

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012
FINDINGS DATE: June 1, 2012
PROJECT ANALYST: Fatimah Wilson
SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: F-8810-12 / Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center / Add four dialysis stations to the existing facility for a total of 19 stations upon project completion / Cabarrus 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.

C

Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center currently operates a 15-station dialysis facility located at 3310 Perry Street NW in Concord, NC. The applicant proposes to add four dialysis stations to the existing facility for a total of 19 stations upon project completion.

The 2012 State Medical Facilities Plan (2012 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 Cabarrus 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 Harrisburg Dialysis Center in the January 2012 SDR is 3.66 patients per station, or 92%. This utilization rate was calculated based on 55 in-center dialysis patients and 15 certified dialysis stations as of June 30, 2011 (55 patients / 15 stations = 3.66 patients per station;

4.00 patients per station / 3.66 patients per station = 91.5%). 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
 April Review—January SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11		92%
Certified Stations		15
Pending Stations		0
Total Existing and Pending Stations		15
In-Center Patients as of 6/30/11 (SDR2)		55
In-Center Patients as of 12/31/10 (SDR1)		51
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change.	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/10	0.1569
(ii)	Divide the result of Step (i) by 12	0.0131
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July [2011] SDR (12/31/11) until the end of calendar year (6 months)	0.0784
(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	59.3137
(v)	Divide the result of Step (iv) by 3.2 patients per station	18.5355
	and subtract the number of certified and pending stations as recorded in SDR2 [30] to determine the number of stations needed	4

[NOTE: "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). 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 four 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 also 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

The applicant discusses its quality index in Section I, pages 6-8. Also, in Section II.3, pages 15-16, the applicant states,

“DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development.

... The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.

...

The Harrisburg Dialysis Center is attended by Dr. Charles Stoddard, admitting Nephrologists who directly oversees the quality of care of the dialysis facility. In addition, Dr. Stoddard serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”

The applicant also discusses its safety measures in Section XI.6(g), pages 52-53. In Exhibit 4 the applicant provides published articles about its clinical outcomes and a copy of an article which describes DaVita’s quality index. In Exhibit 13, the applicant provides a copy of its isolation policies and procedures and in Exhibit 21, the applicant provides a copy of its safety training outline. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Cabarrus County.

Promote Equitable Access

In Section VI, pages 28-31, the applicant provides information about accessibility to its services. On page 30, the applicant states,

“The Harrisburg Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, or handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

The Harrisburg Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. The facility provides dialysis six days per week with two patient shifts per day to accommodate patient need.

The Harrisburg Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

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

Maximize Healthcare Value

In Section III.9, pages 20-21, the applicant states,

“The Harrisburg Dialysis Center will promote cost-effective approaches in the facility in the following ways:

...

- *The Harrisburg Dialysis Center will purchase all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- *The Harrisburg Dialysis Center will utilize the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *The Harrisburg Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *The Harrisburg Dialysis Center Bio-Medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*

- *The Harrisburg Dialysis Center will also have an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.*

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.

In addition, Policy Gen-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2011 SMFP states, “Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.” The capital costs of this project are less than \$2 million. Therefore, Policy Gen-4 is not applicable to this review.

The application is conforming to 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

Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center currently operates a 15-station dialysis facility located at 3310 Perry Street NW in Concord, NC. The applicant proposes to add four dialysis stations to the existing facility for a total of 19 stations upon project completion. The January 2012 SDR indicates a total of 15 certified stations at Harrisburg Dialysis Center, as of June 30, 2011. Based on patient origin information provided in the table in Section III.7, page 19 of the application, the applicant does not propose any home training.

Population to be served

In Section IV.1, page 22, the applicant states that the number of in-center patients served at the Harrisburg Dialysis Center as of June 30, 2011 is as follows:

<i>COUNTY OF RESIDENCE</i>	<i># OF PATIENTS DIALYZING IN-CENTER</i>
<i>Cabarrus</i>	<i>46</i>
<i>Mecklenburg</i>	<i>8</i>
<i>Stanley [sic]</i>	<i>1</i>
<i>Total</i>	<i>55</i>

In Section III.7, page 19, the applicant provided the projected patient origin for Harrisburg Dialysis Center for the first two years of operation following completion of the project as follows:

<i>COUNTY</i>	<i>OPERATING YEAR 1 2013</i>		<i>OPERATING YEAR 2 2014</i>		<i>COUNTY PATIENTS AS A PERCENT OF TOTAL</i>	
	<i>IN-CENTER PATIENTS</i>	<i>HOME DIALYSIS PATIENTS</i>	<i>IN-CENTER PATIENTS</i>	<i>HOME DIALYSIS PATIENTS</i>	<i>YEAR 1</i>	<i>YEAR 2</i>
<i>Cabarrus</i>	<i>53</i>	<i>0</i>	<i>58</i>	<i>0</i>	<i>85.5%</i>	<i>86.6%</i>
<i>Mecklenburg</i>	<i>8</i>	<i>0</i>	<i>8</i>	<i>0</i>	<i>12.9%</i>	<i>11.9%</i>
<i>Stanley [sic]</i>	<i>1</i>	<i>0</i>	<i>1</i>	<i>0</i>	<i>1.6%</i>	<i>1.5%</i>
<i>TOTAL</i>	<i>62</i>	<i>0</i>	<i>67</i>	<i>0</i>	<i>100%</i>	<i>100%</i>

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

In Section II, pages 12-13, and in Section III.7, pages 19-20, the applicant provides the assumptions and methodology it used to project need for four additional dialysis stations at Harrisburg Dialysis Center. The applicant states,

- *“The Harrisburg Dialysis Center had 55 in-center patients as of June 30, 2011 based on information included on Page 10 of the January 2012 Semiannual Dialysis Report (SDR).*
- *Of the 55 in-center patients cited in the SDR, 46 of the patients live in Cabarrus County.*
- *The period of growth begins with January 1, 2012 forward to December 31, 2014.*
- *The following are the in-center patient projections using the 8.3% Average Annual Change Rate for the Past Five Years as indicated on page 19 of the January 2012 Semiannual Dialysis Report for the 46 in-center patients residing in Cabarrus County.*

January 1, 2012-December 31, 2012—46 patients X 1.083=49.818
January 1, 2013-December 31, 2013—49.818 patients X 1.083=53.952894
January 1, 2014-December 31, 2014—53.952894 patients X 1.083=58.4309842

Operating Year One is projected to begin January 1, 2014 [2013] and end on December 31, 2013 [2014]

Operating Year Two is projected to begin January 1, 2014 [2014] and end on December 31, 2014 [2015]

We did not provide a growth rate for the 8 patients living in Mecklenburg County or the one patient living in Stanley [sic] County. Therefore, the Harrisburg Dialysis Center is projected to have 62 in-center patients at the end of operating year one (53 Cabarrus County patients, 8 [eight] Mecklenburg County patients and one Stanley [sic] County patient = 62 patients). The facility is projected to have 67 in-center patients at the end of operating year two (58 Mecklenburg [Cabarrus] County patients, 8 [eight] Mecklenburg County patients and one Stanley County patient = 67 patients.”

In Section II.1, pages 12-13, the applicant states,

“Based on the patients and stations above, Harrisburg Dialysis Center is projected to have at least 62 in-center patients by the end of operating year 1 [one] for a utilization rate of 81% or 3.2 patients per station and at least 67 in-center patients by the end of operating year 2 [two] for a utilization rate of 88% or 3.5% patients per station.”

The following shows the average number of in-center patients per station per week and the utilization rate for each of the first two operating years following completion of the project.

Year 1 (January 1, 2013 – December 31, 2013)

Average # of Patients/Station/Week: 62 in-center patients dialyzing on 19 stations = 3.26
Utilization Rate: $62 / (4 \times 19) = .815$ or 81% utilization

Year 2 (January 1, 2014 – December 31, 2014)

Average # of Patients/Station/Week: 67 in-center patients dialyzing on 19 stations = 3.52
Utilization Rate: $67 / (4 \times 19) = .881$ or 88% utilization

Projected utilization at the end of Year One equals 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b) and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for four additional dialysis stations at the Harrisburg Dialysis Center. Consequently, the application is conforming to 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, page 20, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo or increase the number of dialysis stations at the facility. The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (12), (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 to this criterion subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall materially comply with all representations made in its certificate of need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall develop and operate no more than four (4) additional dialysis stations for a total of 19 certified stations which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall install plumbing and electrical wiring through the walls for four additional dialysis stations for a total of 19 dialysis stations which shall include any isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Dialysis Harrisburg Dialysis Center 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, the applicant states that the capital cost is projected to be \$69,162. In Sections IX.3, page 41, the applicant projects that there will be no start-up expenses associated with the proposed project.

Based on information provided by the applicant in Section X.1, page 43, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$240.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,313.00
VA	\$240.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.2-X.4, pages 43-46, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$3,249,760	\$3,493,774
Total Operating Costs	\$2,716,503	\$2,886,025
Net Profit	\$533,257	\$607,749

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 demonstrated the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrated that the financial feasibility of the proposal is based on 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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Total Renal Care of North Carolina, LLC, d/b/a Harrisburg Dialysis Center proposes to add four in-center dialysis stations to the existing facility for a total of 19 dialysis stations upon project completion. Harrisburg Dialysis Center is currently serving 55 patients weekly at 3.67 patients per station, which exceeds 91% of capacity. Dialysis facilities that operate four shifts per week (2 / day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant discusses projections for the in-center patient population on pages 12 and 19 of the application. At the end of Operating Year Two, with 19 dialysis stations and 67 dialysis patients after the four-station addition, the Harrisburg Dialysis Center projects the utilization will be 3.52 in-center patients per station (67 patients / 19 dialysis stations = 3.52). The growth projections are based on Cabarrus County projected Average Annual Growth Rate in the number of dialysis patients.

The applicant adequately demonstrates the need to add four dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the applicant 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 current and projected staffing for Harrisburg Dialysis Center, as provided by the applicant in Section VII.1, page 32:

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
RN	2	1	3
PCT	6	2	8
Bio-Med Tech	.5	0	.5
MD			
Admin	1	0	1
Dietician	.5	0	.5
Social Worker	.5	0	.5
Unit Secretary	1	0	1
Other-Reuse	1	0	1
Total	12.5	3	15.5

As shown in the above table, the applicant proposes to employ a total of 15.5 full-time equivalent (FTE) positions to staff the Harrisburg Dialysis Center upon completion of the proposed project. In Section VII.1, page 32, the applicant states,

“The Medical Director is not employed by the facility. There is a signed agreement between the facility and the Medical Director. The fee to be paid is estimated to be \$75,000 annually for the Medical Director responsibilities.”

In Section V.4, page 26, the applicant states that Dr. Charles E. Stoddard will serve as medical director of the facility. Exhibit 11 contains a letter signed by Dr. Stoddard, which states that he has agreed to serve as medical director for the Harrisburg Dialysis Center. In Section VII.2, page 33, the applicant states Dr. Stoddard is Board-Certified in Nephrology.

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 24, the applicant provides a list of providers of the necessary ancillary and support services. The applicant adequately demonstrated 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

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 28, the applicant reports that 81.6% of the patients who received treatments at Harrisburg Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

HARRISBURG DIALYSIS CENTER	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	28.3%
Medicaid	1.7%
Medicare/Medicaid	25.0%
Commercial Insurance	11.7%
VA	6.7%
Medicare/Commercial	26.6%
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 November 15, 2011. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Cabarrus	14%	4.9%	18.5%
Statewide	17%	6.7%	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 Harrisburg Dialysis Center.

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. However, as of May 17, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' 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 applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Harrisburg Dialysis Center. 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;

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In Section VI.6 (a), page 31, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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 29, 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 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.

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In Section VI.5, page 30, the applicant states that:

“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at Harrisburg Dialysis Center. These referrals most commonly come from primary care physicians in Cabarrus County and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and

*friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which compromise **Exhibit 12**. The patient, again, will be referred to a qualified Nephrologist for final evaluation and subsequent admission if medically necessary.” [Emphasis in original.]*

The applicant adequately demonstrated that it will provide a wide range of means by which a person can access the 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.

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Exhibit 10 contains the existing student training agreement between the facility and Brookstone College of Business. In Section V.3, the applicant states, “*Harrisburg Dialysis Center will provide access to any area health professional training programs upon execution of an agreement.*” The information provided in Section V.3 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.

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See Sections II, III, V, VI and VII in the Harrisburg Dialysis Center application. In particular, see Section V.7 page 27 in which the Harrisburg Dialysis Center discusses the impact of the project 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 proposal would have a positive impact on cost-

effectiveness, quality and access to dialysis services in Cabarrus County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add four dialysis 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 (more than 80% are Medicare or Medicaid patients). The proposed project improves geographic access to patients who wish to transfer their care to a closer facility.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Harrisburg Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to 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, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is 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- See Section IV.1, page 22, and Exhibit 7 (copy of the January 2012 SDR, Tables A and B).
- .2202(a)(2) *Mortality rates;*
-C- In Section IV.2, page 22, the applicant reports the 2009, 2010 and 2011 facility mortality rates.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
-NA- In Section IV.3, page 22, the applicant states that Harrisburg Dialysis Center has an agreement with Dialysis Care of Kannapolis for the provision of home training services. However, the applicant does not propose to have any home hemodialysis patients at the facility.
- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 23, the applicant stated that Harrisburg Dialysis Center referred 7 patients for transplant evaluation in 2011. Harrisburg Dialysis Center did not have a patient receive a transplant in 2011.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 23, the applicant states that the Harrisburg Dialysis Center has 4 patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- See Section IV.6, page 23, the applicant reports a total of 101 hospital admissions in 2011; 94.1% were non-dialysis related and 5.9% were dialysis-related.
- .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- In Section IV.7, page 23, the applicant reports that in 2011 there were no patients with an infectious disease. No patients converted to infectious status in 2011.

(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- Harrisburg Dialysis Center 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- Harrisburg Dialysis Center 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- Harrisburg Dialysis Center 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 8 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- Harrisburg Dialysis Center 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 Sections II.1, page 10; VII.2, pages 32-33 and, XI.6(e), page 52.
- .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, page 19.
- .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- Harrisburg Dialysis Center 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- In Section II, page 11, the applicant states, “*Total Renal Care of North Carolina, LLC d/b/a Harrisburg Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”
- 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- Harrisburg Dialysis Center 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- In Section III.7, page 20, the applicant projects to serve 62 in-center patients by the end of Year 1, which is 3.26 patients per station ($62 / 19 = 3.26$).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, page 12 and Section III.7, pages 19-20, 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 24.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 24.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 24.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.1, page 24 and V.1(d), page 25.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 24.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 24.
- .2204(7) *Blood bank services;*
 - C- See Section V.1, page 24.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 24.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 24.
- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 24.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 24.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
 - C- See Section V.1, page 24.
- .2204(13) *Transportation*
 - C- See Section V.1, page 24.

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 Section VII.1, page 32, the applicant provides the proposed staffing. In Section VII.2, pages 32-33, 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 34, and Exhibit 15.