

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

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

January 24, 2014

William R. Shenton Poyner Spruill P.O. Box 1801 Raleigh, NC 27602-1801

No Review

Facility:

Charlotte East Dialysis Center

Project Description:

Relocate existing home hemodialysis and peritoneal dialysis training

services from Charlotte Dialysis Center to Charlotte East Dialysis Center

County:

Mecklenburg

FID #:

120164

Dear Mr. Shenton:

The Certificate of Need Section (CON Section) received your letter of December 27, 2013 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.

Moreover, your client needs to contact the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation 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 by you. 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 the Certificate of Need Section. 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.



Certificate of Need Section

www.ncdhhs.gov
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William R. Shenton January 24, 2014 Page 2

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) for an existing facility.

Sincerely,

Martha J. Frisone, Interim Chief Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Poyner Spruill¹¹⁰

FID# 120164

December 27, 2013

William R. Shenton Partner D: 919.783.2947 F: 919.783.1075 wshenton@poynerspruill.com

VIA HAND DELIVERY

Craig R. Smith, Chief CON Section Division of Health Service Regulation N.C. Dept. of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

VIA HAND DELIVERY

Martha Frisone, Assistant Chief CON Section Division of Health Service Regulation N.C. Dept. of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

RE: Exemption for Relocation of DVA Healthcare Renal Care Home Training Program

Dear Mr. Smith and Ms. Frisone:

I am writing as counsel to DVA Healthcare Renal Care, Inc. ("DVA"), an affiliate of DaVita Healthcare Partners, Inc. As you may be aware from prior conversations about this matter with Bill Hyland, DVA currently operates a program in Charlotte to train patients on home peritoneal dialysis as well as home hemodialysis. The home training program is located on the second floor of the Charlotte Dialysis Center located at 2321 West Morehead Street.

Due to ongoing physical plant problems in the building, DVA has concluded that it is critical to move the home training program from the Charlotte Dialysis facility to its Charlotte East facility. DVA plans to submit a certificate of need application in January proposing to build on about 3,500 square feet to its existing Charlotte East facility to house six home dialysis training rooms. However, at this point DVA is seeking:

A determination that relocating the home training program immediately, on a temporary basis, to existing space in its Charlotte East facility is not a new institutional health service that is subject to the Certificate of Need Law; or

Alternatively, an exemption from review allowing DVA to relocate the home training program immediately and to continue to operate the home training program at DVA's Charlotte East facility for a period of one year, or until the point when the additional space for home training rooms that will be proposed in the upcoming application has been constructed and is ready for use.

This letter will present background information on the physical plant problems at the Charlotte Dialysis Center, and the details of what DVA is proposing.

BACKGROUND

The Charlotte Dialysis facility has been in operation at 2321 Morehead Street since the building was built around 30 years ago. The first floor of the building contains the in-center dialysis facility and office space

for facility staff and physicians, as well as other space that is used to support the in-center treatments. The second floor of the building is the area where patients receive both their initial training in home dialysis as well as follow-up care. A floor plan of both floors is attached as Exhibit A.

Unfortunately, ongoing physical plant problems involving both the elevator and the HVAC system are making it infeasible to continue operating the home training program on the second floor.

Problems With The Elevator

Most dialysis patients have other serious health problems, including obesity and diabetes, and few if any can easily climb the stairs to the second floor of the building on Morehead Street, so the elevator is an essential means of their access to the home training area on the second floor. However, there have been many times over the past few years when the elevator at 2321 Morehead Street has not been operating smoothly and a number of periods when the elevator has been closed for repairs. On a few occasions, DaVita teammates have been trapped on the elevator, and on one occasion a patient was on the elevator when it malfunctioned. The elevator problems have significantly impeded the training of new home dialysis patients, as well as the provision of follow-up care to existing home patients.

HVAC Problems at 2321 Morehead Street

Another factor affecting the home training operations on the second floor has been the malfunctioning HVAC system, which has resulted in a number of service calls over the past 18 months. At various points over this period, the air conditioning has been running when heat is needed, and heat has been on when air conditioning is required. With the overall health status of dialysis patients, this poses significant problems for providing home training and follow-up care.

Impact on Patient Care

Patients are identified as appropriate candidates for home dialysis after a detailed review and analysis of the patient's history, prognosis, and family circumstances. Patients who have undergone this process have a justifiable expectation that once they complete it, they will be able to receive training and be able to start on a home modality in the near future, which can have a significant positive impact in avoiding trips to a dialysis facility for in-center dialysis several times each week. DVA and all affiliates in the DaVita Healthcare Partners system emphasize home training as an important alternative for dialysis patients and their families. However, the issues with the elevator and HVAC system make it difficult and uncomfortable for new home patients to be trained and existing patients to continue their training at the Charlotte Dialysis facility. Additionally, it bears noting that these building issues also touch on requirements under the Medicare Conditions of Participation for Dialysis Facilities which include a requirement at 42 CFR § 494.60 that the facility must be "designed, equipped and maintained to provide dialysis patients, staff and the public a safe, functional and comfortable treatment environment." The combination of the elevator and HVAC issues make it imperative to relocate the home training program.

Alternative Explored

In looking at ways to solve these issues, DVA has considered an alternative to the relocation of the home training program including the hemodialysis stations; but has determined that it will not solve the problem. The alternative that was identified would be moving the home training program to the first floor of the 2321 Morehead Street building; but that is impractical because there is no space there that could be used. The treatment area does have hemodialysis machine hook ups, but of course all of those stations are devoted to in-center treatments. There are no other suitable areas on the first floor that are available due to their current uses in supporting the in-center program.

THE PROPOSED RELOCATION

The Charlotte East Dialysis facility recently completed a certificate of need project for the addition of stations. The relocation of the home training program will involve the use of two examination rooms at the Charlotte East Dialysis facility for the home training program. This space can easily be adapted to this use and will not entail any additional capital expenditure. DVA will be using the NxStage Hemodialysis machine to train patients on home hemodialysis, which plugs into a standard electrical outlet and contains its own internal water purification system, and only requires access to a sink for a source of water. No specialized plumbing or electrical features will be required for home peritoneal dialysis either. Therefore, there will be no capital costs associated with the use of these examination rooms to serve as the home training area. Two existing hemodialysis stations at the Charlotte East facility will be dedicated to home hemodialysis training.

In January, DVA plans to submit a certificate of need application to authorize the permanent relocation of its home training program, and will request expedited review for this proposal. If the CON Section agrees, based on the analysis below, that a permanent relocation of the home training program may be implemented without a certificate of need, then DVA will simply withdraw that application. However, if the CON Section determines to grant an exemption only for a temporary relocation, then DVA will implement the temporary relocation and await the outcome of the review of the CON application.

ANALYSIS

The Relocation of the Home Dialysis Program is not a New Institutional Health Service.

The relocation of the home training program, with no associated relocation of hemodialysis stations, is not a new institutional health service under N.C. Gen. Stat. § 131E-176(16):

DVA's Charlotte East facility is an existing facility that already offers dialysis services, so this proposal will not entail establishing a new health service facility, that would require review under N.C. Gen. Stat. § 131E-176(16)(a).

With no capital expenditure involved in this project, the capital expenditure threshold in N.C. Gen. Stat. § 131E-176(16) (b) will not be exceeded. Likewise, with no capital expenditure involved, the relocation will not involve a change of more than 15 per cent in the authorized amount under the certificate of need issued for the most recent expansion of the Charlotte East facility, so there will be no Change in a Project under N.C. Gen. Stat. § 131E-176(16)(e) resulting from an additional capital expenditure.

Since dialysis services already are offered at the Charlotte East facility, this proposal will not result in starting to offer dialysis services from that site, so N.C. Gen. Stat. § 131E-176(16) (d) does not apply. For the same reason, there will be no addition of a health service that results in a Change in a Project on that ground under N.C. Gen. Stat. § 131E-176(16) (e)

Since the relocation of the home training program will not involve moving hemodialysis stations from Morehead Street to Charlotte East, there is no Change in Bed capacity under N.C. Gen. Stat. § 131E-176(16) (c).

Finally, the relocation of the home dialysis training program should not be deemed to be a reduction of a facility under N.C. Gen. Stat. § 131E-176(16) (q) since both the Charlotte Dialysis and Charlotte East facilities will remain at their current locations, and only the site of the home training program will be transferred from one facility to the other.

No other part of N.C. Gen. Stat. § 131E-176(16) has any possible application to this proposal, and for these reasons, the relocation of the home training program is not a new institutional health service at all.

Finally, a determination that DVA's proposed transfer of the home training program is not governed by the CON Law is consistent with A determination which the CON Section reached in August about the addition of Home Peritoneal and Home Hemodialysis training at the BMA Kinston facility. A copy of the correspondence to and from the CON Section relating to that request is attached as Exhibit B. The CON Section determined that the addition of home dialysis training at the Kinston facility is not governed by the CON Law. The net effect of DVA's proposal is the addition of home training at an existing facility, like the BMA Kinston proposal which the CON Section determined was not governed by the CON Law.

Even if the CON Section determines the relocation to be a new institutional health service, the circumstances establish that an exemption for a temporary relocation should be granted.

Based on the information presented in this letter, even if the temporary relocation of the home training program described in this letter is determined to be a new institutional health service, it should be exempt from review under N.C. Gen. Stat. § 131E-184(a)(1) and (1b). The temporary relocation is being proposed to eliminate the potential safety hazard posed by the dysfunctional elevator, an action which falls within the scope of the exemption from review granted by N.C. Gen. Stat. § 131E-184(a)(1), exemptions for actions that eliminate or prevent safety hazards. In addition, the relocation will resolve concerns that might arise under 42 CFR § 494.60 (see copy of 42 CFR § 494.60, attached as Exhibit C) in regard to the impact of the malfunctioning HVAC system on the patient environment, so this relocation also qualifies for an exemption under N.C. Gen. Stat. § 131E-184(a)(1b)), relating to compliance with Medicare standards. Based on this statutory authority, and in the alternative to a determination that the proposed relocation is not a new institutional health service, DVA requests that the CON Section confirm that the temporary relocation of its home training program to the Charlotte East facility may proceed without a certificate of need.

CONCLUSION

Therefore, DVA requests that the CON Section confirm that the home training program may be relocated to its Charlotte East facility without a certificate of need.

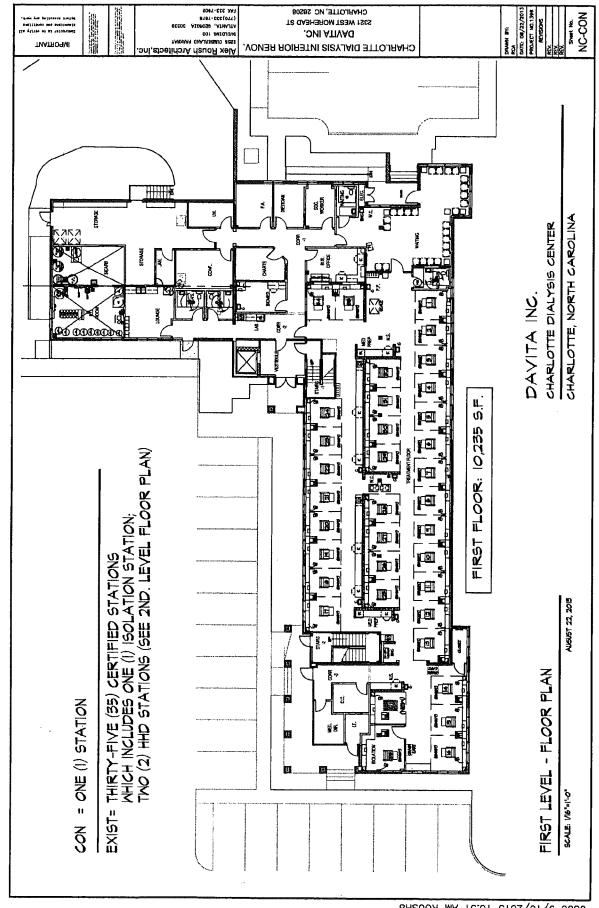
In the alternative DVA requests that an exemption for a relocation of the home training program, be issued, allowing the home training program to be transferred to the Charlotte East facility on a temporary basis until the completion of the construction of the additional home training rooms that are to be added to the Charlotte East facility in the project that will be described in the application that will be filed in January.

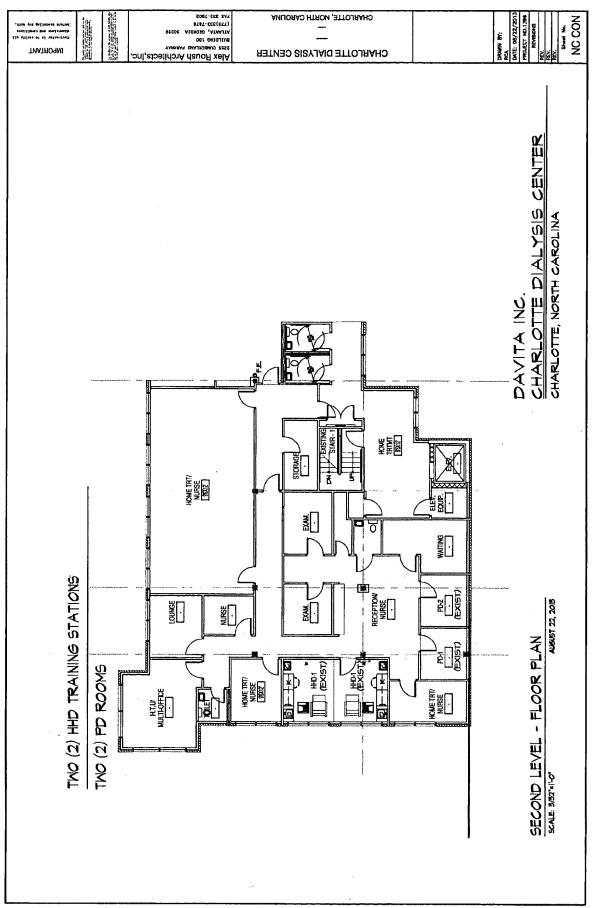
Thank you for your prompt attention to this and please advise if there is any additional information or detail that we can provide in order to expedite your analysis of this proposal.

Very truly yours,

William R. Shenton

Partner







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

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> **Drexdal Pratt Division Director**

August 26, 2013

Jim Swann, Director of Market Development Fresenius Medical Care 3725 National Drive, Suite 206 Raleigh, NC 27612

No Review

Facility or Business: BMA Kinston

Project Description:

Offer home peritoneal dialysis and home hemodialysis training and

support services

County:

Lenoir

FID #:

944593

Dear Mr. Swann:

The Certificate of Need Section (CON Section) received your letter of August 12, 2013 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 provided that the offering of home hemodialysis training and support services does not result in the development of certified dialysis stations that are in addition to the 39 certified stations authorized in the scope of the certificate of need issued for Project ID# P-6238-00. 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.

Further, it should be noted that the Acute and Home Care Licensure and Certification Section is responsible for counting the number of dialysis stations developed in a facility as part of their survey process. It is our understanding that the surveyors count the total number of stations located in the facility not the number of stations in use in the facility at any given time.

At this time, the CON Section authorizes Bio-Medical Applications of North Carolina d/b/a BMA Kinston to offer home peritoneal dialysis and home hemodialysis training and support services without an increase in the number of certified stations.



Jim Swann August 26, 2013 Page 2

In other words, the total number of "stations" (i.e. home hemodialysis training and home peritoneal training plus hemodialysis) reported on line 22 of Form CMS-3427 may not exceed 39 dialysis stations, the total number of stations that is authorized in the scope of the certificate of need for Project ID# P-6238-00.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

Jane Rhoe-Jones, Project Analyst

Craig R. Smith, Chief

Certificate of Need Section

c: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR



August 12, 2013

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RECEIVED

OFFICE

DIVISION

Mr. Craig R. Smith, Chief Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Ralelgh, NC 27603

Re'

Request for No Review Determination, BMA Kinston, Add Home Peritoneal Dialysis and Home Hemo-dialysis training and support / Lenoir County

FID # 944593

Dear Mr. Smith:

BMA is requesting a No Review Determination by the Certificate of Need Section which will allow the BMA Kinston facility to add home therapies to its service offerings. As you are probably aware, the number of patients in our state choosing home dialysis is increasing. More and more patients are choosing home dialysis. Fresenius Medical Care is committed to offering patients a choice of dialysis modalities.

BMA Kinston seeks to add home dialysis therapies for both Peritoneal Dialysis, (PD), and home hemo-dialysis to its service offerings. BMA Kinston is currently certified as a 39 station dialysis facility, providing in-center dialysis services only.

BMA Kinston will dedicate one of its 39 dialysis stations exclusively to the provision of home hemo-dialysis training and support. The facility will convert existing office space into a home training room dedicated to the provision of home hemo-dialysis. Additionally, the facility will refresh two other offices which were previously used for home training, and provide peritoneal dialysis training and support from these offices.

The facility will continue to offer in-center dialysis through the remaining 38 dialysis stations. This change will not adversely impact the patient population of the facility. The July 2013 SDR reports that the facility utilization was 66.67%. The facility will continue to have ample capacity for additional in-center dialysis patients.

BMA requests an expedited review and approval of this request. We have patients waiting to begin training at BMA Kinston. If you have any questions, please contact me.

Sincerely.

Jim Swann

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Director of Operations, Certificate of Need

EXHIBIT C

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CFR > Title 42 > Chapter IV > Subchapter G > Part 494 > Subpart B > Section 494.60

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42 CFR 494.60 - Condition: Physical environment.

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§ 494.60

CFR

Condition: Physical environment.

Updates

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

- (a) Standard: Building. The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.
- (b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.
- (c) Standard: Patient care environment. (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.
 - (2) The dialysis facility must:
 - (i) Maintain a comfortable temperature within the facility; and
 - (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.
 - (3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is regulred.
 - (4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).
- (d) Standard: Emergency preparedness. The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.
- (1) Emergency preparedness of staff. The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:
- (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—
 - (A) What to do;
 - (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;
 - (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to

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forward calls to a working phone number under such emergency conditions); and

- (D) How to disconnect themselves from the dialysis machine if an emergency occurs.
- (ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification;
- (iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.
- (2) Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.
- (3) Emergency equipment. Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.
- (4) Emergency plans. The facility must-
- (i) Have a plan to obtain emergency medical system assistance when needed;
- (ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and
- (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.
- (e) Standard: Fire safety. (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter).
 - (2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits.
 - (3) If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.
 - (4) After consideration of State survey agency recommendations, CMS may walve, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met:
 - (i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and
 - (ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

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