



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 1, 2022

Jonathan Paull
jonathan@dialyzedirect.com

New Institutional Health Service

Record #: 3801
Date of Request: November 19, 2021
Business Name: Dialyze Direct
Business #: 3519
Project Description: Offer home dialysis training and support in nursing facilities as a new provider in North Carolina
County: Multi-county

Dear Mr. Paull:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the project described above is a new institutional health service within the meaning of G.S. 131E-176(16)(d) - *“The offering of dialysis services or home health by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility.”*

Therefore, you may not proceed to offer or develop the proposal without first obtaining a certificate of need. This decision is based on the following:

1. Dialyze Direct has not offered the proposed dialysis services in North Carolina within the previous 12 months.
2. Dialyze Direct is not certified as an end-stage renal disease (ESRD) provider in North Carolina by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 405.
3. Dialyze Direct does not have a certificate of need to own or operate dialysis stations in North Carolina.

Any person aggrieved by this decision may file a petition for a contested case hearing in accordance with G.S.150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings 6714 Mail Service Center, Raleigh, North Carolina 27699-6714 within thirty (30) days of the date of this decision. Effective October 1, 2009, OAH requires a filing fee with submittal of petitions for contested cases. Please direct all questions regarding this fee to OAH Clerk’s Office (919-431-3000).

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

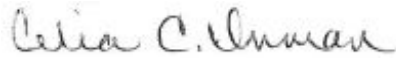
Mr. Paull
February 1, 2022
Page 2

Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Lisa G. Corbett
Department of Health and Human Services,
Office of Legal Affairs,
Adams Building – Room 154
2001 Mail Service Center
Raleigh, North Carolina, 27699-2001

It is requested that a copy of the petition also be served on the Agency.

Sincerely,



Celia C. Inman
Project Analyst



Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR



DialyzeDirect.com

3297 State Route 66, Neptune, NJ 07753
Phone Number: 732.806.9990

November 19, 2021

Re: Staff-Assisted Home Hemodialysis in SNFs

Dear Michaela,

It was a pleasure speaking with you yesterday regarding Dialyze Direct's interest in entering the North Carolina market for purposes of providing our unique and innovative staff-assisted home hemodialysis model in nursing facilities.

As we mentioned during our call, we have experienced an enormous amount of demand from various stakeholders in the North Carolina market requesting our service. Specifically, ESRD Network 6 (for North Carolina) reached out to us directly and requested we enter the NC market due to patient demand and lack of service options within the state. Additionally, over 30 nursing facilities in North Carolina have contacted us requesting our service. Ms. Azzie Conley and Ms. Greta Hill, both from the Division of Health Service Regulation-Acute & Home Care Licensure & Certification Section, acknowledged the great need for our service in the North Carolina market and expressed excitement in us entering the state.

Per your request on our call, the following will be an explanation of our unique service model that has led to best-in-class outcomes in reducing re-hospitalizations and dialysis related infection rates, while also serving as an excellent asset in COVID-19 infection risk mitigation among nursing facility residents and staff:

I. Model of Care

Dialyze Direct ("Dialyze") is a Home Dialysis Training and Support End-Stage Renal Dialysis ("ESRD") Company interested in providing our unique, patient-centric model of care within the State of North Carolina. Under the leadership of a North Carolina-licensed physician and board-certified Nephrologist, Dialyze intends to provide on-site staff-assisted home hemodialysis to patients residing in skilled-nursing facilities ("SNFs").

Dialyze's model is based on current research demonstrating the health benefits of rendering short, more frequent home hemodialysis treatments to geriatric dialysis patient residing in skilled-nursing facilities. Dialyze's model is specifically designed to tackle the complex co-morbidities generally shared among the geriatric dialysis community.

Dialyze currently operates in Florida, Texas, New York, New Jersey, Pennsylvania, Ohio, Illinois, Tennessee, Kentucky, Indiana, and Missouri. In each region, Dialyze maintains a home dialysis training and support facility (“Facility”) which is used for staff training and education. We do not treat patients in this Facility, rather patients are only treated in nursing facilities or residential homes. Generally speaking, the Facility includes a training room and space for clean and dirty areas.

Dialyze maintains an interdisciplinary care team consisting of the following personnel:

- Board-certified Medical Director
- Registered Nurse Manager
- Registered Dietician Nutritionist
- Licensed Social Worker
- Licensed Practical Nurses
- Patient Care Technicians

Dialyze’s own Registered Nurses, Licensed Practical Nurses, and Patient Care Technicians serve as the trained caregivers to provide the staff-assisted home hemodialysis services to patients residing in SNFs. Additionally, Dialyze’s interdisciplinary team coordinates with the SNF staff on a continual basis in order to provide personalized, individual care to Dialyze patients.

Our staff-assisted treatments are under the guidance and oversight of a Dialyze hemodialysis Registered Nurse, who is available on-site at the SNF during treatment hours and is additionally available on-call during after-hours. As a prerequisite for employment, Dialyze requires all Registered Nurses to have at least one year of hemodialysis experience. A Dialyze Licensed Social Worker and a Dialyze Registered Dietician Nutritionist provides ongoing services to patients in accordance with all federal and state requirements. Additionally, the Dialyze Medical Director is available and accessible at all times.

Dialyze utilizes the NxStage System One Home Hemodialysis Machine (“System One”) for dialysis treatments. The System One is a self-contained system that does not require a water source, making it an excellent choice for home hemodialysis. Additionally, Dialyze provides each patient with their own personal System One, virtually eliminating the risk of patient cross contamination of infectious diseases stemming from contaminated touch surfaces.

We have seen the advantages of our SNF home dialysis den in other markets in that it enables the dialysis provider and the SNF to provide a controlled environment that allows for greater coordination and quality of care, infection control, quality assurance, and patient privacy. It is these benefits that Dialyze Direct was founded upon, and remains the present-day mission of the company in improving the quality of care and quality of life for our patients. Under the leadership of Dr. Nathan Levin, Chairman of the Medical Advisory Board and founder of the Renal Research Institute, Dr. Allen Kaufman, Chief Medical Officer, and Alice Hellebrand, Chief Nursing Officer and former President of the American Nephrology Nurses’ Association, Dialyze Direct has been a driving force in other states for lowering hospital readmissions among dialysis patients residing in nursing facilities.

Presently, our company has conducted over one million treatments in accordance with all federal regulations. Our improved dialysis therapy methods have demonstrated significant improvements in

our patients lives and have resulted in lowering dialysis-related re-hospitalization rates by over 70% and reducing permcath infection rates by over 96%. Additionally, during current COVID-19 pandemic, our data showed that nursing facilities that had our onsite staff-assisted home hemodialysis model had a 50% lower risk of a COVID-19 outbreak within the nursing facility.

II. Market Regulatory Review

We mentioned during our call that other states, namely Illinois, Texas, and Tennessee, reviewed the uniqueness of our model in comparison to their existing CON and state regulations, and made determinations that either their CON process did not apply to our model, or allowed waivers to the process, or issued expedited licensure approvals to roll-out our model as fast as possible. *Please note, in all of these states the fact that we do not treat patients in our home dialysis training and support facility factored into the result.*

During the Illinois CON regulatory review, the IL Department of Health made the determination that due to the fact our model was a “home dialysis training and support center” and not an “ESRD facility”, the standard CON process did not apply and exempted our model from obtaining a CON. In Texas, our CON process was expedited and they removed the Architectural Review Board component of the process due to similar reasons that Illinois held, namely the uniqueness of the model and the lack of availability of the model within the state. And in Tennessee, the Department of Health held an emergency licensure review meeting, and granted Dialyze Direct an emergency license for purposes of expediting roll-out of our model due to the COVID-19 pandemic.

We very much appreciate you looking into these questions on our behalf. In the event you need any additional information, please do not hesitate to contact me directly at jonathan@dialyzedirect.com. We look forward to the opportunity to provide our service in North Carolina in order to improve quality of care while simultaneously lowering costs for all stakeholders involved.

Sincerely,



Jonathan Paull

General Counsel and Chief Compliance Officer
Dialyze Direct

From: [Mitchell, Micheala L](#)
To: [Waller, Martha K](#)
Cc: [Pittman, Lisa](#)
Subject: Fw: [External] Re: ESRD CON Process in NC
Date: Wednesday, December 29, 2021 1:00:51 PM
Attachments: [image003.png](#)
[image004.png](#)
[image005.png](#)
[image563388.png](#)
[image485818.png](#)
[image129173.png](#)
[image217545.png](#)
[DDNC_Memo_CONReview.pdf](#)

Martha,

Would you mind logging this for us? There was confusion about whether this was an official request or a hypothetical inquiry. We had to consult with the DOJ attorneys for guidance.

Thanks,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

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From: Jonathan Paull <jonathan@dialyzedirect.COM>
Sent: Friday, November 19, 2021 12:49 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Josh Rothenberg <josh@dialyzedirect.com>
Subject: Re: [External] Re: ESRD CON Process in NC

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Hi Michaela,

Thank you so much for the call yesterday, it was very helpful in providing greater clarity on our end of the North Carolina CON landscape. As discussed, I am attaching a memo that provides greater detail on our model of care, as well as a brief regulatory summary of other CON-oriented states and how they interacted with our model.


Please let me know if you have any questions or if there is anything you need from us to help with this.

Sincerely,


Jonathan


Jonathan Paull
General Counsel & Chief Compliance Officer



 **Email:** jonathan@dialyzedirect.COM

 **Main:** 732-806-9990

 **Direct:** 732-806-8362

 **Fax:** 732-806-8363

DialyzeDirect.com

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From: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>

Sent: Friday, November 12, 2021 5:13 PM

To: Jonathan Paull <jonathan@dialyzedirect.COM>

Cc: Josh Rothenberg <josh@dialyzedirect.com>

Subject: RE: [External] Re: ESRD CON Process in NC

Jonathan,

Thanks for reaching back out to me. The office was closed yesterday and today has been unusually busy.

Based on what you've explained, a CON would be required to set up home training facilities in NC. I've attached an FAQ regarding the overall CON process to this correspondence for your review.

I'm available to speak with you next week on:

11/15- 1-1:30

11/15- 3-3:30

11/16 -11:11:30

11/18 10-10:30

Let me know if any of those days/times work for you and whether you will establish the bridge or need me to.

Best,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

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From: Jonathan Paull <jonathan@dialyzedirect.COM>
Sent: Thursday, November 11, 2021 9:32 AM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Josh Rothenberg <josh@dialyzedirect.com>
Subject: [External] Re: ESRD CON Process in NC

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Hi Michaela,

Just wanted to follow up on this - do you have any availability next week to discuss? We are really excited to begin the process in getting our model up and going in North Carolina, and it will be a huge win in providing greater health care equity for the dialysis residents currently residing in nursing facilities who do not have access to home dialysis modalities.


Thanks,

Jonathan


Jonathan Paull
General Counsel & Chief Compliance Officer



 **Email:** jonathan@dialyzedirect.COM

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From: Jonathan Paull <jonathan@dialyzedirect.COM>

Sent: Monday, November 8, 2021 1:34 PM

To: Micheala.Mitchell@dhhs.nc.gov <Micheala.Mitchell@dhhs.nc.gov>

Cc: Josh Rothenberg <josh@dialyzedirect.com>

Subject: ESRD CON Process in NC

Hi Michaela,

I hope you are doing well. We were referred to you by Azzie Conley and Greta Hill following our discussion on entering North Carolina for the purposes of providing home dialysis within the state. From what I understand, NC might have a CON process.

We would like to learn more about this to ensure we follow everything correctly in getting up

and going in NC. Please let me know when works best for you to jump on a call.

Thanks,

Jonathan