



**North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section**

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<http://www.ncdhhs.gov/dhsr/>

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July 6, 2012

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
P. O. Box 6338
Raleigh, NC 27628-6338

RE: No Review / Mt. Airy Dialysis Center of Wake Forest University / Provision of Home Dialysis to Residents of Nursing Facilities / Surry County
FID #: 944348

Dear Mr. Hemphill:

The Certificate of Need (CON) Section received your letters of June 6, 2012 and June 21, 2012 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, subject to the following conditions:

1. Mt. Airy Dialysis Center of Wake Forest University will provide dialysis training in all home modalities, including home peritoneal dialysis and home hemodialysis.
2. Mt. Airy Dialysis Center of Wake Forest University will continue to provide home dialysis training for its patients.
3. Mt. Airy Dialysis Center of Wake Forest University will enter into written coordination agreements with each nursing home as required by the Centers for Medicare & Medicaid Services (CMS) in CMS S&C: 04-24 and 04-37.
4. Mt. Airy Dialysis Center of Wake Forest University will comply with the survey standards imposed by the Acute and Home Care Licensure and Certification Section.
5. Mt. Airy Dialysis Center of Wake Forest University will coordinate with the nursing facility to ensure conformity with any requirements imposed by the Nursing Home Licensure and Certification Section.
6. Mt. Airy Dialysis Center of Wake Forest University will provide home dialysis to the following nursing facility:

<u>Facility</u>	<u>FID #</u>
Golden Living Center-Surry Community	953479



A. Todd Hemphill

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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.

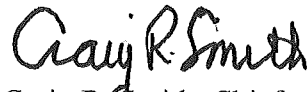
It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by 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.

In addition, you should contact the Acute and Home Care Licensure and Certification Section, DHSR & Nursing Home Licensure and Certification Section, DHSR 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,



Lisa Pittman
Team Leader



Craig R. Smith, Chief
Certificate of Need Section

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

BODE, CALL & STROUPE, L.L.P.

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ODES L. STROUPE, JR.
S. TODD HEMPHILL
MATTHEW A. FISHER

June 21, 2012

HAND DELIVERY

Craig R. Smith, Chief
Certificate of Need Section
NC Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



Re: Mt. Airy Dialysis Center of Wake Forest University – Home Dialysis in Nursing Homes

Dear Mr. Smith:

This letter is in follow-up to my June 6, 2012 letter, sent on behalf of Piedmont Dialysis Center of Wake Forest University (“PDC”), requesting that you issue a letter determining that PDC’s proposal to offer home dialysis services to patients residing within nursing homes in Forsyth County, does not constitute a new institutional health service and is not subject to certificate of need review. To date, you have not yet made a determination on that request.

Since that letter was sent, our client has been made aware of a similar situation in which patients of one of its facilities in Surry County would like to have home dialysis training and services in the patient’s nursing home. Specifically, Mt. Airy Dialysis Center of Wake Forest University (“MADC”), like PDC, is certified to offer all ESRD modalities, and serves 83 in-center patients and 17 home therapy patients who have chosen peritoneal dialysis or home-hemodialysis (NxStage). At least one of the facility’s home peritoneal dialysis patients is a resident of Golden Living Center-Surry Community, a 120 NF bed facility in Mt. Airy, Surry County (License No. NH0276, Provider No. 345191). Currently, that patient must go to MADDC five days a week to receive home peritoneal dialysis. The nursing facility staff includes nurses with dialysis training, and they believe that the patient would significantly benefit if he/she were not required to travel to MADDC every weekday for home dialysis.

William McDonald, Director of Development for Health Systems Management, Inc. which manages Wake Forest University Health Sciences’ dialysis facility, has spoken again with Beverly Speroff, Chief of the Nursing Home Licensure and Certification Section, regarding the provision of home dialysis services in nursing homes. It is his understanding that Ms. Speroff is aware of the situation at MADDC, and has contacted or intends to contact you directly, to advocate

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for allowing existing, approved dialysis centers to provide home dialysis services to patients in the nursing homes where they reside.

In essence, this request is identical to the one made on June 6, 2012 on behalf of PDC. As with PDC, MADC's proposal to offer home dialysis within a patient's home (in this case, a nursing home) does not create a "new institutional health service" under G.S. §131E-176(16). MADC does not propose to transfer dialysis stations or change bed capacity. MADC does not propose to offer a service (home dialysis) that it is not already certified to provide, and has been providing for greater than 12 months. MADC does not propose to expend capital in an amount greater than \$2,000,000 to develop or expand a health service.

MADC will comply with the survey standards imposed by the Acute and Home Care Licensure and Certification Section, and as needed, will coordinate with Golden Living Center (and any other nursing facilities in Surry County which may have patients needing home dialysis in the nursing facility) to ensure conformity with any requirements imposed by the Nursing Home Licensure and Certification Section.

Based on all of the foregoing, MADC respectfully requests confirmation that the services proposed do not constitute a new institutional health service and are not subject to certificate of need review. Given the immediate health care needs of these patients, anything you can do to expedite your response to this request would be helpful.

Please let us know if you need further information or if there are questions we can answer.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh

cc: William F. McDonald