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December 28, 2023

RV2024-006
RECEIVED

Dec 28 2023

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

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(1927-2013)

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Ms. Emily T. Marsal, Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, Alabama 36104

Re: RV2024 -006 - Dialysis Clinic, Inc., Moulton
Response to Request for Additional Information

Dear Ms. Marsal:

This letter is written in response to the Agency's December 21, 2023, letter requesting that we provide the Agency with additional information related to the Reviewability Determination Request submitted on behalf of Dialysis Clinic, Inc., Moulton.

The Agency's letter requests that Dialysis Clinic, Inc., Moulton provide a disclosure of financial interests in the entity requesting the reviewability determination held by any other healthcare facilities or groups. The Moulton dialysis clinic is wholly owned by Dialysis Clinic, Inc. which is a non-stock, non-profit corporation with no other parties maintaining a financial interest.

We appreciate your assistance with this Reviewability Determination Request. As always, please do not hesitate to contact us if you have any questions or if we can address any further issues relating to this Project.

Sincerely,



C. Mark Bain

CMB/aj

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December 15, 2023
Via Electronic Mail

Ms. Emily T. Marsal, Executive Director
State Health Planning and Development Agency
100 North Union Street, Suite 870
Montgomery, Alabama 36104

Re: Request for Reviewability Determination
Dialysis Clinic, Inc., Moulton

Dear Ms. Marsal:

Our firm represents Dialysis Clinic, Inc., Moulton which is an In-Center Hemodialysis provider with 12 In-Center Hemodialysis Stations in Moulton, Lawrence County, Alabama.

The purpose of this letter is to request your determination, pursuant to Section 410-1-7-.02 of the Alabama Certificate of Need Program Rules & Regulations ("Regulations"), that Dialysis Clinic, Inc., Moulton is not required to obtain a Certificate of Need ("CON") from the State Health Planning and Development Agency ("SHPDA") to add one Peritoneal Dialysis training/Support/Urgent Start treatment room to its existing clinic in Moulton, Lawrence County, Alabama. The services to be provided are as follows:

Home Peritoneal Dialysis (PD) Training and Support

Peritoneal Dialysis is dialysis using a peritoneal dialysis catheter surgically implanted into the abdominal cavity. This catheter allows sterile, high glucose fluids, to be instilled into the peritoneum, the membrane surrounding the intestines. The peritoneal membrane is very vascular, thus acting as a filter for the removal of waste products, from the patient's bloodstream. A peritoneal dialysis exchange consists of 3 steps: instillation of fluid into the abdominal cavity, dwelling of fluid into the abdominal cavity, and draining of fluid from the abdominal cavity. This process can be performed manually or with a machine called a cycler.

Home Peritoneal Dialysis training provides the patient and/or designated care partner dialysis training at the dialysis clinic for up to 15 days. Once the initial training process is complete the home dialysis training and support staff provides ongoing monitoring and support services to the peritoneal dialysis patient in order for their dialysis to be performed at home. The Home Support Staff are Registered Nurses who have the knowledge and experience to assist the peritoneal dialysis patients, if and when a problem (s) arises. Home Peritoneal Dialysis includes

the following services: Continuous Ambulatory Peritoneal Dialysis (CAPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Urgent Start Peritoneal Dialysis.

Continuous Ambulatory Peritoneal Dialysis (CAPD)

This type of dialysis does not require an automated machine. With CAPD, the patient is trained to perform the dialysis exchange manually at home. To start a treatment, the patient will "fill" the abdominal cavity with glucose solutions, via gravity. Once the fluid is instilled, the patient will allow the fluid to "dwell" or remain in the abdominal cavity for a specific period of time. Lastly, to complete the exchange, the patient will "drain" the fluid out of the abdominal cavity, via gravity into a special drain bag. A patient who chooses CAPD as a treatment option can be required to perform multiple exchanges per day to achieve adequate clearance.

Continuous Cycling Peritoneal Dialysis (CCPD)

This type of dialysis requires a dialysis machine called a cycler. With CCPD the patient is trained to use the cycler machine at home to complete the "fill", "dwell", and "drain", procedures involved with the CCPD treatment. CCPD is typically performed at night while the patient sleeps. A patient who chooses CCPD as an option will utilize the cycler to perform the required exchanges throughout the night to achieve adequate clearance.

Urgent Start Peritoneal Dialysis

This dialysis service is offered for the initiation of peritoneal dialysis as early as two weeks following the placement of a peritoneal dialysis catheter. This option is to avoid the insertion of a central line when the patient requires dialysis urgently. Urgent Start Peritoneal Dialysis allows the facility to provide the patient's dialysis services until the patient's dialysis catheter is healed and training is completed. Typically, patients will receive peritoneal dialysis treatments in the facility up to five days/week, over an eight-hour period. Urgent Start Peritoneal Dialysis can be accomplished with an automated cycler or with the manual peritoneal dialysis approach and is performed in the home dialysis clinic. This process usually lasts between two to four weeks. During this period the patient will not receive training for home dialysis. After the Urgent Start peritoneal dialysis phase is completed the patient will begin routine home peritoneal dialysis training in the facility.

The above services are being requested in Lawrence County at Dialysis Clinic, Inc., 1962 Main Street, Moulton, AL 35650.

These services will require the addition of one home training room. The addition will be achieved with the renovation of one existing exam room, located as marked on the schematic that is included with this letter. The addition of these services will not involve the acquiring of any assets or stock.

Ms. Emily T. Marsal
State Health Planning and Development Agency
December 15, 2023
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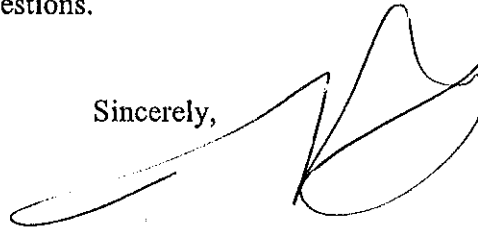
This Project will not exceed any of the CON expenditure thresholds specified in Section 410-1-2-.07 of the Regulations: of \$3,322,582 for major medical equipment; of \$1,327,734 for new annual operating costs, or of \$6,638,679 for total capital expenditures. Dialysis Clinic, Inc., Moulton represents that the proposed Project will not exceed the following approximate costs:

Total Construction Costs:	\$2,500
Total Equipment Costs:	\$7,500
Annual Operating Costs	\$214,748

In accordance with SHPDA Rule 410-1-7-.02, the filing fee of \$1,000 for this Letter of Non-Reviewability has been paid via the SHPDA electronic payment portal.

Based on the above, we respectfully request your determination that Dialysis Clinic, Inc., Moulton is not required to obtain a CON in order to complete the above-described Project. We certainly appreciate your consideration of this request and please feel free to contact me if you need further information or have any questions.

Sincerely,



James E. Williams

JEW/lmr

Ms. Emily T. Marsal
State Health Planning and Development Agency
December 15, 2023
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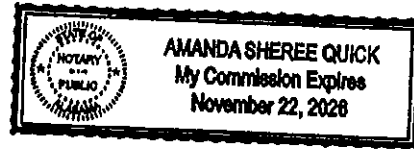
The undersigned, being first duly sworn, hereby makes oath or affirms that she is the Area Operations Director for Dialysis Clinic, Inc., Moulton, has knowledge of the facts in this request, and to the best of her information, knowledge and belief, such facts are true and correct.

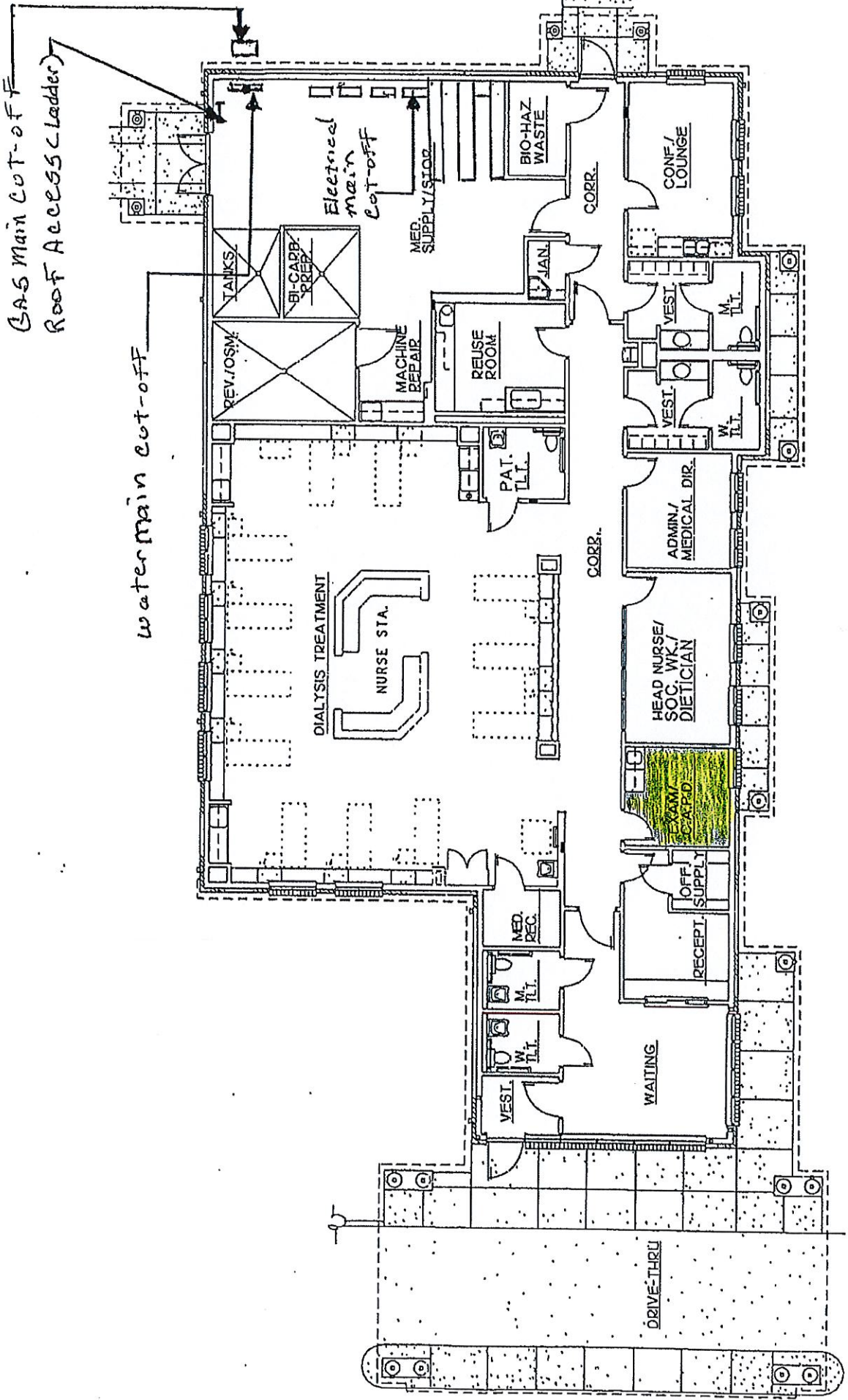
Affiant,

Misty Folds
MISTY FOLDS
Area Operations Director

SWORN TO and subscribed before me
on this the 18th day of December, 2023

Amanda Quick
NOTARY PUBLIC
My Commission Expires: 11-22-24





(Gas Main cut-off
Roof Access Ladder)

water main cut-off

FLOOR PLAN, Moulton