

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012

PROJECT ANALYST: Les Brown  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: C-8785-12 / Dialysis Clinic, Inc. d/b/a DCI Shelby / Add five dialysis stations to the existing facility for a total of 34 stations upon completion of this project / 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 Shelby (DCIS) currently operates a 25-station dialysis facility located at 1016 North Lafayette Street, Shelby, NC. The applicant proposes to add five dialysis stations to the existing facility for a total of 34 stations upon completion of this project and Project I.D. #C-8732-11 [Add four station to the existing DCIS dialysis facility (25 + 4 + 5 = 34 stations)]. Project I.D. #C-8732-11 was approved by the CON Section on January 20, 2012.

The 2012 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 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Cleveland County. 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 DCIS in the January 2012 SDR is 3.96 patients per station, or 99.00%. This utilization rate was calculated based on 99 in-center dialysis patients and 25 certified dialysis stations as of June 30, 2011 (99 patients / 25 stations = 3.96 patients per station; 3.96 patients per station / 4.00 patients per station = 99.00%). 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 6/30/2011		99.00%
Certified Stations		25
Pending Stations		4
<b>Total Existing and Pending Stations</b>		<b>29</b>
In-Center Patients as of 6/30/2011 (SDR2)		99
In-Center Patients as of 12/31/2010 (SDR1)		91
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change.	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2010	0.1758
(ii)	Divide the result of Step (i) by 12	0.0147
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January [2012] SDR (6/30/11) until the end of calendar year 2011 (6 months)	0.0879
(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	107.7033
(v)	Divide the result of Step (iv) by 3.2 patients per station	33.6580
	and subtract the number of certified and pending stations as recorded in SDR2 [30] to determine the number of stations needed	<b>5</b>

[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 five stations, and the applicant proposes to add five new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2012 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

On pages 43-48, the applicant discusses its quality improvement program. On page 45 the applicant states:

*“DCI’s quality management system is managed through its corporate office, which collects data from each of its 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.”*

On page 46 the applicant states:

*“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 6 contains the 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

On pages 75-80 the applicant provides information about accessibility to its services. On page 75 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 2011 57.9% of DCIS’s services were for Medicare and Medicaid patients.

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

### Maximize Healthcare Value

On page 87 the applicant states that there are no construction costs involved in this project. On page 92 the applicant states that there are no start-up or initial operating expenses involved in this project. On pages 100-101 the applicant describes the methods that will be used to maintain efficient energy operations and contain the cost of utilities.

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c). The application is consistent with Policy GEN-3.

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.

CA

Dialysis Clinic, Inc. d/b/a DCI Shelby (DCIS) currently operates a 25-station dialysis facility located at 1016 North Lafayette Street, Shelby, NC. The applicant proposes to add five dialysis stations to the existing facility for a total of 34 stations upon completion of this project and Project I.D. #C-8732-11 [Add four stations to the existing DCIS dialysis facility (25 + 4 + 5 = 34 stations)]. Project I.D. #C-8732-11 was approved by the CON Section on January 20, 2012.

**Population to be served**

On page 55 the applicant provides the projected in-center patient origin for DCIS for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 CY 2013	OPERATING YEAR 2 CY 2014	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Cleveland	94	98	87%	87%
Gaston	12	13	11%	11%
Lincoln	1	1	1%	1%
Rutherford	1	1	1%	1%
<b>TOTAL</b>	<b>108</b>	<b>113</b>	<b>100%</b>	<b>100%</b>

On page 56 the applicant provides the projected home dialysis patient origin for DCIS for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 CY 2013	OPERATING YEAR 2 CY 2014	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	HOME DIALYSIS PATIENTS	HOME DIALYSIS PATIENTS	YEAR 1	YEAR 2
Cleveland	13	13	68%	68%
Gaston	2	2	11%	11%
Lincoln	1	1	5%	5%
Rutherford	1	1	5%	5%
Cherokee (SC)	2	2	11%	11%
<b>TOTAL</b>	<b>19</b>	<b>19</b>	<b>100%</b>	<b>100%</b>

On page 54 the applicant states that it assumes that the projected patient origin will be the same as the current patient origin. The applicant adequately identifies the population it proposes to serve.

**Demonstration of Need**

On page 52 the applicant states:

*“Moreover, the SDR methodology projection of 104 patients by the end of 2012 is conservative in that the Shelby clinic is already treating 99 patients, and given the facility need methodology, which projects 108 patients by the end of 2012. DCI recognizes that the projected growth in patients may require the operation of a third shift if the installation of the four stations approved in January 2012 is not completed before the growth occurs. However, as all three of the other DCI clinics are expected to be operating at or near capacity as well (two of the clinics are applying for additional stations concurrently with DCI Shelby’s application) and likely will not be able to accommodate many additional patients from the Shelby clinic, few other alternatives exist in the short term. Clearly, the long term capacity solution is CON approval for additional stations at all the DCI clinics.”*

On pages 51-52 the applicant projects the total number of in-center patients for the first three years of operation, as shown in the table below. The applicant states that the projected number of in-center patients is based on the five-year average annual change rate for Cleveland County (4.1%), as shown in Table B of the January 2012 SDR.

Year	Total In-Center Patients	Annual Growth Rate	# of Approved and Proposed Stations	Patients Per Station*
2012	104	NA	29	3.6
2013 (Year 1)	108	4.1%	34	3.17
2014 (Year 2)	112	4.1%	34	3.29
2015 (Year 3)	117	4.1%	34	3.49

\*Calculated by Project Analyst

The applicant projects that it will serve only 3.17 patients per station per week by the end of operating year one, which is not consistent with the requirement in 10A NCAC 14C .2203(b). However, as conditioned to develop only 4 additional stations, DCIS conforms to the performance standard. In summary, the applicant adequately identifies the population to be served and demonstrates the need for four additional dialysis stations based on the population it proposes to serve. Therefore, the application is conforming with this criterion, subject to Condition 2 in Criterion (4).

- (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.

- (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 56-60, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo, operate a third shift, relocate patients to other DCI facilities or increase the number of dialysis stations at the existing facility. The application is conforming or conditionally conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Consequently, the application is conforming with this criterion subject to the following conditions:

- 1. Dialysis Clinic, Inc. d/b/a DCI Shelby shall materially comply with all representations made in its certificate of need application, as amended by the conditions of approval.**
  - 2. Dialysis Clinic, Inc. d/b/a DCI Shelby shall develop and operate no more than four additional dialysis stations for a total of 33 certified stations following completion of this project and Project I.D. #C-8732-11 (add four dialysis stations) which shall include any home hemodialysis training or isolation stations.**
  - 3. Dialysis Clinic, Inc. d/b/a DCI Shelby shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 33 dialysis stations which shall include any isolation stations.**
  - 4. Dialysis Clinic, Inc. d/b/a DCI Shelby 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, pages 86-87, the applicant projects that the capital cost for the proposed project will be \$82,000 for dialysis machines, televisions and chairs. In Sections IX.3, page 92, the applicant projects that there will be no start-up expenses or initial operating expenses associated with the proposed project. On page 88 the applicant states that the capital cost will be financed with the accumulated reserves of DCI Shelby. Exhibit 21 contains a letter from the Treasurer of Dialysis Clinic, Inc., which states: “DCI, Inc. will finance the capital costs through DCI Shelby reserves.” Exhibit 22 contains the balance sheet of DCI Shelby. As of January 2012, DCI Shelby had \$7,095,148 in cash.

On page 94 the applicant states the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$208.00
Medicaid	\$145.00
Blue Cross/Blue Shield	\$1,029.00
Commercial Insurance	\$561.00
VA	\$342.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. On pages 110 and 113 the applicant provides projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$4,959,233	\$5,121,772
Total Operating Costs	\$4,274,465	\$4,465,774
Net Profit	\$684,768	\$655,998

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. See Section X of the application for the applicant’s assumptions.

In summary, the 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 on reasonable projections of revenues and operating costs. Therefore, the application is conforming with 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.

DCIS proposes to add five in-center dialysis stations to the existing and approved 29-station facility for a total of 34 dialysis stations upon completion of this project and Project I.D. #C-8732-11. The facility need methodology indicates that five additional stations are needed (See table in Criterion (1)). However, the applicant only demonstrates that the projected growth in the patient population is sufficient to result in the need to add four dialysis stations to the existing and approved stations for a total of 33 stations. Four stations were approved by the CON Section in January 2012. Therefore, the applicant is conforming with this criterion as conditioned to develop 4 additional stations in Criterion (4).

- (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.

C

The following table illustrates the existing and projected staffing for DCIS, as provided by the applicant in Exhibit 6.

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Director of Nursing	1.00	0	1.00
RN	4.00	1.00	5.00
LPN	4.00	1.00	5.00
Home Training Nurse	1.00	0	1.00
Patient Care Technician	8.00	3.00	11.00
Chief Technician	1.00	0	1.00
Reuse Technician	1.00	0	1.00
Machine Technician	0.37	0	0.37
Administrator	0.47	0	0.47
Dietitian	0.94	0	0.94
Social Worker	0.47	0	0.47
Social Work Assistant	0.47	0	0.47
Vascular Access Coordinator	0.47	0	0.47
Unit Secretary / Receptionist	2.00	0	2.00
Bookkeeper	0.94	0	0.94
Billing	1.00	0	1.00
Accounts Payable	0.47	0	0.47
<b>Total</b>	<b>27.60</b>	<b>5.00</b>	<b>32.60</b>

As shown in the table above, the applicant proposes to employ a total of 32.60 full-time equivalent (FTE) positions to staff DCIS upon completion of the proposed project. On page 70 the applicant states that Dr. Aamir Iqbal, MD will serve as medical director of the facility. Exhibit 18 contains a letter signed by Dr. Iqbal, which states that he is board certified in nephrology and that he has agreed to continue to serve as medical director for DCIS.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming with 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.

C

In Section V.1, pages 64-65, the applicant provides a list of providers of the necessary ancillary and support services. 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 with 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

NA

- (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(b), page 75, the applicant reports that 87.1% of the patients who received in-center treatments at DCIS had some or all of their services paid for by Medicare or Medicaid in 2011. The table below illustrates the historical payment source of the facility:

DCIS	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	82.8%
Medicaid	4.3%
Commercial Insurance	4.3%
Blue Cross /Blue Shield	3.2%
Other Govt / VA	5.4%
Total	100.0%

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 as of June 2010 and CY 2009, respectively. The data in the table were obtained on April 17, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	<b>Total # of Medicaid Eligible as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Cleveland	23%	10.6%	18.6%
Statewide	17%	6.8%	19.7%

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 DCIS.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 are available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race and gender do 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 applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at DCIS. Therefore, the application is conforming with 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. On page 77 the 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.”*

On page 80 the applicant states that there have been no civil rights access complaints filed against any of the DCI facilities in Cleveland County during the past five years. Therefore, the application is conforming with 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 76, the applicant provides the projected payor mix for the proposed services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming with 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, page 78, 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 Shelby clinic.”*

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

On page 68 the applicant states that DCIS has existing clinical training 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, Crest High School's health occupation program. Students from Winston Salem State University and Western Carolina University also utilize the DCIS clinic for training in nursing, social work and nutrition. Exhibit 16 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.

#### CA

See Sections II, III, V, VI and VII. In particular, see Section V, pages 72-74, in which DCIS discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and 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 the information in the application, and the following::

- The applicant adequately demonstrates the need to add only four dialysis stations to the existing and approved stations, and that it is a cost-effective alternative.
- The applicant has and will continue to provide quality services: and
- The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion, as conditioned to develop only 4 dialysis stations in Criterion (4).

- (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 DCIS in Shelby, NC. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming with this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(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.

CA

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

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

*.2202(a)(1) Utilization rates;*

-C- On page 61 the applicant provides the utilization rates for DCIS for FYs 2008 – 2011.

*.2202(a)(2) Mortality rates;*

-C- On page 61 the applicant provides the mortality rates for DCIS for FYs 2008 – 2011.

*.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*

-C- On page 61 the applicant provides the current number of patients that are home trained and the number of patients on home dialysis.

*.2202(a)(4) The number of transplants performed or referred;*

-C- On page 62 the applicant states that 77 patients were transferred for transplants during the past 12 months.

*.2202(a)(5) The number of patients currently on the transplant waiting list;*

-C- On page 62 the applicant states that as of February 1, 2012, eight patients were on the transplant waiting list.

*.2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

- C- On page 62 the applicant provides the hospital admissions by admission diagnosis for CY 2011.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
- C- On page 63 the applicant states that during the last calendar year, there were three HIV patients, two Hepatitis B patients and nine Hepatitis C patients, and that none of the DCIS patients converted to infectious status during 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:*
- .2202(b)(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- DCIS is an existing facility.
- .2202(b)(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- DCIS is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- DCIS is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 5 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(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- DCIS is an existing facility.
- .2202(b)(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- See Exhibits 5 and 6.

- .2202(b)(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.7, pages 54-55.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- DCIS is an existing facility.
- .2202(b)(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 for such services.*
- C- On page 20 the applicant states that DCIS serves all patients without regard to income or ability to pay.

#### **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

- .2203(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- DCIS is an existing facility.
- .2203(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.*
- CA- On page 52 the applicant projects to serve 108 in-center patients by the end of Year 1, which is only 3.17 patients per station ( $108 / 34 = 3.17$ ). However, as conditioned in Criterion (4) to develop only 4 additional stations, DCI conforms with the rule ( $108 / 33 = 3.27$ ).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- On pages 50-51 the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

#### **10 NCAC 14C .2204 SCOPE OF SERVICES**

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

- .2204(1) *Diagnostic and evaluation services;*
- C- See Section V.1, page 64.
- .2204(2) *Maintenance dialysis;*
- C- See Section V.1, page 64.
- .2204(3) *Accessible self-care training;*
- C- See Section V.1, page 64.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V.2, pages 67-68.
- .2204(5) *X-ray services;*
- C- See Section V.1, page 64.
- .2204(6) *Laboratory services;*
- C- See Section V.1, pages 65.

- .2204(7) *Blood bank services;*
  - C- See Section V.1, page 65.
- .2204(8) *Emergency care;*
  - C- See Section V.1, page 64.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 64.
- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- See Section V.1, page 65.
- .2204(11) *Transplantation services;*
  - C- See Section V.1, page 64.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
  - C- See Section V.1, page 65.
- .2204(13) *Transportation*
  - C- See Section V.1, page 65.

**10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(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- In Exhibit 20 the applicant provides the proposed staffing. In Section VII.2, page 81 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 discussion.
- .2205(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 82, and Exhibit 8.