

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 25, 2014
PROJECT ANALYST: Julie Halatek
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: D-10244-14 / WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center / Add two dialysis stations to Wilkes Regional Dialysis Center for a total of 21 certified dialysis stations / Wilkes County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center (WRDC) proposes to add two dialysis stations for a total of 21 certified dialysis stations.

The 2014 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology to determine need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), there is a need for five additional stations to serve Wilkes County patients. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for WRDC in the January 2014 SDR is 3.26 patients per station. This utilization rate was calculated based on 62 in-center dialysis patients and 19 certified dialysis stations as of June 30, 2013 (62 patients / 19 stations = 3.26 patients per station). Application of the facility need methodology indicates two additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW - JANUARY 2014 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		81.6%
Certified Stations		19
Pending Stations		0
Total Existing and Pending Stations		19
In-Center Patients as of 6/30/13 (SDR2)		62
In-Center Patients as of 12/31/12 (SDR1)		56
Step	Description	
(i)	Difference (SDR2 - SDR1)	6
	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 12/31/12	0.2143
(ii)	Divide the result of Step (i) by 12	0.0179
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.1071
(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	68.6429
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.4509
	and subtract the number of certified and pending stations as recorded in SDR2 [19] to determine the number of stations needed	2

As shown in the table above, the facility need methodology shows a need for two additional stations. 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.”* The applicant proposes to add only two new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles of the 2014 SMFP is applicable to this review. **POLICY GEN-3: BASIC PRINCIPLES** states:

“A certificate of need 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 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 certificate of need 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 certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II.3, page 16, the applicant states,

“As discussed in Section VII and documented in Exhibit 22, the WRDC staff undergoes training and attends routine in-service education. Section VII.10, page 41 documents that the average patient/staff ration will be equal to or less than three patients per staff member.

‘As patient census increases over time, staffing numbers will be adjusted accordingly to ensure safe, quality care of the patients and continuous coverage for the facility. The average number of patients to staff will be no more than three (3) patients per staff member, which further emphasizes the commitment of the facility to providing safe, quality care to the ESRD patient.’

Exhibits 9 and 20 include the facility’s safety and quality policies and procedures.”

Exhibit 22 does not contain information about training and routine in-service education; however, in supplemental information, the applicant provides copies of mandatory annual training for staff.

The applicant adequately demonstrates the proposal will promote quality and safety.

Promote Equitable Access

In Section II.3, page 16, the applicant states:

“As seen in Section VI page 33 and Exhibit 14, WRDC is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment. In Section VI, page 33 includes the discussion of the WRDC indigent care and payment policies.”

In Section VI.1(a), page 33, the applicant states:

“WRDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin or disability. WRDC will continue to accept patients regardless of Medicare, Medicaid, other insurance coverage or the patients’ ability to pay. The existing and proposed dialysis services will continue to be available to all residents including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other medically underserved persons. The facility will not require payment upon initial treatment for those patients transferring their care to the facility.”

The applicant adequately demonstrates the proposal will promote equitable access.

Maximize Healthcare Value

In Section II.3, page 17, the applicant states:

“As discussed in Section XI, WRDC was constructed utilizing modern technologies to maintain efficient energy operations and to control costs. The proposed project will utilize existing facility space and hold down operating costs through increased staff efficiency and economies of scale that relate to facility costs and overhead.”

The utilization projections in Section III demonstrate that WRDC expects that future utilization will increase based on the facility adding capacity to keep pace with the expected increase in demand. Future years’ projections are based on conservative assumptions as compared to the recent growth. WRDC reasonably expects to serve patients from Wilkes County and nearby communities based on strong physician support, patient choice and geographical access. Future years’ projections are based on reasonable assumptions as compared to historical data regarding patient origin and payor mix.”

The applicant adequately demonstrates the proposal will maximize healthcare value. Consequently, the applicant demonstrates the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the January 2014 SDR and Policy GEN-3. Therefore, 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.

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WRDC proposes to add two dialysis stations to its existing facility for a total of 21 certified dialysis stations. In Section IV.1, page 26, the applicant states that, as of June 30, 2013, 59 patients are from Wilkes County; two patients are from Ashe County; and one patient is from Alexander County.

Population to be Served

In Section III.7, pages 23-24, the applicant provides the projected patient origin for WRDC for in-center dialysis and home dialysis patients for the first two years of operation following completion of the project, as shown below:

Projected Patient Origin						
County	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Wilkes	60	0	64	0	89.55%	90.14%
Ashe	4	0	4	0	5.97%	5.63%
Alleghany	2	0	2	0	2.99%	2.82%
Alexander	1	0	1	0	1.49%	1.41%
Total	67	0	71	0	100.00%	100.00%

The applicant adequately identifies the population WRDC proposes to serve.

Demonstration of Need

In Section III.2, pages 19-23, the applicant states the application is filed pursuant to the facility need methodology in the 2014 SMFP due to high historical utilization rates and the prevalence of end stage renal disease (ESRD) in Wilkes County. The applicant proposes to add two stations to WRDC for a total of 21 certified stations. The applicant uses the following assumptions:

1. Historical Wilkes County ESRD patient population is based on the January 2014 SDR. Future growth of Wilkes County ESRD patients is projected based on the 5.5% growth rate for Wilkes County per the January 2014 SDR. Wilkes County population statistics are taken from the NC Office of State Budget and Management.
2. Wilkes County home dialysis patients, who are served by Statesville Dialysis and Piedmont Dialysis Centers, are calculated at 20.5% of total Wilkes County ESRD patients, per the January 2014 SDR percentage.
3. The market share assumption of 77.6% is based on the analysis of historical market share data for WRDC. The applicant provides documentation of how the 77.6% market share assumption is calculated in supplemental information.
4. The projected number of Wilkes County in-center patients to be served at WRDC is based on the current total number of Wilkes County in-center patients (all facilities) multiplied by WRDC's market share (77.6%).
5. A Wilkes County patient origin percentage of 90% is utilized to determine what percentage of the ESRD population served by WRDC will originate from Wilkes County. The applicant states that although the January 2014 SDR shows a 95% patient

origin from Wilkes County, historically, WRDC has served patients from Ashe, Alleghany, Alexander, and occasionally other counties.

6. To determine the number of stations needed, the total number of ESRD patients are divided by 3.2 patients per station.

The applicant’s methodology is summarized in the following tables.

Historical Wilkes County Population			
	12/31/2010	12/31/2011	12/31/2012
Total Wilkes County ESRD Patients*	75	72	83
Wilkes County Population**	69,233	69,791	69,625
ESRD Patients/1000 Population	1.08	1.03	1.19

*Source: January 2014 SDR

**Source: Annual Population Totals 2010-2019, NC Office of Budget and Management, accessed 2/13/2014—calculated for July of each year

Projected Wilkes County Population					
	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
Total Projected Wilkes County ESRD Patients	88	92	97	103	108
Home Dialysis Patients—20.5%	18.0	18.9	20.0	21.1	22.2
In-Center Patients	69.6	73.4	77.5	81.7	86.2
Market Share Estimate for WRDC (77.6%)	77.6%	77.6%	77.6%	77.6%	77.6%
Wilkes County In-Center Patients at WRDC	54.0	57.0	60.1	63.5	66.9
Wilkes County Percent of WRDC Patient Origin	90.0%	90.0%	90.0%	90.0%	90.0%
Projected Number of Patients at WRDC	60.0	63.3	66.8	70.5	74.4
ESRD Stations Needed at 3.2 Patients per Station	18.8	19.8	20.9	22.0	23.2
Total Currently Available Stations at WRDC	19	19	19	19	19
Additional Dialysis Stations Needed	NA	NA	1.9	3.0	4.2

Note: Assumptions for 2013-2017 total ESRD patients are based on the January 2014 SDR increase of 5.5%.

While some of the numbers in this table are rounded improperly, when the rounding is done accurately, it further supports the applicant’s calculations.

The applicant projects to serve 67 in-center patients or 3.2 patients per station ($67 / 21 = 3.2$) by the end of Operating Year 1 and 71 in-center patients or 3.4 patients per station ($71 / 21 = 3.4$) by the end of Operating Year 2 for the proposed 21-station facility. This conforms to the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable, credible, and adequately supported assumptions regarding historical market share and continued growth.

Access

In Section VI.1(a), page 33, the applicant states:

“WRDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin or disability. WRDC will continue to

accept patients regardless of Medicare, Medicaid, other insurance coverage or the patients' ability to pay."

The applicant projects 93.34% of its in-center patients will have some or all of their treatments covered by Medicare and/or Medicaid. The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional dialysis stations at WRDC, and demonstrates all residents of the area, and, in particular, underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming 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.

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In Section III.9, page 24, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo – WRDC's utilization is greater than 3.2 patients per station, and the applicant states that the high level of utilization demonstrates a need for increased capacity. Additionally, the applicant states that there is a waiting list of patients wishing to change their treatment times. The applicant states that without increased capacity, future patients will face potential delays in treatment, resulting in utilization of more costly and intensive healthcare services. Thus, the applicant rejected this alternative.
2. Relocate to a new location and expand the facility – The applicant states that this alternative was rejected because there is existing space in the current facility, which is close to the hospital; has ample parking; and is in a central location. The applicant also states that relocating and expanding would be much more costly.

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 this 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. **WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center shall materially comply with all representations made in its certificate of need application and in the supplemental information materials submitted during the review. In those instances where representations conflict, WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center shall materially comply with the last made representation.**
 2. **WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center shall develop and operate no more than two additional dialysis stations for a total of no more than 21 certified stations which shall include any home hemodialysis training or isolation stations.**
 3. **WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations for a total of no more than 21 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 4. **WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional 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 the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 44, the applicant projects a capital cost of \$120,200 for the proposed project, funded through accumulated cash and reserves. In Section IX, page 47, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Exhibit 30 includes a letter, dated March 4, 2014, from the Chief Financial Officer of Wilkes Regional Medical Center. The letter states:

"As the Chief Financial Officer of Wilkes Regional Medical Center, I have responsibility for managing the funds of the hospital. I am writing to confirm that Wilkes Regional Medical Center is committed to finance the total capital cost amount of \$120,000_ [sic] for the renovation of space and the addition of two dialysis stations at Wilkes Regional Dialysis Center.

I can verify that the organization has sufficient financial resources to provide this funding. As seen in the audited financial statements dated September 30, 2013, the hospital has over \$2.1 million in cash and cash equivalents. The hospital currently maintains approximately \$3,055,840 in cash and cash equivalents. This source of funds is available for financing the Wilkes Regional Dialysis Center renovation."

In Exhibit 31, the applicant provides the audited financial statements for WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center for the years that ended September 30, 2012 and September 30, 2013. As of September 30, 2013, WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center had cash and cash equivalents totaling \$2,180,415, with \$82.5 million in total assets and \$42.7 million in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 48, the applicant projects the following charge per treatment for each payment source:

WRDC Projected Charges by Payment Source	
Payor	In-Center Charge
Private Pay	\$1,260.00
Medicare	\$234.00
Medicaid	\$137.29
BCBS and Commercial	\$1,260.00
VA	\$193.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Section X.2, page 48, and X.4, pages 50-51, the applicant reported projected revenues and expenses as follows:

WRDC Projected Revenues and Expenses		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$1,893,536	\$2,006,582

Total Expenses	\$1,754,670	\$1,788,046
Net Profit	\$138,866	\$218,536

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X.2, page 49, 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 (charges) 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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WRDC proposes to add two in-center dialysis stations for a total of 21 dialysis stations upon project completion. WRDC is the only existing dialysis facility located in Wilkes County and there are no approved facilities. WRDC served 62 patients weekly on 19 stations, which is 3.26 patients per station (81.6% of capacity), as of June 30, 2013. Dialysis facilities that operate four shifts per week (two per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve in Section III.2, pages 19-22, of the application. The growth projections are based on a projected 5.5% average annual growth rate in the number of dialysis patients in Wilkes County. At the end of Operating Year Two, WRDC projects the utilization will be 3.4 in-center patients per station (71 patients / 21 dialysis stations = 3.4), which is 85% of capacity.

The applicant adequately demonstrates the need to develop two additional dialysis stations at 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 application is conforming to this criterion.

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

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The following table illustrates current and projected staffing for WRDC, as provided by the applicant in Section VII.1, page 38:

WRDC Current and Projected Staffing			
Position	Current FTEs	# of FTE Positions to be Added*	Total FTE Positions
RN	4.0	1.0	5.0
LPN	1.0	0.0	1.0
Tech	7.0	1.0	8.0
Unit Manager	1.0	0.0	1.0
Medical Director	0.1	0.0	0.1
Admin	0.2	0.0	0.2
Dietician	0.4	0.0	0.4
Social Worker	1.0	0.0	1.0
Biomedical Tech	1.0	0.0	1.0
Clerical	2.0	0.0	2.0
Total	17.7	2.0	19.7

*Positions to be added are current vacant positions that will be filled.

As shown in the above table, the applicant proposes to employ a total of 19.7 full-time equivalent (FTE) positions to staff WRDC upon completion of the proposed project. In Section V.4(c), page 31, the applicant states that William Halstenburg, M.D. will continue to serve as medical director of the facility. Exhibit 32 contains a letter from Dr. Halstenburg stating his support for the expansion of WRDC as well as a copy of the employment agreement for the position of medical director.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming 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 28, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 32 contains a letter from the medical director of the facility expressing his support for the proposed project, and Exhibits 23 and 24 contain letters of support for the project signed by local physicians and community members. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

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

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

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In Section VI.1(b), page 33, the applicant reports that 93.34% of the in-center patients who received treatments at WRDC had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

WRDC In-Center Patients	
Source of Payment	Percentage
Medicare	90.52%
Medicaid	2.82%
Commercial Insurance	6.06%
Private Pay	0.61%
Total	100.00%

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 Wilkes County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population*	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)*
Wilkes County	20%	8.70%	19.1%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by WRDC. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race 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 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.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”¹ (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender - 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		

¹ www.usrds.org/adr.aspx

0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network
6. Table includes North Carolina statistics only.²

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor*		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

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² www.esrdnetwork6.org/publications/reports.html

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1(e), page 35, the applicant states:

“Wilkes Regional Dialysis Center has no federal (Hill-Burton) obligation to provide uncompensated care or community service. The facility is accessible to minorities and handicapped persons.”

In Section VI.6(a), page 36, 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

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In Section VI.1(c), pages 33-34, the applicant provides the projected payer mix for the proposed services at WRDC. The applicant projects no change from the current payer mix for in-center dialysis services, which documents 93.34% of patients have some or all of their treatments covered by Medicare and/or Medicaid. The applicant demonstrates that medically underserved populations will 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.

C

In Section VI.5(a), page 36, the applicant states:

“Patients seeking treatment at Wilkes Regional Dialysis Center are considered for admission by contacting the Nurse Administrator, Medical Director, Social Worker, or by referral from public health or social service entities, a nursing home, or a personal physician. Once the appropriate medical documentation has been received, it is reviewed and the patient is considered for admission. ...”

The applicant adequately demonstrates that WRDC will provide a 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.

C

In Section V.3(b), page 30, the applicant states:

“Wilkes Regional Dialysis Center provides opportunities for nursing students and health occupation students to tour the facility and interact with the staff in accordance with the terms of the clinical training agreements. ...”

Exhibit 22 contains a letter from the Nurse Manager at WRDC to the Dean of the Health Sciences Division at Wilkes Community College. The letter states in part:

“Wilkes Regional Dialysis Center is committed to continuing to provide access to the facility for health education programs, including the programs provided by Wilkes Community College.”

Exhibit 22 also contains a letter from the dean of the Health Sciences Division at Wilkes Community College expressing support for the proposed project. The information provided in Section V.3(b) is reasonable and credible and supports a finding of conformity to 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

WRDC proposes to add two dialysis stations to the existing facility for a total of 21 dialysis stations upon project completion. The applicant operates the only dialysis facility in Wilkes County. A small portion of the patient population at WRDC originate from Alleghany and

Ashe Counties, where there are no dialysis facilities. The only other county where the patient population at WRDC routinely originates from, Alexander County, has a utilization rate of 35%. However, most of the patients who receive treatment at WRDC are from Wilkes County and new ESRD patients may not wish to travel to Alexander County for treatment.

In Section V.7, page 32, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The proposed project will add needed capacity to the facility and enable Wilkes Regional Dialysis Center to more effectively compete in terms of scheduling efficiency and timeliness of services.

Increasing the number of dialysis stations at the current location is the most cost effective alternative in terms of the capital requirements and the time for construction. The proposed project will have minimal impact on overall operational costs because the facility will gain economies of scale related to staffing. Existing fixed costs such as building rent and insurance will be spread over a larger treatment volume.

Access will be increased for Wilkes County residents as well as for patients from contiguous counties where no dialysis centers exist (Ashe and Alleghany Counties). Quality of care will be enhanced by the ongoing quality assurance / performance improvement programs, staff education, accreditation and certification participation. Adding dialysis stations to the existing facility will enable these new stations to be fully utilized and integrated into the current quality management program.”

See also Sections II, III, V, VI, and VII where the applicant discusses 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 any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application and the following analysis:

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

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 files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, WRDC 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.
- (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 application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below:

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

.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:*
- (1) *Utilization rates;*
- C- See Section III.2, page 18, which documents WRDC had an 81.58% utilization rate as of June 30, 2013.
- (2) *Mortality rates;*

- C- In Section IV.2, page 26, the applicant reports 2010, 2011, 2012, and 2013 facility mortality rates of 25.6%, 39.3%, 35.2%, and 20.6%, respectively.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
 - C- In Section IV.3, page 26, the applicant states that home dialysis therapy is arranged for appropriate patients by referral to Piedmont Dialysis Center or Statesville Dialysis Center, and the patients from WRDC then become patients of the respective facility offering home dialysis therapy.
 - (4) *The number of transplants performed or referred;*
 - C- In Section IV.4, page 27, the applicant states WRDC referred 6 patients for transplant evaluation in 2013. WRDC had no patients who received transplants in 2013.
 - (5) *The number of patients currently on the transplant waiting list;*
 - C- In Section IV.5, page 27, the applicant states WRDC has 6 patients on the transplant waiting list.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
 - C- In Section IV.6, page 27, the applicant reports a total of 156 hospital admissions in 2013; 119 were non-dialysis related and 37 were dialysis related.
 - (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 27, the applicant reports in 2013 there were no patients with an infectious disease, and no patients converted to infectious status in 2013.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to*

patients of the dialysis facility. The agreement must comply with 42 C.F.R. Section 405.2100.

-NA- WRDC is an existing facility.

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

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

-NA- WRDC is an existing facility.

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

-NA- WRDC is an existing facility.

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

-C- Exhibit 11 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.

(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- WRDC is an existing facility.

- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section II.1, pages 11-12; Section VII.2, page 38, Section XI.6(g), page 56, and Exhibit 26 for documentation of conformity with the applicable laws and regulations.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, pages 23-24, WRDC provides projected patient origin based on historical experience for the first two years of operation following completion of the project. See Criterion (3) for discussion of projected patient origin which is incorporated hereby by reference as if set forth fully herein.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- WRDC is an existing facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Exhibit 14, a copy of a letter, signed by the Nurse Manager for WRDC, states:
- “Wilkes Regional Dialysis Center shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section II.1, pages 12-13, and Section III.2, pages 18-22, the applicant projects to serve 67 in-center patients by the end of Operating Year 1, which is 3.2 patients per station ($67 / 21 = 3.2$). See Criterion (3) for discussion which is incorporated hereby by reference as if set forth fully herein.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II.1, pages 12-13, and Section III.2, pages 18-22, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See Criterion (3) for discussion which is incorporated hereby by reference as if set forth fully herein.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) *Diagnostic and evaluation services;*
- C- These services are provided by Wilkes Regional Medical Center. See Section V.1, page 28.
- (2) *Maintenance dialysis;*
- C- This service is provided at Wilkes Regional Medical Center. See Section V.1, page 28.
- (3) *Accessible self-care training;*
- C- WRDC does not have a home dialysis program. The applicant refers patients who need self-care training to Piedmont Dialysis Center or Statesville Dialysis Center. See Section V.1, page 28.
- (4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- WRDC does not have a home dialysis program. The applicant refers patients who need support for home dialysis to Piedmont Dialysis Center or Statesville Dialysis Center. See Section V.1, page 28.

(5) *X-ray services;*

-C- These services are provided by Wilkes Regional Medical Center. See Section V.1, page 28.

(6) *Laboratory services;*

-C- These services are provided by Meridian Lab, NC Baptist Hospital, and Wilkes Regional Medical Center. See Section V.1, page 28.

(7) *Blood bank services;*

-C- These services are provided by Wilkes Regional Medical Center. See Section V.1, page 28.

(8) *Emergency care;*

-C- This service is provided by Wilkes Regional Medical Center. See Section V.1, page 28.

(9) *Acute dialysis in an acute care setting;*

-C- This service is provided by Wilkes Regional Medical Center. See Section V.1, page 28.

(10) *Vascular surgery for dialysis treatment patients;*

-C- These services are provided by surgeons at Wilkes Regional Medical Center, Lake Normal Regional Hospital, and Wake Forest University Baptist Medical Center. See Section V.1, page 28.

(11) *Transplantation services;*

-C- These services are provided by NC Baptist Hospital, Carolinas Medical Center, Duke Medical Center, UNC Hospitals, and VA Pittsburgh. See Section V.1, page 28.

(12) *Vocational rehabilitation counseling and services; and,*

-C- These services are provided by the NC Division of Vocational Rehabilitation in North Wilkesboro. See Section V.1, page 28.

(13) *Transportation.*

-C- This service is provided by Wilkes Transportation Association and Carolina Mobility. See Section V.1, page 28.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

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

- C- In Section VII.1, page 38, the applicant provides the proposed staffing. In Section VII.2, page 38, 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 which is incorporated hereby by reference as if set forth fully herein.

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

- C- See Section VII.5, page 39, Exhibits 18 and 19, and supplemental information for documentation of ongoing training for staff at WRDC.