

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

April 1, 2016

Marcus C. Hewitt
434 Fayetteville Street, Suite 2800
Raleigh, NC 27601

No Review

Record #: 1914
Business Name: Fresenius Vascular Care, Inc.
Business #: 2373
Project Description: Acquire majority ownership interest in an existing vascular access center which is not a health service facility
County: Caldwell

Dear Mr. Hewitt:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of March 29, 2016 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Marcus C. Hewitt
April 1, 2016
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Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Julie Halatek
Project Analyst



Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Kelli Fisk, Program Assistant, Healthcare Planning, DHSR

March 29, 2016

Via Email to lisa.pittman@dhhs.nc.gov

Lisa Pittman
North Carolina Dept. of Health and Human Services
Div. of Health Svc. Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704



Re: Fresenius Vascular Care, Inc.

Dear Ms. Pittman:

We are writing on behalf of Fresenius Vascular Care, Inc. ("Fresenius"), to request confirmation from the Agency that a potential acquisition being considered by Fresenius is not subject to CON review. I previously spoke with you by telephone about this potential acquisition on Tuesday, February 16th, at which time you indicated that the potential acquisition does not require CON review. This letter is to confirm that conversation.

Fresenius is considering an acquisition whereby Fresenius would form and have a majority ownership interest in an entity (the "Management Company"), in which an existing medical practice (the "Practice") would have a minority ownership interest. The Management Company would acquire certain assets currently held by the Practice and manage that Practice under a management services agreement. Among the assets to be acquired is an existing vascular access center in Lenoir, NC (Caldwell County), including an office lease, equipment and other assets currently used by the Practice to perform in-office vascular access procedures.

The Practice currently does not and is not required to have a CON for its vascular access center. The procedures performed there do not require a licensed operating room and the total of medical diagnostic equipment in the vascular access center is less than \$500,000. Therefore the existing vascular access center is neither an ambulatory surgery center, a diagnostic center, nor any other type of health service facility as defined by N.C. Gen. Stat. § 131E-176(9b).

Fresenius anticipates spending more than \$2,000,000 for the assets to be acquired from the Practice, including the vascular access center. However, we do not believe the acquisition and change of ownership of those assets is subject to CON review. First, an acquisition of an

SMITHMOORE
LEATHERWOOD
ATTORNEYS AT LAW

March 29, 2016

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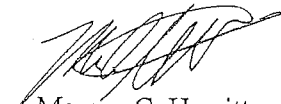
existing vascular access center is not a "health service" under N.C. Gen. Stat. § 131E-176(9a) because a change of ownership is merely an administrative activity not integral to clinical management. The Practice's sale and contribution of assets to the Management Company entity would be administrative in nature, and would not change or expand the services offered by the practice or by the existing vascular access center. Therefore, there would be no capital expenditure relating to the provision of a health service pursuant to § 131E-176(16)(b).

Second, the existing vascular access center is not a health service facility, and is therefore not regulated by the Agency. Consequently, no CON would be required to acquire an ownership interest in the vascular access facility.

We would appreciate if the Agency would confirm that the acquisition and change of ownership described herein is not subject to CON review. Thank you, and please let us know if you have questions or would like to discuss.

Sincerely,

Smith Moore Leatherwood LLP



Marcus C. Hewitt

MCH/akb