

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 10, 2012

PROJECT ANALYST: Les Brown

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: C-10033-12 / Dialysis Clinic, Inc. d/b/a DCI South / Add four dialysis stations to the existing facility for a total of 14 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 applications⁰ 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.

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Dialysis Clinic, Inc. d/b/a DCI South currently operates a 10-station dialysis facility located at 1530 South Lafayette Street, Shelby, NC. The applicant proposes to add four dialysis stations to the existing facility for a total of 14 stations upon completion of this project.

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 July 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 DCI South in the July 2012 SDR is 3.90 patients per station, or 97.5%. This utilization rate was calculated based on 39 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2011 (39 patients / 10 stations = 3.90 patients per station; 3.90 patients per station / 4.00 patients per station = 97.5%). 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
 October Review**

| | | |
|--|--|-----------|
| Required SDR Utilization | | 80% |
| Center Utilization Rate as of 12/31/2011 | | 97.5% |
| Certified Stations | | 10 |
| Pending Stations | | 0 |
| Total Existing and Pending Stations | | 10 |
| In-Center Patients as of 12/31/2011 (SDR2) | | 39 |
| In-Center Patients as of 6/30/2011 (SDR1) | | 33 |
| Step | Description | |
| | Difference (SDR2 - SDR1) | 6 |
| (i) | Multiply the difference by 2 for the projected net in-center change. | 12 |
| | Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/2011 | 0.3636 |
| (ii) | Divide the result of Step (i) by 12 | 0.0303 |
| (iii) | Multiply the result of Step (ii) by the number of months from the most recent month reported in the July [2012] SDR (12/30/11) until the end of calendar year 2012 (12 months) | 0.3636 |
| (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 | 53.1818 |
| (v) | Divide the result of Step (iv) by 3.2 patients per station | 16.6194 |
| | and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed | 7 |

[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 seven stations, and the applicant proposes to add four 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 11 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

On pages 73-79, the applicant provides information about accessibility to its services. On page 73 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, 92.1% of DCI South’s services were for Medicare patients.

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

Maximize Healthcare Value

On page 98 the applicant states that the proposed project does not include any new construction, but involves only the removal of a wall to provide space for the additional stations. On page 91 the applicant states that there are no start-up or initial operating expenses involved in this project. On page 99 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.

The application is consistent with Policy GEN-3.

The application is consistent with the facility need determination in the 2012 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.

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Dialysis Clinic, Inc. d/b/a DCI South currently operates a 10-station dialysis facility located at 1530 South Lafayette Street, Shelby, NC. The applicant proposes to add four dialysis stations to the existing facility for a total of 14 stations upon completion of this project.

Population to be Served

On page 54 the applicant provides the projected patient origin for DCI South for the first two years of operation following completion of the project. The applicant assumes that the projected patient origin will be the same as the current patient origin, as shown in the following table.

| 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 | 49 | 56 | 97% | 97% |
| Gaston | 1 | 2 | 3% | 3% |
| TOTAL | 50 | 58 | 100% | 100% |

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

On pages 50-51 the applicant states:

“As shown in the 2012 SDR, DCI South had 39 in-center patients as of December 31,2011. The methodology above demonstrates that the annual growth rate of 36.36 percent represented by the growth from the January 2012 SDR, results in a need for seven additional stations. DCI is taking a more conservative approach, first by starting

with only 39 patients for 2012 (i.e. assuming no growth from 2011 to 2013), and second by projecting only one-half the historical growth rate or 18.18 percent.

...

[E]ven with the addition of four more stations proposed in this application and a growth rate of one-half the most recent actual growth rate, DCI South will continue to have over 3.2 patients per station through the projection period.”

On page 51 and in supplemental information, the applicant projects the total number of in-center patients for the first two full years of operation, as shown in the table below.

| Year | Total In-Center Patients | # of Approved and Proposed Stations | Patients Per Station* |
|---|---------------------------------|--|------------------------------|
| 2012 | 39 | 10 | 3.90 |
| Interim Period (January – June 2013) | 46 | 10 | 4.60 |
| First Full Year (July 2013 - June 2014) | 50 | 14 | 3.57 |
| Second Full Year (July 2014 – June 2015) | 58 | 14 | 4.14 |

On pages 50-51, the applicant states that the projected number of in-center patients is based on *“only one-half the historical growth rate or 18.18 percent.”* In the table above, the applicant projects 46 patients during project development (January – June, 2013). This results in 4.6 patients per station [46 patients / 10 stations = 4.6 patients per station]. On page 83 and in supplemental information, the applicant states that the facility will add a third shift on a temporary basis when the number of patients exceeds its current capacity of 40 patients on two shifts.

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).

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.

- (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, pages 54-57, 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 South is operating at capacity and the facility need methodology in the 2012 SMFP indicates the facility could have 53 patients by the end of 2012, 13 more than the facility can serve without adding a third shift.
- 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 Four Stations to the Existing Facility – DCI South chose this alternative because it is operating at capacity. Many of its 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 South shall materially comply with all representations made in its certificate of need application and supplemental responses. In those instances where representations conflict, DCI South shall materially comply with the last-made representation.**
 - 2. Dialysis Clinic, Inc. d/b/a DCI South shall develop and operate no more than four additional dialysis stations for a total of 14 certified stations which shall include any home hemodialysis training or isolation stations.**
 - 3. Dialysis Clinic, Inc. d/b/a DCI South shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 14 dialysis stations which shall include any isolation stations.**
 - 4. Dialysis Clinic, Inc. d/b/a DCI South 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, page 86, the applicant projects that the capital cost for the proposed project will be \$195,800 for renovation, dialysis machines, televisions, and other furniture and equipment. In Section IX, pages 91-92, the applicant projects that there will be no start-up expenses or initial operating expenses associated with the proposed project. On page 87 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 will finance the capital costs through DCI Shelby cash reserves.”* Exhibit 21 contains the balance sheet of DCI Shelby. As of January 2012, DCI Shelby had \$7,095,148 in cash.

On page 93 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 | \$217.00 |
| Commercial Insurance | \$256.00 |

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. On pages 106 and 110, the applicant provides projected revenues and expenses as follows:

| | OPERATING YEAR 1 | OPERATING YEAR 2 |
|-----------------------|------------------|------------------|
| Total Net Revenue | \$2,069,845 | \$2,403,265 |
| Total Operating Costs | \$2,028,834 | \$2,217,652 |
| Net Income | \$41,011 | \$185,613 |

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..
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 an annual growth rate which is one-half the growth rate in the July 2012 SDR. See Section X of the application for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs 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.

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The applicant proposes to add four dialysis stations to the existing facility for a total of 14 stations upon completion of the proposed project. Based on the facility need methodology in the 2012 SMFP, the applicant adequately demonstrates the need for four additional stations based on the number of in-center patients it proposes to serve. As of December 31, 2011, the 10-station facility was operating at 97.5% capacity ($39 / 10 = 3.9$; $3.9 / 4 = 97.5\%$). Upon completion of this project, the facility will have 14 stations serving 50 patients (end of first full year) which is an occupancy rate of 89.3% ($50 / 14 = 3.57$; $3.57 / 4 = 89.3\%$).

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 with 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.

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

| POSITION | CURRENT FULL-TIME EQUIVALENT (FTE) POSITIONS | # OF FTE POSITIONS TO BE ADDED | TOTAL FTE POSITIONS |
|-----------------------------|---|---|--------------------------------|
| Registered Nurse | 2.00 | 1.00 | 3.00 |
| Patient Care Technician | 4.00 | 3.00 | 7.00 |
| Chief / Reuse Technician | 1.00 | 0 | 1.00 |
| Administrator | 0.15 | 0 | 0.15 |
| Dietitian | 0.15 | 0 | 0.15 |
| Social Worker | 0.15 | 0 | 0.15 |
| Social Work Assistant | 0.15 | 0 | 0.15 |
| Vascular Access Coordinator | 0.15 | 0 | 0.15 |
| Unit Secretary | 1.00 | 0 | 1.00 |
| Bookkeeper | 0.15 | 0 | 0.15 |
| Billing | 0.29 | 0 | 0.29 |
| Accounts Payable | 0.15 | 0 | 0.15 |
| Total | 9.34 | 4.00 | 13.34 |

As shown in the table above, the applicant proposes to employ a total of 13.34 FTE positions to staff DCI South upon completion of the proposed project. Exhibit 18 contains three letters signed by the three physicians of Nephrology Associates of the Carolinas, PA, which states that they are board certified in nephrology and that they have agreed to continue to serve as medical directors for DCI South.

The applicant documents the availability of adequate health manpower and management personnel, including medical directors, 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.

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In Section V.1, pages 61-62, the applicant provides a list of providers of the necessary ancillary and support services. Exhibit 14 contains agreements with Cleveland Regional Medical Center for acute dialysis services and laboratory services. Exhibit 17 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 care 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;

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In Section VI.1(b), page 73, the applicant reports that 92.1% of the patients who received treatments at DCI South had some or all of their services paid for by Medicare in the past year. The table below illustrates the historical payment source of the facility:

| DCI SOUTH | |
|----------------------|------------|
| SOURCE OF PAYMENT | PERCENTAGE |
| Medicare | 92.1% |
| Commercial Insurance | 7.9% |
| 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 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 * | 2009 % Uninsured (Estimate by Cecil G. Sheps Center) * |
|---------------------|--|---|---|
| Cleveland County | 23% | 10.6% | 18.6% |
| Statewide | 17% | 6.8% | 19.7% |

* More current data, particularly with regard to the estimated uninsured percentages, were 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 South. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (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 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 or 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the CMS website states:

“Although the ESRD population is 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.”

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

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

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 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% |

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender, as shown below:

| Number and Percent of Dialysis Patients by Age, Race, and Gender | | |
|---|---------------------------|---------------------------------|
| | # of ESRD Patients | % of Dialysis Population |
| Age | | |
| 0-19 | 89 | 1.0% |
| 20-34 | 451 | 4.8% |
| 35-44 | 773 | 8.3% |
| 45-54 | 1529 | 16.4% |
| 55-64 | 2370 | 25.4% |
| 65-74 | 2258 | 24.2% |
| 75+ | 1872 | 20.0% |
| Gender | | |
| Female | 4,237 | 45.35% |
| Male | 5,105 | 54.65% |
| Race | | |
| African American | 5,096 | 54.55% |
| White | 4,027 | 43.11% |
| Other | 219 | 2.3% |
| Total | 9,342 | 100.0% |

Source: SKC Network 6, which includes North Carolina, South Carolina and Georgia.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at DCI South. 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;

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 76 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 78 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 74, the applicant provides the projected payor mix for the proposed services at the facility. The applicant projects no change from the current payor mix which is 92.1% Medicare. The applicant demonstrates that medically underserved populations will 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 77, 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 South clinic.”

The applicant adequately demonstrates that it will offer a range of means by which a person can access its 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.

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On page 65 the applicant states that DCI South 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 and Crest High School’s health occupation program. Students from Winston Salem State University and Western Carolina University also utilize the DCI South 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.

C

DCI South proposes to add four dialysis stations to the existing facility for a total of 14 stations upon completion of this project. DCI is the only ESRD provider in Cleveland County which has four dialysis centers, as shown in the table below.

| FACILITY | EXISTING STATIONS | APPROVED NOT CERTIFIED | TOTAL STATIONS |
|---------------------|-------------------|------------------------|----------------|
| DCI Shelby | 29 | 4 | 33 |
| DCI Boiling Springs | 11 | 2 | 13 |
| DCI Kings Mountain | 14 | 1 | 15 |
| DCI South* | 10 | 0 | 10 |
| Total | 64 | 7 | 71 |

* DCI South is proposing 4 additional stations in this application.

In Section V, pages 70-72, 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 where the applicants discuss the impact of the project on 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 in the service area 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 (including the supplemental information), and the following analysis:

- ◆ The applicant adequately demonstrates the need to add four dialysis stations and that it is a cost-effective alternative to meet that need;
- ◆ 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.

The application is conforming with 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 South 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.

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 regulatory review criteria. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANTS

(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 49 the applicant provides the utilization rate for DCI South as of December 31, 2011, which was 97.5%.

.2202(a)(2) Mortality rates;

-C- On page 58 the applicant provides the mortality rates for DCI South for CYs 2010 – 2011: 15% in 2010 and 8% in 2011.

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

-NA- On page 18 the applicant states that none of the DCI South patients is home trained or on home dialysis.

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

-C- On page 59 the applicant states that 28 patients were referred for transplants during the past 12 months and one patient received a transplant.

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

- C- On page 59 the applicant states that as of August 1, 2012, two 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 59 the applicant provides the hospital admissions by admission diagnosis for FFY 2011: 81% for non-dialysis related admissions and 19% for dialysis related admissions.
- .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 59 the applicant states that currently there are three HIV patients, no Hepatitis B patients and one Hepatitis C patient, and that none of the 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- DCI South 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- DCI South 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- DCI South 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 4 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- DCI South 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 4 and 11.
- .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 53-54.
- .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- DCI South 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 22 the applicant states that DCI South 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- DCI South 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.*
- C- On page 51 the applicant projects to serve 50 in-center patients by the end of Year 1, which is 3.57 patients per station ($50 / 14 = 3.57$).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- On pages 49-51, 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- These services are provided by Cleveland Regional Medical Center (CRMC). See Section V.1, page 61.
- .2204(2) *Maintenance dialysis;*
 - C- These services are provided by DCI South. See Section V.1, page 61.
- .2204(3) *Accessible self-care training;*
 - C- These services are provided by DCI South, DCI Shelby and CRMC. See Section V.1, page 61.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

- NA- DCI South does not provide home dialysis. Home dialysis is provided by DCI Shelby.
- .2204(5) *X-ray services;*
 - C- These services are provided by CRMC. See Section V.1, page 61.
- .2204(6) *Laboratory services;*
 - C- These services are provided by DCI South and CRMC. See Section V.1, pages 61-62.
- .2204(7) *Blood bank services;*
 - C- These services are provided by CRMC. See Section V.1, page 62.
- .2204(8) *Emergency care;*
 - C- This service is provided by CRMC. See Section V.1, page 61.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- This service is provided by CRMC. See Section V.1, page 61.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- This service is provided by Shelby Surgical and Dilworth Surgical. See Section V.1, page 62.
- .2204(11) *Transplantation services;*
 - C- These services are provided by Carolinas Medical Center in Mecklenburg County. See Section V.1, page 61.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- These services are provided by Shelby Vocational Rehabilitation. See Section V.1, page 62.
- .2204(13) *Transportation*
 - C- This service is provided by the Transportation Authority of Cleveland County or the family. See Section V.1, page 62.

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 6 the applicant provides the proposed staffing. In Section VII.2, page 80, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided.
- .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 81, and Exhibit 7.