

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

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November 25, 2013

Daniel F. Murphy, Esq. Bradley Arant Boult Cummings One Federal Place 1819 Fifth Ave N Birmingham AL 35203-2119

Dear Mr. Murphy:

On November 13, 2013, the Alabama Board of Medical Examiners met and considered your request for an advisory opinion concerning joint ownership of an Alabama limited liability limited partnership by physician owned legal entities and a non-physician owned legal entity. The question you presented was the following:

May a legal entity owned and operated by non-physicians (FVC) enter into an equity joint venture organized as an Alabama limited liability limited partnership ("LLLP") under the Alabama Business and Nonprofit Entities Code with legal entities owned and operated by Alabama-licensed physicians (MKS and RAM) or one or more investment entities owned by physicians of MKS and RAM) for the purpose of providing professional medical services (physician office-based vascular access procedures)?

Based upon the facts and information presented in your September 26, 2013, letter, it is the opinion of the Alabama Board of Medical Examiners that the question you have posed should be answered in the affirmative, and that a plain reading of the statutory provisions concerning LLPs or LLLPs does not prohibit or otherwise restrict the joint venture which you describe in your letter.

Please be advised that this opinion rendered by the Board of Medical Examiners is based upon the information and facts presented in your September 26, 2013, letter to Larry Dixon, is for guidance only, and should not be considered to have the force and effect of a standard promulgated as an administrative rule.

Daniel F. Murphy, Esq. November 25, 2013 Page 2

If you have any questions, please contact my office.

Sincerely,

ALABAMA BOARD OF MEDICAL EXAMINERS

Patricia E. Shaner General Counsel

PES:chk

cc: Cynthia Ransburg-Brown, Esq.

Mr. Larry D. Dixon



September 26, 2013

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BY FEDEX AND E-MAIL

Mr. Larry Dixon Executive Director Alabama Board of Medical Examiners 848 Washington Avenue Montgomery, AL 36104

RE: Request for Advisory Opinion; Joint Ownership of Alabama Limited Liability Limited Partnership by Physician-Owned Legal Entities and a Non-Physician Legal Entity

Dear Mr. Dixon:

On behalf of Fresenius Vascular Care, Inc. ("FVC"), Montgomery Kidney Specialist, L.L.P. ("MKS"), and Renal Associates of Montgomery, P.C. ("RAM"), we are writing to request an advisory opinion from the Alabama Board of Medical Examiners ("Board") regarding a potential joint venture (the "Joint Venture") among FVC, MKS, and RAM (collectively, the "Parties") that would own and operate a vascular access center ("VAC"). As described more specifically below, we request the Board's opinion on the following question:

May a legal entity owned and operated by non-physicians (FVC) enter into an equity joint venture organized as an Alabama limited liability limited partnership ("LLLP") under the Alabama Business and Nonprofit Entities Code with legal entities owned and operated by Alabama-licensed physicians (MKS and RAM or one or more investment entities owned by physicians of MKS and RAM) for the purpose of providing professional medical services (physician office-based vascular access procedures)?

Facts

FVC is an affiliate of Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, the largest operator of end-stage renal disease ("ESRD") clinics in the nation. FVC focuses on owning, operating and/or managing VACs in which physicians perform vascular access procedures, such as arteriovenous fistulae and fistula grafts, to, among other matters, prepare patients with late-stage chronic kidney disease or ESRD for renal replacement therapy by creating permanent vascular access sites. MKS and RAM are physician group practices located in Montgomery, Alabama comprised of Alabama-licensed nephrologists.

The VAC operated by the Joint Venture would function as a physician group practice, perform only procedures appropriate for physician offices (as opposed to ambulatory surgery centers or hospital outpatient surgery departments), and enroll with third-party payors (e.g.

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Medicare) as a physician group. 1 Certain individual physician owners and employees of MKS and RAM may provide professional services at the Joint Venture VAC, while FVC would provide non-professional administrative services to the Joint Venture pursuant to an Administrative Services Agreement. Additionally, the Joint Venture VAC may contract for professional services with a third-party physician unaffiliated with the investors. In all matters related to the Joint Venture, FVC would exercise no control over the professional judgment of the physicians and the Joint Venture agreements would contain contractual provisions prohibiting such control by FVC.

The Joint, Venture would be organized and governed as an Alabama LLLP, a form of legal entity that (1) was first recognized in Alabama as of January 1, 2011 pursuant to the Alabama Business and Nonprofit Entities Code (the "Code") and (2) did not exist in the state of Alabama prior to 2011. The Joint Venture would be owned 51% by FVC and 49% by MKS and RAM, either as separate investors, or through one or more newly-formed entities to be owned by MKS and RAM or their physicians.

Discussion

For the reasons described below, we respectfully request that the Board respond to the advisory opinion question stated above in the affirmative. Based on our review of applicable law, regulations, and other guidance, it does not appear that (1) the Alabama Medical Practice Act, Board rules, or guidance, or (2) the Code prohibit physicians and non-physician corporate entities from forming a joint venture that is organized as an Alabama LLLP to provide professional vascular access services.

Medical Practice Act and Previous Board Advisory Opinions

We have reviewed the Medical Practice Act, as well as the Alabama Administrative Code regulations promulgated under the Medical Practice Act, and found no provisions that would prohibit the ownership structure contemplated by the Joint Venture LLLP described above.

The Board previously issued advisory opinions prohibiting certain forms of physician joint ventures with non-physicians. Specifically, in a June 26, 2008 opinion, the Board held that a limited liability company ("LLC") through which a licensed physician performs medical services must be officially organized to perform medical services in the LLC's initial organizational documents. In the 2008 advisory opinion, the Board answered the following question in the negative: "[C]an a licensed physician perform medical services in a LLC that was not organized (either initially or by amendment) to specifically perform professional services?"

¹ The Parties will separately seek a determination of non-reviewability from the Alabama State Health Planning and Development Agency with respect to the Alabama certificate of need law.

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In a Board opinion dated January 24, 1994 (*sic*) in response to a request made in November 1998, the Board held that physicians and non-physicians could not jointly own either a LLC or a limited liability partnership ("LLP").

Both the 2008 and the 1994 (*sic*) opinions are based on statutory interpretations of Alabama business entity laws that are no longer in effect. *See* Ala. Code §10-12-45 (Limited Liability Company Act) and §10-8A-1010 (Limited Liability Partnership Act), which have been replaced by the Code. In addition to being based on statutes that have since been repealed, the 2008 and 1994 opinions (1) do not address the LLLP entity form and (2) are based on the concept of a "qualified" professional that does not exist within the statutory text governing Alabama LLLPs.

The Board's previous opinions restricting joint ownership of LLCs and LLPs were not based on concerns about non-professionals influencing physicians' professional judgment. This makes sense because non-physicians are not prohibited from 100% ownership of legal entities that perform professional medical services. Rather, the 2008 and 1994 opinions are based solely on statutory interpretations of the applicable business entity laws in effect at the time of the advisory opinion requests. For example, we are aware of no current state law or Board guidance that would prohibit general business corporations (as opposed to professional corporations) with physician and non-physician owners from furnishing professional medical services. This also makes sense because, to date, the Board's joint venture opinions have (1) relied on statutory interpretations of the Code and other Alabama business entity laws; and (2) the pre-Code business corporation statute would not support restrictions on physician / non-physician ownership.

Statutory Construction of Alabama Business and Nonprofit Entities Code on LLLPs

Since January 1, 2011, the Code³ has governed business entities formed under Alabama law or qualified to do business as foreign entities in Alabama. Prior to the adoption of the Code, including when the Board previously issued its advisory opinions related to joint-ventured LLCs and LLPs, the LLLP legal entity form did not exist in Alabama. We note that the Code is structured as a "hub-and-spoke" statute with certain general provisions that apply to all business entities (the hub) and other provisions that apply only to specific types of entities (the spokes). Due to the novelty of the LLLP under Alabama law, our request is specifically limited to this entity type only. We are not requesting the Board's opinion on joint physician / non-physician ownership of any other type of legal entities under the Code. In addition, we do not believe that an opinion based on the statutory interpretation of the Code provisions applicable to LLLP's would impact other types of legal entities, but rather would be confined in effect to the LLLP "spoke" of the Code.

Pursuant to Section 10A-9-1.02 of the Code, a limited partnership ("LP") may elect to be treated as an LLLP by stating on its certificate of formation that it is an LLLP. The LLLP is,

² See, 1992 Declaratory Rulings - Brookwood Health Services, Inc.

³ Title 10A of the Code of Alabama.

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therefore, a special sub-category of LP. Neither the LP section of the Code (the Alabama Uniform Limited Partnership Law of 2010, Chapter 9 of Title 10A), nor the generally applicable (a/k/a "hub") provisions of the Code (Chapter 1 of Title 10A) contain any provisions that would require an LLLP that provides professional services to organize itself as a professional form of LLLP, nor do any restrictions exist in these section of the Code that would prevent professional and non-professional partners in an LLLP that provides professional services. Moreover, the generally applicable, LP and LLLP-specific provisions of the Code do not include a concept similar to that of a "qualified person" (e.g. a professional licensed in the type of service provided by the entity) such as exists in the context of Professional Corporations (Chapter 4 of Title 10A) and LLCs.

We, therefore, do not interpret the text of the statutory provisions concerning LPs or LLLPs to prohibit or otherwise restrict the Joint Venture described above.

Please do not hesitate to contact us with any questions.

Sincerely,

Daniel F. Murphy Counsel to FVC

Cynthia Ransburg-Brown

Counsel to

Renal Associates of Montgomery, P.C. Montgomery Kidney Specialists, LLP

DFM/rl

cc:

Patricia Shaner, Esq. William Addison, Esq.

QUESTIONS AND ANSWERS NOVEMBER, 2004

WHAT IS FISTULA FIRST?

Fistula First is the name given to the National Vascular Access Improvement Initiative. This quality improvement project is being conducted by all 18 ESRD Networks to promote the use of Arteriovenous Fistulas (AVFs) in all suitable dialysis patients.

WHAT IS AN ARTERIOVENOUS FISTULA (AVF)?

Hemodialysis is a process of cleaning the blood of waste products when the kidneys can no longer perform this function. All hemodialysis patients need a "connection" that allows blood from an artery to flow into the vein and provide access for dialysis. An Arteriovenous Fistula (AVF) is considered by professionals to be the "gold standard." National practice guidelines, which were developed by renal experts, recommend that 40% of all current patients and 50% of new patients should have an AV fistula as their primary access. Currently, only about 30% of Medicare beneficiaries dialyze with a fistula.

ARE AVFS BETTER FOR PATIENTS?

AVFs are considered the best vascular access because they demonstrate the best overall performance, have fewer infections which can lead to hospitalizations, tend to last for a longer time than other access types and allow for increased blood flow resulting in a more adequate dialysis treatment.

HOW ARE AVFS PLACED?

A surgeon creates an AVF by connecting an artery directly to a vein, usually in the forearm. Connecting the artery to the vein causes more blood to flow into the vein. As a result, the vein grows larger and stronger, making repeated needle insertions easier. The procedure can be performed on an outpatient with a local anesthetic but requires some advanced planning.

ARE THERE OTHER TYPES OF ACCESSES?

Yes, patients can also have a graft or a catheter, which is usually a temporary access. If you have small veins that won't develop properly into a fistula, you can have a vascular access that uses a synthetic tube implanted under the skin in your arm. The tube becomes an artificial vein that can be used repeatedly for needle insertion. If your kidney disease has progressed quickly, you may not have time to get a permanent vascular access before you start hemodialysis treatments. A catheter is a tube inserted into a vein in your neck, chest or leg. It has two chambers to allow two-way flow of blood. Catheters are not ideal for permanent access as they can clog, become infected or cause narrowed veins. It is recognized that fistulas are the best access.

WHAT IS CMS DOING TO INCREASE FISTULAS?

CMS has identified this project as a CMS Breakthrough Initiative. To qualify as a breakthrough initiative, a project must meet certain criteria: there is a substantial gap between known good practice and actual practice; and a very substantial improvement in performance seems possible. CMS intends to coordinate work in these areas across the organization, using payment, coverage, public information, partnership development and other strategies to leverage greater change.

HAVE GOALS BEEN ESTABLISHED?

CMS would like to see the percentage of patients with fistulas as their access increase to 66% over the next 5 years. Each of the ESRD Networks, as CMS contractors, has been assigned a goal to achieve in their area before June 2006.

ARE THE GOALS ACHIEVABLE?

All across the United States, there are examples of providers who have achieved fistula rates in their patients well above the goals of this initiative. By harnessing the knowledge of the many disciplines whose care influence vascular access choices for patients, this project aims to create a new level of cooperation and communication across professional disciplines and care settings.

WHO IS INVOLVED?

In addition to CMS, project partners include the 18 ESRD Networks, dialysis providers across the country, nephrologists, vascular access surgeons, interventional radiologists, interventional nephrologists, nursing and other care giver groups, beneficiary representative groups, Quality Improvement Organizations, Federal Agencies, and other CKD and ESRD stakeholders. The Institute for Healthcare Improvement (IHI) and Clinical Chair Lawrence Spergel, MD, have assisted in developing a package of 11 "change concepts" and are supporting the ESRD Networks as they develop and implement strategies for spreading the recommended changes.

WHEN DID THIS PROJECT START?

Work began on the early phase of the initiative in July 2003. A multi-disciplinary team from CMS, the ESRD Networks and major stakeholder groups was convened to develop a firm and broad understanding of the challenges and successes for fistula placement within the dialysis and surgical communities. Based on this early work, a set of improvement recommendations and tools was developed. In April 2004, the CMS Public Affairs Office released a press release announcing the project. In November 2004 the CMS Administrator recognized the project as a Breakthrough Initiative.

CAN YOU DEFINE A CHANGE CONCEPT?

A change concept is a general approach to change that has shown usefulness in developing specific ideas for changes that lead to improvement. Change concepts are intended to encourage development of specific changes that make sense within a particular setting. There are 11 change concepts that have been identified to help the Networks and dialysis providers implement this project and achieve the desired outcomes.

WHAT CAN NEPHROLOGISTS DO TO PROMOTE A-V FISTULAS?

There are a number of strategies that a nephrologist can pursue to help with this project. A few are listed here.

- Familiarize themselves with and implement applicable National practice guidelines
- Refer pre-ESRD patients for timely permanent access placement
- Advocate for appropriate access selection and placement with surgeons
- Participate in and support staff vascular access education initiatives
- Implement access monitoring and intervention protocols at the facility level
- Educate and encourage patients to seek AVFs as a permanent access

CAN NURSES AND TECHNICIANS HELP?

Of course. Here are some things that nurse and technicians can do.

- Familiarize themselves with and help implement applicable National practice guidelines
- Establish CQI programs in vascular access/monthly review of vascular access outcomes
- Educate pre-ESRD patients about the importance of AVF, and encourage them to seek AVF as permanent access
- Educate patients on proper care and preventive measures that increase access longevity
- Participate in routine monitoring access programs for stenosis and complications, and prompt referral for abnormal findings (e.g., stenosis, recirculation, unexplained decreased Kt/V)
- Cannulation education and training
- Offer patients self-cannulation where feasible
- Rotate needle cannulation sites