

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 9, 2013
PROJECT ANALYST: Fatimah Wilson
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: C-10100-13 / Dialysis Clinic, Inc. d/b/a DCI Boiling Springs / Add two dialysis stations to the existing facility for a total of 15 stations upon completion of this project and Project I.D. #C-8784-12 / Cleveland County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Dialysis Clinic, Inc. d/b/a DCI Boiling Springs currently operates an 11-station dialysis facility located at 108 Creekside Drive, Shelby, NC. The applicant proposes to add two dialysis stations to the existing facility for a total of 15 stations upon completion of this project and Project I.D. #C-8784-12 [add two dialysis stations to the existing facility for a total of 13 stations].

The 2013 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one station in Cleveland County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. As of June 30, 2012, two stations were pending certification pursuant to Project I.D. #C-8784-12. According to the January 2013 SDR, the facility was certified for 10 dialysis station as of June 30, 2012. As of December 21, 2012 the facility was certified for 11 dialysis stations pursuant to Project I.D.# C-8733-11 and a decision rendered for two additional stations pursuant to Project I.D. #C-8784-12 [add two stations for a total of 13]. The project analyst notes that the January 2013 SDR does not reflect the stations for which a decision had been rendered for Project I.D. #C-8784-12 to

add two stations for a total of 13. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology. The utilization rate reported for DCI Boiling Springs in the January 2013 SDR is 4.20 patients per station, or 105.0%. This utilization rate was calculated based on 42 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2012 (42 patients / 10 stations = 4.20 patients per station; 4.20 patients per station / 4.00 patients per station = 105.0%). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

ESRD Facility Need Methodology April Review

Required SDR Utilization		80%
Center Utilization Rate as of 12/21/2012		105.0%
Certified Stations		11
Pending Stations		2
Total Existing and Pending Stations		13
In-Center Patients as of 6/30/2012 (SDR2)		42
In-Center Patients as of 12/31/2011 (SDR1)		37
Step	Description	
	Difference (SDR2 - SDR1)	5
(i)	Multiply the difference by 2 for the projected net in-center change.	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2012	0.2703
(ii)	Divide the result of Step (i) by 12	0.0225
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January [2013] SDR (6/30/12) until the end of calendar year 2012 (6 months)	0.1351
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	47.6757
(v)	Divide the result of Step (iv) by 3.2 patients per station	14.8986
	and subtract the number of certified and pending stations as recorded in SDR2 [13] to determine the number of stations needed	2

[NOTE: "Rounding" to the nearest whole number is allowed only in ... Step ... (v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.]

Step (C) of the facility need methodology states: *“The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.”* As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is two stations, and the applicant proposes to add two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2013 SMFP is applicable to this review. Policy GEN-3 states:

“A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In response to a request for additional information, the applicant discusses its quality improvement program. The applicant states:

“DCI has exceptionally high quality standards which are not only obvious in the clinics themselves but are recognized nationally by quality organizations. For example, the most recent annual report (2012) from the United States Renal Data System (URDS) found that DCI clinics consistently rank at the top in many of the important ESRD categories related to outpatient care. This report data is the tenth year in a row that DCI has been recognized as providing the best care for the least cost.

Specifically, the data indicate that:

- *DCI has lower mortality rates than other providers;*
- *DCI has lower hospitalization rates than other providers;*
- *DCI is most consistent at meeting target hemoglobin levels/*
- *DCI is best at maintaining hemoglobin levels for three months or more;*
- *DCI patients are staying at hemoglobin levels longer than patients with other providers;*
- *DCI has a higher percentage of patients in their target hemoglobin range of 10-12 grams/deciliter;*
- *DCI has fewer patients likely to exceed hemoglobin levels of 12, 13, 14, and*
- *DCI is the national provider with the lowest monthly costs to CMS at \$1,366 per patient per month compared to a national average of \$1,425 per patient per month.*

...

There are many reasons why DCI clinics are able to maintain such high levels of clinical excellence; however, one obvious reason is its quality data collection system in which all DCI clinics participate.

DCI's quality management system is managed through its corporate office, which collects data from each of the 222 dialysis centers throughout the United States. Because of the centralized data collection, each DCI facility is able to compare the quality aspects of its service with other clinics of similar size and/or scope of service. Each facility also can follow the quality indicators of DCI as a corporation.

...

In other national initiatives, DCI Inc. has formed a partnership with all not-for-profit dialysis companies in the country, representing approximately 21,500 patients, and the Centers for Medicare and Medicaid (CMS). The alliance meets weekly via conference call with CMS to talk about the major changes going on in the dialysis industry and to discuss ways of improving dialysis care.

...

Locally, DCI utilizes a team approach to the quality improvement process. With this method, each staff member performs functions within his or her capabilities in his or her defined role based on the specific needs of the individual patient. Patient care is assessed, planned, implemented, and evaluated with the consistent aim of improving care and finding more efficient and effective methods of delivery of care. Realistic goals, which promote safe, therapeutically effective and individualized care for each patient, are defined in the patient care plan."

Exhibit 5 contains DCI's Quality Policies. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Cleveland County.

Promote Equitable Access

In response to a request for additional information, the applicant provides information about accessibility to its services. The applicant states: "*DCI willingly serves any and all population groups without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status.*" In 2012, 82.3% of DCI Boiling Springs' patients were recipients of Medicare or Medicaid. Exhibit 6 contains DCI Boiling Springs' equal treatment policy which states, "*all persons presenting for treatment of End Stage Renal Disease will be admitted without regard for race, sex, color, creed, religion, physical disability, ability to pay, or any other consideration other than medical need and referral from physician.*"

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

Maximize Healthcare Value

In response to a request for additional information, the applicant states,

“The proposed project is indicative of DCI’s commitment to containing health care costs. The project will meet the need for additional dialysis stations at the Boiling Springs facility with minimal capital costs, as the project proposes to utilize existing space to add two new stations. Further, the project will be consistent with DCI’s ongoing efforts to conserve water and energy. DCI, as a corporate entity, has always been conscious of its energy consumption and has established in all its clinics, including those in Cleveland County, North Carolina, efficient energy operations that also carefully manage the use of utilities. Specifically, DCI uses three phase pumps to treat the water used in the dialysis process; uses programmable thermostats to lower the temperature automatically when no one is in the building; provides routine maintenance on the HVAC system; and, maintains a holding tank with water purified through reverse osmosis (R/O) to provide a steady supply of water for the dialysis process, even when the water supply is lost. In the future, as technology advances, DCI will investigate the use of any new technology for its dialysis clinics and acquire and install any improved equipment that will more efficiently manage energy consumption at the DCI clinics.”

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with Policy GEN-3.

The application is consistent with the facility need determination in the 2013 SMFP and Policy GEN-3. Therefore, the application is conforming with this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Dialysis Clinic, Inc. d/b/a DCI Boiling Springs currently operates an 11-station dialysis facility located at 108 Creekside Drive, Shelby, NC. The applicant proposes to add two dialysis stations to the existing facility for a total of 15 stations upon completion of this project and Project I.D. #C-8784-12 [add two dialysis stations to the existing facility for a total of 13 stations]. The January 2013 SDR indicates a total of 10 certified stations at DCI Boiling Springs, as of June 30, 2012. Based on patient origin information provided in the

table in Section III.7, page 54 of the application, the applicant does not propose any home training. In Section IV.3, page 60, the applicant states, “DCI Boiling Springs does not provide home dialysis services.”

Population to be Served

In Section IV.1, page 60, the applicant states the number of in-center patients served at DCI Boiling Springs as of February 6, 2013 as follows:

Current Dialysis Patients as of February 6, 2013		
County of Residence	# of patients dialyzing at home	# of patients dialyzing in-center
Cleveland	NA	26
Rutherford	NA	10
Totals	NA	36

In Section III.7, page 54, the applicant provides the projected patient origin for DCI Boiling Springs for the first two years of operation following completion of the project. The applicant assumes that its projected patient origin for both project years will remain the same as its current patient origin, as shown in the following table.

COUNTY	OPERATING YEAR 1 CY 2014	OPERATING YEAR 2 CY 2015	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Cleveland	35	37	72% [73%]	72% [73%]
Rutherford	13	14	28% [27%]	28% [27%]
TOTAL	48	51	100%	100%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.2, pages 49-52, the applicant provides the assumptions and methodology it used to project need for two additional stations at DCI Boiling Springs. The applicant states:

“As demonstrated in the table above, DCI Boiling Springs currently needs 1.89 or two additional stations in order to meet a facility need indicated by the January 2013 Revised Semiannual Dialysis Report data. This growth in Boiling Springs is not an aberration but rather an indication of a continuing need for dialysis treatment capacity at the clinic.

For example, in September of 2011, DCI Boiling Springs submitted an application to develop four stations based on the July 2011 SDR data. DCI was approved to develop one station for a total of 11 stations at the Boiling Springs clinic. Six months later in March 2012, DCI Boiling Springs submitted another application to develop two additional stations at the clinic based on the January 2012 SDR data and was approved, for a total of 13 stations at DCI Boiling Springs. Thus, for the past two

years, DCI Boiling Springs has consistently required additional stations to support the patient growth in the greater Boiling Springs area.”

On page 51, the applicant states:

“In the past, DCI projected patient need using the State need methodology as defined in the applicable Semiannual Dialysis Report and the current State Medical Facilities Plan. While the application of the ESRD facility methodology from the SMFP using SDR data demonstrates the immediate need for two additional stations, DCI believes the SMFP growth rate methodology of 13.5 percent is not likely to be sustained in the coming months. For that reason, DCI believes a more conservative approach is reasonable. DCI has chosen to project growth from 2012 to 2016 using one-half the SDR growth rate of 13.5 percent or 6.75 percent. Additionally, this growth rate is comparable to the five-year Cleveland County growth rate of 6.0 percent.”

The applicant projects the total number of in-center patients for 2012-2016 using one-half the SDR growth rate, as shown in the table below.

Year	Total In-Center Patients	Annual Growth Rate ^
2012	42	NA
2013	45	6.75%
2014	48	6.75%
2015	51	6.75%
2016	55	6.75%

^Based on one-half the facility methodology (6.75%) as used in the SMFP methodology.

On pages 51-52, the applicant states that the projected number of in-center patients is based on *“only one-half the historical growth rate or 6.75 percent.”* In the table above, the applicant projects 48 patients during project year one (2014). This results in 3.2 patients per station [48 patients / 15 stations = 3.2 patients per station].

Projected patient utilization in the first two operating years is based on reasonable and supported assumptions regarding continued growth. The applicant projects it will serve at least 3.2 patients per station per week by the end of operating year one, which is consistent with the requirement in 10A NCAC 14C .2203(b).

Access

In Section VI, page 77, the applicant projects that 82.3% of patients at DCI Boiling Springs will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved at DCI Boiling Springs.

In summary, the applicant adequately identifies the population to be served, demonstrates the need for two additional dialysis stations based on the population it proposes to serve and demonstrates all residents of the area, and in particular, underserved groups are likely to have access to the services proposed. Therefore, the application is conforming with this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.9, pages 54-59, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant did not choose this alternative because DCI Boiling Springs is operating at capacity and the facility need methodology in the 2013 SMFP indicates the facility could have 48 patients by the end of 2014, which is three more patients than DCI has projected (45) in its more conservative need methodology in Section III.2. If DCI were treating 48 patients by the end of 2014 as projected, it would be treating four fewer patients than the number needed to initiate a third shift ($52-48 = 4$).
- 2) Operate a Third Shift – The applicant did not choose this alternative because some patients would have difficulty arranging for transportation, particularly those who live outside the immediate vicinity of Shelby. Some patients are not willing to stay at the center until 10 PM to complete their treatments.
- 3) Add Two Stations to the Existing Facility – DCI Boiling Springs chose this alternative because it is operating at capacity. The applicant projects an annual growth rate of 6.75% with an accompanying 80% utilization rate by the end of the first operating year. Many of the facility's patients have one or more diseases in addition to kidney disease and these patients require a higher level of staffing, which can be provided more efficiently by adding stations to the existing facility.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1) **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall materially comply with all representations made in its certificate of need application and supplemental responses. In those instances where representations conflict, DCI Boiling Springs shall materially comply with the last-made representation.**
 - 2) **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall develop and operate no more than two additional dialysis stations for a total of 15 certified stations which shall include any isolation stations upon completion of this project and Project I.D. #C-8784-12.**
 - 3) **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations for a total of no more than 15 dialysis stations which shall include any isolation stations.**
 - 4) **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5) **Dialysis Clinic, Inc. d/b/a DCI Boiling Springs shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 86, the applicant states that the capital cost for the proposed project will be \$37,000 for dialysis machines, chairs, televisions and plumbing. In Section IX.3, page 94, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project. On page 89, the applicant states that the capital cost will be financed with the accumulated reserves of DCI Shelby. Exhibit 20 contains a letter from the Secretary and Treasurer of Dialysis Clinic, Inc., which states: *“DCI, Inc. will finance the capital costs through DCI Shelby reserves.”* Exhibit 21 contains the balance sheet of DCI Shelby. As of December 2012, DCI Shelby had \$7,740,024 in cash, \$8,913,302 in total assets and \$8,746,096 in net assets (total assets – total liabilities).

On page 95, the applicant states the dialysis facility's projected allowable charges per treatment for each payment source in 2012 as follows:

Source of Payment	Charge Per Treatment
Private Pay	NA
Medicare	\$213.00
Medicaid	\$145.00
Commercial Insurance	\$358.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. On pages 108-113, the applicant provides projected revenues and expenses as follows:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,144,549	\$2,276,842
Bad Debt	\$216,891	\$231,531
Total Operating Costs	\$1,562,452	\$1,635,196
Profit	\$365,206	\$410,115

Assumptions:

1. Average number of patients for the current year is increased by one-half the facility growth rate for the first two operating years;
2. Average of three treatments per patient per week reduced by 7.0% allowance for missed treatments; and
3. Revenues include both hemodialysis in-center and all ancillary revenues; all revenues except in-center revenues are inflated by 3% per year.

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. Projected utilization is based on one-half the annual growth rate of the facility. See pages 108-113 of the application for the applicant's assumptions.

On page 111, the applicant provides projected staffing and salaries. On pages 20 and 82, the applicant states that DCI Boiling Springs will continue to operate within the applicable laws and regulations pertaining to staffing. Staffing by shift is provided on page 85. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrates that the

financial feasibility of the proposal is based upon reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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The applicant proposes to add two dialysis stations to its existing facility for a total of 15 certified dialysis stations upon completion of the proposed project and Project I.D. #C-8784-12 [add two dialysis stations to the existing facility for a total of 13 stations]. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis stations in Cleveland County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. Although the January 2013 SDR shows there is a deficit of one dialysis station in Cleveland County, in this application, the applicant is applying for additional stations based on the facility need methodology. According to the January 2013 SDR, DCI Boiling Springs is one of four dialysis facilities in Cleveland County with utilization rates ranging from 76.79% to 105%. All four dialysis facilities are owned by DCI. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it currently serves and proposes to serve. Per the January 2013 SDR, as of June 30, 2012, the 10 station DCI Boiling Springs facility was operating at 105% capacity ($42 / 10 = 4.2$; $4.2 / 4 = 1.05$ or 105%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 15 stations serving 48 patients (end of year 1) which is a utilization rate of 80% ($48 / 15 = 3.2$; $3.2 / 4 = .8$ or 80%). Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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The following table illustrates the existing and projected staffing for DCI Boiling Springs, as provided by the applicant on page 111.

Position	Current # of FTEs	Total Positions to be Filled	Total FTE Positions Upon Completion
RN	3.00	0.00	3.00

LPN	1.00	0.00	1.00
PCT	6.00	1.00	7.00
Chief/Reuse Technician	1.00	0.00	1.00
MD	Contract		
Admin*	0.15	0.00	0.15
Dietician*	0.15	0.00	0.15
Social Worker*	0.15	0.00	0.15
Social Worker Assistant*	0.15	0.00	0.15
Vascular Access Coordinator*	0.15	0.00	0.15
Unit Secretary	1.00	0.00	1.00
Bookkeeper*	0.15	0.00	0.15
Biller*	0.29	0.00	0.29
Accounts Payable*	0.15	0.00	0.15
TOTAL	13.34	1.00	14.34

As shown in the above table, the applicant proposes to employ a total of 14.34 full-time equivalent (FTE) positions to staff DCI Boiling Springs upon completion of the proposed project. Exhibit's 18 and 19 contains letters signed by three physicians of Nephrology Associates of the Carolinas, which state that each is board certified in nephrology and that each has agreed to continue to serve as medical directors for DCI Boiling Springs.

In Section VII.10, page 85, the applicant provides the direct care staff for each shift offered in the facility as shown in the table below:

	Shift Times	Sun	Mon	Tues	Wed	Thur	Fri	Sat
Morning	6:00am to 12:00pm		4	4	4	4	4	4
Afternoon	12:00pm to 5:00pm		4	4	4	4	4	4
Evening	NA							

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section V.1, page 63, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, pages 23-25 of the application. Emergency care, diagnostic and evaluation services, x-ray services, blood bank services and acute dialysis in an acute care setting will be provided by Cleveland Regional Medical Center. An agreement is provided in Exhibit 15. Exhibit 16 contains an agreement with Carolinas Medical Center for transplantation services. Most of the

other services will be provided by DCI Boiling Springs and DCI Shelby. Exhibit 18 contains letters of support from area physicians.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1(a), page 76, the applicant discusses DCI Boiling Springs' history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

“...DCI is a not-for profit corporation that was created solely to meet the needs of dialysis patients. This commitment to patient need has remained strong not only at the corporate level but also at the clinic level. Because of this commitment, DCI willingly serves any and all population groups without regard to income, race or ethnic minority, sex, ability, age, or any other perceived underserved status.”

On page 76, the applicant states that historically, 82.3 % of patients at DCI Boiling Springs have some or all of their services paid for by Medicare or Medicaid. Thus, 82.3% of the center revenue is derived from government payors. The table below illustrates the 2012 historical payor mix for the facility.

DCI Boiling Springs 2012 – Source of Patient Revenue

Payor Source	In-Center
Private Pay	0.0%
Commercial Insurance	17.6%
Medicare	73.5%
Medicaid	8.8%
Total	100.0%

Note: Percentages are based on number of patients by payor category; net revenue by payor will differ because of the differences in reimbursement among payors.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Cleveland County and Statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2008-2009 % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)*
Cleveland	23.0%	10.6%	18.6%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by DCI Boiling Springs. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”¹

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues

¹ www.cms.gov/medicare/end-stage-renal_disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf

to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6
 Includes North Carolina, South Carolina and Georgia

The applicant demonstrates that it provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving

federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(f), page 78 applicant states:

“None of the DCI clinics have any obligation under any federal regulations to provide uncompensated care, community service or access by minorities and handicapped persons.”

In Section VI.6(a), page 81, the applicant states, *“There have been no civil rights equal access complaints filed against DCI Shelby, DCI Kings Mountain, DCI Boiling Springs, DCI South or Dialysis Clinic, Inc., the parent company, during the past five years.”* The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.1(c), page 77, the applicant does not anticipate any change to the future payor mix as indicated in this table.

DCI Boiling Springs – Proposed Patient Revenue

Payor Source	In-Center
Private Pay	0.0%
Commercial Insurance	17.6%
Medicare	73.5%
Medicaid	8.8%
Total	100.0%

Note: Percentages are based on number of patients by payor category; net revenue by payor will differ because of the differences in reimbursement among payors.

In Section VI.1(d), page 77, the applicant states, *“DCI clinics have a commitment to serve all patients with a medical need for dialysis. As stated in the DCI admission policy in Exhibit 6, ‘all persons presenting for treatment of end state renal disease will be admitted without regard for race, sex, color, creed, religion, physical disability, **ability to pay**, or any other consideration other than medical need and referral from physician.”* [emphasis in original]

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5(a), page 79, the applicant states:

“Any patient with a medical need for dialysis treatments may be admitted to DCI clinics by any nephrologist who has admitting privileges with the clinic. To facilitate patient access, DCI has an open-door policy regarding physician admitting privileges and any licensed nephrologist may apply to admit his or her patients to any of the DCI clinics, including the Boiling Springs clinic.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.3, pages 67-68, the applicant states that DCI Boiling Springs has existing clinical relationships with several programs in the service area, including Cleveland County Emergency Medical Services, Gardner-Webb University’s nursing program, Cleveland Community College allied health program and Crest High School’s health occupation program. Students from Winston-Salem State University and Western Carolina University also utilize the DCI Boiling Springs clinic for training in nursing, social work and nutrition. Exhibit 17 contains agreements with Gardner-Webb and Cleveland County EMS.

The information provided is reasonable and credible and supports a finding of conformity with this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

DCI Boiling Springs proposes to add two dialysis stations to the existing facility for a total of 15 stations upon completion of this project and Project I.D. #C-8784-12 [add two dialysis stations to the existing facility for a total of 13 stations]. DCI, the only ESRD provider in Cleveland County, has four dialysis centers, as shown in the table below.

Facility	Existing Stations	Approved Not Certified	Total Stations
DCI Shelby	25	4	29
DCI Boiling Springs	11	2	13
DCI Kings Mountains	14	1	15
DCI South Shelby	10	4	14

Source: January 2013 SDR

In Section V.7, pages 73-75, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. See also Sections II, III, V, VI, and VII. The information provided by the applicant in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost effectiveness, quality, and access to dialysis services in Cleveland County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicant adequately demonstrates the need to add two dialysis stations and that it is a cost-effective alternative to meet that need;
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services at DCI Boiling Springs. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, DCI Boiling Springs has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:
- (1) Utilization rates;

-C- In Section IV.1, page 60, the applicant provides the current utilization rate as of February 6, 2013 of 90% with 3.6 (36 / 10 = 3.6 for 0.90) patients per station.
 - (2) Mortality rates;

-C- In Section IV.2, page 60, the applicant provides the mortality rates as 19%, 12% and 14% for 2010, 2011 and 2012, respectively.
 - (3) The number of patients that are home trained and the number of patients on home dialysis;

-NA- In Section IV.3, page 60, the applicant states, “*DCI Boiling Springs does not provide home dialysis services.*” The applicant does not propose to have any home hemodialysis patients at the facility.

- (4) The number of transplants performed or referred;
- C- In Section IV.4, page 61, the applicant states that during the past twelve months, DCI Boiling Springs referred 20 patients for transplants and none of the patients received a kidney transplant.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section IV.5, page 61, the applicant states, that as of February 1, 2013, two patients are on the transplant waiting list.
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section IV.6, page 61, the applicant states that there were 30 total hospital admissions in 2012, 24 (80%) of which were dialysis related and six (20%) non-dialysis related.
- (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.
- C- In Section IV.7, page 61, the applicant states, *“Currently, DCI Boiling Springs has no HIV patients, no Hepatitis B patients, and one Hepatitis C patient. None of the DCI Boiling Springs patients converted from negative to positive within the past 12 months.”*

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- DCI Boiling Springs is an existing facility.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,
- (B) composition of the assessment/evaluation team at the transplant center,
- (C) method for periodic re-evaluation,
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.

-NA- DCI Boiling Springs is an existing facility.

(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-NA- DCI Boiling Springs is an existing facility.

(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- See Exhibit 4 for a copy of DCI's policies and procedures following a power outage or other power loss event.

(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-NA- DCI Boiling Springs is an existing facility.

(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section XI.6(g), the applicant states, "*As an existing licensed and certified dialysis clinic, all of DCI's services are provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, and physical environment.*" Exhibits 4, 5 and 6 include documentation of DCI's operational policies and procedures, quality polices and admission and treatment policies.

(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- See Section III.2 and III.7, pages 51-52 and page 54 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

County	Operating Year 1 2014	Operating Year 2 2015	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
Cleveland	35	37	72%	72%
Rutherford	13	14	28%	28%
Total	48	51	100.0%	100.0%

The applicant states that its projected patient origin for both project years will remain the same as its current patient origin
 Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.

-NA- DCI Boiling Springs is an existing facility.

(9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.

-C- In Section II.1, page 22, the applicant states, “DCI willingly serves all population groups without regard to income, race or ethnic minority, sex, ability, age, or any perceived underserved status.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- DCI Boiling Springs does not propose to establish a new End Stage Renal Disease facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for

the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section III.7, page 54, DCI Boiling Springs projects utilization of 48 patients as of the end of the first operating year (3.2 patients per station per week). Assumptions are provided in Section III.2, pages 51-52.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section III.2, pages 51-52. The applicant states that the SMFP growth rate methodology of 13.5 percent is not likely to be sustained in the coming months and thus utilized one-half (6.75 percent) the facility need methodology instead to derive at the facility growth rate over the first two project years.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) diagnostic and evaluation services;

-C- In Section V.1, page 63, the applicant states that diagnostic and evaluation services will be referred to Cleveland Regional Medical Center.

(2) maintenance dialysis;

-C- In Section V.1, page 63, the applicant states that dialysis/maintenance will be provided by the applicant.

(3) accessible self-care training;

-C- Based on patient origin information provided in the table in Section III.7, page 54 of the application, the applicant does not propose any home training. Any patient meeting the qualifications for in-home care is referred to DCI Shelby.

(4) accessible follow-up program for support of patients dialyzing at home;

-C- Based on patient origin information provided in the table in Section III.7, page 54 of the application, the applicant does not propose any home training.

(5) x-ray services;

- C- In Section V.1, page 63, the applicant states that x-ray services will be provided by Cleveland Regional Medical Center.
- (6) laboratory services;
- C- In Section V.1, page 63, the applicant states that laboratory services will be provided by the applicant.
- (7) blood bank services;
- C- In Section V.1, page 64, the applicant states that blood bank services services will be provided by Cleveland Regional Medical Center.
- (8) emergency care;
- C- In Section V.1, page 63, the applicant states that emergency care services will be provided by Cleveland Regional Medical Center.
- (9) acute dialysis in an acute care setting;
- C- In Section V.1, page 63, the applicant states that acute services will be provided by Cleveland Regional Medical Center.
- (10) vascular surgery for dialysis treatment patients;
- C- In Section V.1, page 64, the applicant states that vascular surgery will be provided by Shelby Surgical and Dilworth Surgical (local physicians).
- (11) transplantation services;
- C- In Section V.1, page 63, the applicant states that transplantation services will be provided by Carolinas Medical Center.
- (12) vocational rehabilitation counseling and services; and
- C- In Section V.1, page 64, the applicant states that vocational rehabilitation services will be provided by Shelby Vocational Rehabilitation.
- (13) transportation.
- C- In Section V.1, page 64, the applicant states that transportation services will be provided by Transportation Authority of Cleveland County or patient and family.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

- C- Exhibit 7, page 188, the applicant provides the current and proposed staffing. In Section VII.2, page 82, the applicant states the proposed facility will comply with

all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- See Section VII.5, page 83.