Orthopaedic Associates and Winchester Neurological Consultants
- QUORUM:** With two members of the Committee present, a quorum was established.
- PURPOSE OF MEETING:** **TUCKAHOE MRI, LLC AND WINCHESTER NEUROLOGICAL CONSULTANTS, INC. AND WINCHESTER ORTHOPAEDIC ASSOCIATES, LTD. AND MEDICAL CIRCLE, LLC.**
In accordance with §2.2-4019 of the *Code of Virginia (1950)*, as amended, the Committee meeting was held to provide an opportunity for the members to discuss the advisory opinion requests as well as the Administrative Proceeding Division's draft advisory opinions and make recommendations to the full Board concerning both requests.
- COMMITTEE RECOMMENDATION:** The Committee was in agreement with the draft advisory opinions as presented. The advisory opinions are incorporated into the minutes as Attachments 1 and 2. The Committee will present the advisory opinions to the full Board for approval at the September 2006 meeting.

APPROVAL OF MINUTES:

The Committee approved the minutes of the December 16, 2005 meeting as presented.

NEW BUSINESS:

In the interest of better efficiency and the need for legal expertise rather than clinical, the members requested that the Board consider proposing statutory and regulatory amendments which would allow for an agency subordinate to review applications for Practitioner Self-Referral advisory opinions and make recommendations accordingly to the full Board.

ADJOURNMENT:

There being no further business, the meeting adjourned at 9:30 a.m.

David H. Hettler, O.D., Chair

Elizabeth A. Carter, Ph.D., Executive Director

SELF-REFERRAL ACT ADVISORY OPINION
RE: Application of Tuckahoe MRI, LLC

FACTS

On August 9, 2006, Tuckahoe MRI, LLC ("Tuckahoe"), submitted an application to the Board of Health Professions for an advisory opinion under the Virginia Practitioner Self-Referral Act ("Act"), Sections 54.1-2410 through 54.1-2414 of the Code of Virginia (1950), as amended ("Code").

Tuckahoe is a Virginia limited liability company owned and operated by Tuckahoe Orthopaedic Associates ("TOA"), a group of physicians who provide a full range of orthopaedic services in Virginia, and Bon Secours Virginia Healthsource, Inc. ("BSVH"), a subsidiary of Bon Secours Richmond Health System, Inc.

Tuckahoe was granted a Certificate of Public Need ("COPN") by the Virginia Department of Health on October 25, 2005, to establish and operate positional magnetic resonance imaging ("MRI") services at 1501 Maple Avenue in Richmond, Virginia, on the first floor of the St. Mary's Medical Office Building IV ("St. Mary's Office"), in which TOA is housed and from which TOA physicians provide their services. But for certain limiting engineering factors, the positional MRI unit would be located in the second-floor offices where TOA physicians actually treat patients.

Tuckahoe intends to draw its referrals from three populations: (i) those patients of TOA whose care is reimbursed by Medicare or Medicaid; (ii) TOA patients whose care is paid for

by commercial payors; and (iii) patients referred by practitioners not associated with TOA. TOA will bill Medicare and Medicaid for their patients treated by TOA physicians, and Tuckahoe will bill each other funding source directly. TOA physicians will be present at the St. Mary's Office to provide a general level of supervision at all times during which Tuckahoe provides positional MRI services to TOA patients and to patients referred by third parties. However, there may be circumstances in which the TOA physician who refers a patient to Tuckahoe for positional MRI services will not be among the physicians who are present in the St. Mary's office.

VIRGINIA PRACTITIONER SELF-REFERRAL ACT

Under the Act, a health care practitioner is prohibited from referring a patient for health services to an entity outside his or her office or group practice if he or she or any immediate family member is an investor in such an entity, unless the Board of Health Professions grants an exception or unless certain other conditions are met. Pursuant to § 54.1-2411(A) of the Code, if the practitioner "directly provides health services within the entity and will be personally involved with the provision of care to the referred patient," the prohibition will not apply. The following definitions, found in § 54.1-2410 of the Code, are pertinent to this discussion:

"Entity" means any person, partnership, firm, corporation, or other business ... that delivers health services.

"Investment interest" means the ownership or holding of an equity or debt security, including, but not limited to, shares of stock in a corporation ...

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership interest, including an investment interest.

"Office practice" means the facility or facilities at which a practitioner, on an ongoing basis, provides or supervises the provision of health services to consumers.

Based on the information provided in the application, by virtue of being shareholders in TOA, TOA physicians will have an investment interest in Tuckahoe. Therefore, the Act applies to the practice of the TOA physicians with respect to their referrals to Tuckahoe.

QUESTIONS

1. Do positional MRI services provided by TOA physicians to their Medicare and Medicaid patients, as described in the Application, comply with the Virginia Practitioner Self-Referral Act under § 54.1-2413(E) of the Code?

Section 54.1-2413 of the Code was amended in 2005 to provide as follows:

E. Notwithstanding the provisions of this chapter, a referral to an entity with which the referring practitioner or his immediate family member has an arrangement that would qualify for an exception under federal practitioner self-referral law, 42 U.S.C. § 1395nn, as amended, or any regulations adopted pursuant thereto, permitting a practitioner or an immediate family member to maintain an ownership or investment interest in an entity that provides designated health services shall not be in violation of this chapter, regardless of the type of health services provided or the source of payment for such service.

As indicated in the Application, for purposes of Medicare or Medicaid reimbursement for MRI services, physicians may refer patients to entities in which they have an ownership interest if they meet the In-Office Ancillary Services Exception to the federal self-referral law. Pursuant to 42 CFR § 411.355(b), this exception will be met if the following conditions apply:

(i) the MRI services are performed personally by (a) the referring physician; (b) another physician who is a member of the referring physician's group practice; or (c) an individual who is supervised by the referring physician or another physician in his/her group practice;

(ii) the MRI services are performed in the same building in which the referring physician or members of his group practice regularly practice medicine; and

(iii) the MRI services are billed by the physician performing or supervising the service or his or her group practice under a billing number assigned to the group.

The Application indicates that with respect to their Medicare and Medicaid patients, TOA will lease the space, equipment, supplies, and personnel from Tuckahoe for certain periods of time each week on an exclusive basis and will refer these patients for positional MRI services only during these times. Such services will be provided under the general or direct supervision of TOA physicians and Medicare and Medicaid will be billed by TOA under numbers assigned to the practice. This exclusive sublease arrangement, coupled with the level of supervision and the billing procedure, ensures that the physician shareholders of TOA will meet the In-Office Ancillary Services Exception to the federal prohibition on physician self-referrals. Assuming that it would qualify for an exception under the federal law, this arrangement would meet the exception of § 54.1-2413(E) of the Virginia Code with respect to referrals of TOA's Medicare and Medicaid patients to Tuckahoe.

2. Is the Tuckahoe Positional MRI space within the "office practice" of those TOA physicians who provide general supervision of their patients receiving positional MRI services from Tuckahoe in the manner described in the Application?

For Tuckahoe positional MRI services to be considered part

of the office practice of TOA physicians so as to meet the exception to the self-referral act, the physicians must "on an ongoing basis, provide or supervise the provision of" such services. The Act does not define the terms "supervise" or "on an ongoing basis." Such terms should be given their usual, commonly understood meanings, in accordance with rules of statutory construction. To "supervise" means to watch over a particular activity or task being carried out by other people and ensure that it is carried out correctly (Encarta World English Dictionary). "On an ongoing basis" has been defined as "consistent with the concept of services being available on 'a continuing, day to day basis,' 'an exclusive, permanent and full time' basis or a 'regular or regularly' scheduled basis." (Advisory Opinion of the Board of Health Professions in the Matter of *InVision Healthcare, Inc.*, quoting Advisory Opinion of the Board of Health Professions in the Matter of *Vistar Eye Center, Inc.*, quoting *Tryc v. Michigan Veterans' Facility*, 451 Mich. 129, 545 N.W.2d 642 (1996 Mich.).)

The regulations interpreting the federal self-referral act indicate that the "general supervision" requirement of that act with respect to positional MRI services would be met if "the procedure is furnished under the physician's overall direction and control ... [and] the training of the non physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician." 42 CFR § 410.32(b)(3)(i). The federal regulation does not require the physician to be

physically present during the performance of the procedure.

Similarly, the prevailing standard of care in Central Virginia, as attested to by a radiologist who practices in Richmond, appears to accept that diagnostic radiology services do not require the physical presence of the physician as long as the physician retains supervisory authority over his or her patients' care.

Likewise, neither the Virginia Act nor prior advisory opinions of the Board specifically require that the physicians be physically present in order to be providing supervision of services on an ongoing basis such as to meet the "office practice" exception. Complying with generally accepted medical practices may be considered supervision on an ongoing basis if, in his or her clinical judgment, the referring physician considers himself or herself to be supervising the services provided by non-physician personnel at Tuckahoe MRI.

The Application indicates that TOA physicians will consider themselves to be supervising the care provided at Tuckahoe Positional MRI through their physicians' orders, review of films and diagnostic radiology reports, and revisions to their patients' treatment plans as medically appropriate based on the results of positional MRI studies. Accordingly, as long as TOA physicians' practice is consistent with the generally accepted definition of "supervise on an ongoing basis" as found in federal regulation, prior Board opinions, and the prevailing standard of care in the community, this proposed level of supervision would meet the requirements of the Act.

RECOMMENDATION

For the reasons set forth above, the Committee shall recommend to the Board of Health Professions, pursuant to 18 VAC 75-20-60(E), that:

(1) If a TOA physician refers a patient to Tuckahoe during the period that TOA maintains an exclusive sublease of Tuckahoe equipment, personnel, and services and provides a level of supervision that comports with the In-Office Ancillary Services Exception to the federal self-referral prohibition, the arrangement would satisfy the exception to the Act enumerated in § 54.1-2413(E) of the Code; and

(2) If a TOA physician supervises on an ongoing basis the care provided to his or her patients at Tuckahoe consistent with the generally accepted definition found in federal regulation, prior Board opinions, and the prevailing standard of care in the community, his or her referral of patients to Tuckahoe would satisfy the "office practice" exception of § 54.1-2411(A) of the Code.

Attachment 2

SELF-REFERRAL ACT ADVISORY OPINION
RE: Joint Application of Winchester Neurological Consultants,
Inc.
Winchester Orthopaedic Associates, Ltd. and Medical Circle, LLC

On August 8, 2006, Winchester Neurological Consultants, Inc., Winchester Orthopaedic Associates, Ltd., and Medical Circle, LLC (collectively, the "Applicant"), submitted an application to the Board of Health Professions for an advisory opinion under the Virginia Practitioner Self-Referral Act

("Act"), sections 54.1-2410 through 54.1-2414 of the Code of Virginia (1950), as amended ("Code").

Winchester Neurological Consultants, Inc. ("WNC"), is a Virginia corporation consisting of physician-shareholders who practice in the areas of neurology and neurosurgery. WNC's main office is at 125 Medical Circle in Winchester, Virginia. Five of the practice's ten physicians are housed in the main office, while the other five practice from a satellite office nearby. WNC's shareholders own Neurological Properties, LLC ("NP"), which holds title to the real estate and improvements where WNC's main office is located, and NP leases that space to WNC. Winchester Orthopaedic Associates, Ltd. ("WOA"), is a Virginia professional corporation whose physician-shareholders all practice out of its sole office, located at 128 Medical Circle, Winchester, adjacent to WNC's main office. WOA's shareholders own Medical Associates Specialty Holdings, LLC ("MASH"), which holds title to the real estate and improvements where WOA's office is located, and MASH leases that space to WOA. Medical Circle, LLC, is a limited liability company owned by Winchester Medical Center (the area's regional acute care hospital) and by NP and MASH.

Medical Circle, LLC, was granted a Certificate of Public Need ("COPN") by the Virginia Department of Health on June 19, 2006, to establish and operate magnetic resonance imaging ("MRI") services in Winchester. The Applicant's plan is to house the MRI equipment in a suite that would connect the offices of 125 Medical Circle and 128 Medical Circle, effectively creating a new building in which all three facilities would be housed and which

would be called 125A Medical Circle. Medical Circle, LLC, will lease the MRI suite and adjoining space in the building from NP and MASH.

Medical Circle, LLC, intends to draw its referrals from three populations: (i) those patients of WNC and WOA whose care is reimbursed by Medicare or Medicaid; (ii) WNC and WOA patients whose care is paid for by commercial payors or who are self-insured; and (iii) patients referred by practitioners not associated with WNC or WOA. WNC and WOA will bill Medicare and Medicaid for services provided to their respective patients who are insured by these federally funded programs. Medical Circle, LLC, will bill all other funding sources directly. WNC and WOA physicians will be present in the building to provide a general level of supervision at all times during which Medical Circle, LLC, provides MRI services to their patients. However, there may be circumstances in which the WNC or WOA physician who refers a patient to Medical Circle, LLC, for MRI services will not be among the physicians who are present at the time a particular patient is receiving MRI services.

VIRGINIA PRACTITIONER SELF-REFERRAL ACT

Under the Act, a health care practitioner is prohibited from referring a patient for health services to an entity outside his or her office or group practice if he or she or any immediate family member is an investor in such an entity, unless the Board of Health Professions grants an exception or unless certain other conditions are met. Pursuant to § 54.1-2411(A) of the Code, if the practitioner "directly provides health services within the

entity and will be personally involved with the provision of care to the referred patient," the prohibition will not apply. The following definitions, found in § 54.1-2410 of the Code, are pertinent to this discussion:

"Entity" means any person, partnership, firm, corporation, or other business ... that delivers health services.

"Investment interest" means the ownership or holding of an equity or debt security, including, but not limited to, shares of stock in a corporation ...

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership interest, including an investment interest.

"Office practice" means the facility or facilities at which a practitioner, on an ongoing basis, provides or supervises the provision of health services to consumers.

Based on the information provided in the Application, by virtue of being shareholders in WNC and WOA, WNC and WOA physicians will have an investment interest in Medical Circle, LLC. Therefore, the Act applies to the practice of the WNC and WOA physicians with respect to their referrals to Medical Circle, LLC.

1. Do MRI services provided by WNC and WOA physicians to their Medicare and Medicaid patients, as described in the Application, comply with the Virginia Practitioner Self-Referral Act?

Section 54.1-2413 of the Code was amended in 2005 to provide as follows:

E. Notwithstanding the provisions of this chapter, a referral to an entity with which the referring practitioner or his immediate family member has an arrangement that would qualify for an exception under federal practitioner self-referral law, 42 U.S.C. § 1395nn, as amended, or any regulations adopted pursuant thereto, permitting a practitioner or an immediate family member to maintain an ownership or investment interest in an entity that provides designated health services shall not be in violation of this chapter, regardless of the type of health services

provided or the source of payment for such service.

As indicated in the Application, for purposes of Medicare or Medicaid reimbursement for MRI services, physicians may refer patients to entities in which they have an ownership interest if they meet the In-Office Ancillary Services Exception to the federal self-referral law. Pursuant to 42 CFR § 411.355(b), this exception will be met if the following conditions apply:

(i) the MRI services are performed personally by (a) the referring physician; (b) another physician who is a member of the referring physician's group practice; or (c) an individual who is supervised by the referring physician or another physician in his/her group practice;

(ii) the MRI services are performed in the same building in which the referring physician or members of his group practice regularly practice medicine; and

(iii) the MRI services are billed by the physician performing or supervising the service or his or her group practice under a billing number assigned to the group.

The Application indicates that with respect to their Medicare and Medicaid patients, WNC and WOA will each lease the space, equipment, supplies, and personnel from Medical Circle, LLC, for certain periods of time each week on an exclusive basis and will refer these patients for MRI services during these times only. Such services will be provided under the general or direct supervision of WNC or WOA physicians and Medicare and Medicaid will be billed by each practice, under numbers assigned to the practices. These exclusive sublease arrangements, coupled with the level of supervision and the billing procedure, ensures that the physician shareholders of WNC and WOA will meet the In-Office Ancillary Services Exception to the federal prohibition on

physician self-referrals. Assuming that it would qualify for an exception under the federal law, this arrangement would meet the exception of § 54.1-2413(E) of the Virginia Code with respect to referrals of WNC's and WOA's Medicare and Medicaid patients to Medical Circle, LLC.

2. Is the Medical Circle, LLC, MRI space within the "office practice" of those WNC and WOA physicians who provide general supervision of their patients receiving MRI services from Medical Circle, LLC, in the manner described in the Application?

For the MRI services of Medical Circle, LLC, to be considered part of the office practice of WNC and WOA physicians so as to meet the exception to the self-referral Act, the physicians must "on an ongoing basis, provide or supervise the provision of" such services. The Act does not define the terms "supervise" or "on an ongoing basis." Such terms should be given their usual, commonly understood meanings, in accordance with rules of statutory construction. To "supervise" means to watch over a particular activity or task being carried out by other people and ensure that it is carried out correctly (Encarta World English Dictionary). "On an ongoing basis" has been defined as "consistent with the concept of services being available on 'a continuing, day to day basis,' 'an exclusive, permanent and full time' basis or a 'regular or regularly' scheduled basis." (Advisory Opinion of the Board of Health Professions in the Matter of *InVision Healthcare, Inc.*, quoting Advisory Opinion of the Board of Health Professions in the Matter of *Vistar Eye Center, Inc.*, quoting *Tryc v. Michigan Veterans' Facility*, 451 Mich. 129, 545 N.W.2d 642 (1996 Mich.).)

The regulations interpreting the federal self-referral act

indicate that the "general supervision" requirement of that act with respect to MRI services would be met if "the procedure is furnished under the physician's overall direction and control ... [and] the training of the non physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician." 42 CFR § 410.32(b)(3)(i). The federal regulation does not require the physician to be physically present during the performance of the procedure.

Likewise, neither the Virginia Act nor prior advisory opinions of the Board specifically require that the physicians be physically present in order to be providing supervision of services on an ongoing basis such as to meet the "office practice" exception. Complying with generally accepted medical practices may be considered supervision on an ongoing basis if, in his or her clinical judgment, the referring physician considers himself or herself to be supervising the MRI services provided by non-physician personnel at Medical Circle, LLC.

The Application indicates that WNC and WOA physicians will consider themselves to be supervising the care provided by Medical Circle, LLC, through their physicians' orders, review of films and diagnostic radiology reports, and revisions to their patients' treatment plans as medically appropriate based on the results of MRI studies. Accordingly, as long as WNC and WOA physicians' practice is consistent with the generally accepted definition of "supervise on an ongoing basis" as found in federal regulation and prior Board opinions, this proposed level of

supervision would meet the requirements of the Act.

RECOMMENDATION

For the reasons set forth above, the Committee shall recommend to the Board of Health Professions, pursuant to 18 VAC 75-20-60(E), that:

(1) If a WNC or WOA physician refers a patient to Medical Circle, LLC, for MRI services during the period that each practice maintains an exclusive sublease of Medical Circle, LLC's, equipment, personnel, and services and provides a level of supervision that comports with the In-Office Ancillary Services Exception to the federal self-referral prohibition, the arrangement would satisfy the exception to the Act enumerated in § 54.1-2413(E) of the Code; and

(2) If a WNC or WOA physician supervises on an ongoing basis the care provided to his or her patients by Medical Circle, LLC, consistent with the generally accepted definition found in federal regulation and prior Board opinions, his or her referral of patients to Medical Circle, LLC, would satisfy the "office practice" exception of § 54.1-2411(A) of the Code.