

Gary Griffin & Associates, Inc.

December 18, 2009

Mr. Alva Lambert
Executive Director
State Health Planning & Dev. Agency
P. O. Box 303025
Montgomery, Alabama 36130-3025

RECEIVED
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STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY

Re: CON 2259-ESRD Project Modification Request # 1, Relocation of Four Hemodialysis Stations from FMS of Magnolia to FMC USA Jaguar

Dear Mr. Lambert:

This letter requests Project Modification # 1 concerning the relocation of four hemodialysis stations for which a CON has been issued, but not yet completed. These four hemodialysis stations were granted to FMS of Magnolia by CON 2259-ESRD¹. This Project Modification # 1 proposes to relocate the four stations to FMC USA Jaguar. Both Magnolia and USA Jaguar are owned and operated by Bio-Medical Applications of Alabama, Inc. ("BMA").

The four stations qualify for a project modification per CON Rules and Regulations 410-1-10-.03 Project Modifications After Issuance of CON. Said Rule provides that a physical relocation to a location other than that designated in the CON shall be reviewable by the full Certificate of Need Review Board. These four stations have not been constructed, renovated or placed into operation at Magnolia; thus, a Project Modification After Issuance is applicable. The CON granting these four stations to Magnolia (CON 2259-ESRD) remains valid. There will be no new costs incurred as a result of this Project Modification beyond the \$44,000 approved in association with the original grant of the four dialysis stations for the Magnolia facility in CON 2259-ESRD.

BMA proposes to relocate the four stations granted for the Magnolia facility pursuant to CON 2259-ESRD to its USA Jaguar facility, also in Mobile. USA Jaguar² was granted CON 2204-ESRD, and is a new ESRD facility under construction on the

¹The Magnolia CON Application was drafted in the summer of 2008 with finalization about August 15, 2008. The CON Application was filed with SHPDA on September 2, 2008 and CON 2259-ESRD was issued on February 5, 2009.

²The USA Jaguar facility is anticipated to be completed in December 2009 with state licensure and Medicare Certification to follow. The USA Jaguar facility was granted CON 2204-ESRD for a new twenty-station outpatient hemodialysis facility on the campus of USA Medical Center (nineteen hemodialysis stations and one isolation station).

main campus of the University of South Alabama Medical Center (“USA”). This facility will serve the needs of the patients and physicians of USA’s, Department of Nephrology.

The USA Jaguar facility is anticipated to open with a full patient census, meaning that upon opening, it will have at least an eighty percent occupancy rate. Currently, about 80 outpatient hemodialysis patients of USA’s Department of Nephrology are being served in various other dialysis locations throughout the city of Mobile. The USA Jaguar facility was planned to relocate these patients to one location on USA’s main campus in Mobile. The State Health Plan ESRD Section indicates that one hemodialysis station is needed for every 3.2 hemodialysis patients. With these four hemodialysis stations, plus the nineteen hemodialysis stations previously approved by the CON Review Board, the USA Jaguar facility could serve at least 74 patients, excluding isolation patients.

There are at least three primary reasons for the relocation of the four hemodialysis stations from Magnolia to USA Jaguar: (1) there is a lack of space at Magnolia to achieve updated and mandated facility requirements for isolation; (2) it is significantly less costly to relocate the four stations to the USA Jaguar facility than to construct the additional space at the Magnolia facility to achieve the new isolation facility requirements; and (3) there is a need for the additional four stations due to USA’s Department of Nephrology’s current dialysis patient volume.

As an older facility, Magnolia is more limited in expansion potential for current isolation space requirements. Magnolia was built at a time when design standards and Medicare’s Conditions of Participation for ESRD were less stringent with regards to isolation techniques and separate facility space requirements. Specifically, the December 2008 updated Medicare Conditions of Participation ESRD³ require additional space for isolation techniques and methods. The provision of this additional space⁴ at the Magnolia facility would be much more costly than providing these four stations at the new USA Jaguar facility. The USA Jaguar facility is already designed to achieve the 2008 updated isolation requirements.

Magnolia has been advised that the addition of four stations to the facility will trigger the mandate that the Magnolia facility achieve the 2008 updated Medicare Conditions of Participation ESRD, and specifically the requirements of 42 C.F.R. § 494.30, entitled Isolation Infection Control. Should the Magnolia facility forego adding additional stations, arrange for isolation treatments at other dialysis facilities, and retain the facility in essentially the same physical state as today, the Magnolia facility can continue to serve patients in a manner that can achieve applicable state licensure and Medicare’s Conditions of Participation ESRD.

³ Updated Medicare Conditions of Participation ESRD effective December 2, 2008, pertaining to isolation, which modified the December 11, 1990, and December 16, 1983, Medicare Conditions of Participation.

⁴ Separate station rooms for isolation rather than just separate station areas are part of the 2008 updated Medicare Conditions of Participation ESRD Isolation Requirements.

I understand this Project Modification will be considered by the full CON Review Board since it pertains to relocation of stations from one facility to another. Additionally, the project modification will not be granted prior to ten business days after publication on SHPDA's web site. Please be advised that there were no parties of record in the underlying administrative proceeding and there were no letters filed in opposition.

Thank you for your attention regarding this matter. Please contact me should you have any questions. Please notify me when this Project Modification # 1 will be presented to the CON Review Board.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Griffin". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Gary Griffin

Attachment: CON 2259-ESRD Magnolia Facility

ALABAMA
STATE HEALTH PLANNING & DEVELOPMENT AGENCY
CERTIFICATE OF NEED
FOR HEALTH CARE SERVICES

I. IDENTIFICATION		
1. Certificate of Need 2259-ESRD	2. Date Issued: February 5, 2009	3. Termination Date: February 4, 2010
4. Project Number: AL2008-048	5. Name of Facility: Bio Medical Applications of Alabama, Inc. d/b/a Fresenius Medical Services of Magnolia	
6. Service Area: Mobile County	7. Location of Facility: 7940 Moffat Road, Mobile, Alabama 36575	
8. Type of Facility: ESRD	9. Number of Beds: N/A	10. Estimated Cost: \$44,000
11. Services to be provided: To add four (4) additional hemodialysis stations to the existing facility.		
II. CERTIFICATE OF NEED		
In accordance with Section 22-21-260 through 22-21-279, <u>Code of Alabama</u> , 1975, the Certificate of Need Review Board finds as follows:		
1. There is a need for the project.		
2. There are in force in the State of Alabama reasonable minimum standards of licensure and methods of operation for hospitals and health facilities.		
3. The prescribed standards of licensure and operation will be applied and enforced with respect to the applicant, hospital or other health facility.		
III. ISSUANCE OF CERTIFICATE OF NEED		
This Certificate of Need is issued to Bio Medical Applications of Alabama, Inc. d/b/a Fresenius Medical Services of Magnolia only, for a period not to exceed 12 months from the date of issuance. This Certificate of Need is not transferable and any action on the part of the Applicant to transfer this Certificate of Need will render the Certificate of Need null and void.		
ORIGINAL	 Alva M. Lambert Executive Director	