

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 23, 2015

Findings Date: February 23, 2015

Project Analyst: Julie Halatek

Team Leader: Martha J. Frisone

Project ID #: D-10326-14

Facility: Wilkes Regional Dialysis Center

FID #: 956103

County: Wilkes

Applicant(s): WRMC Hospital Operating Corporation

Project: Add 3 dialysis stations for a total of 24 stations upon completion of this project and Project I.D. #D-10244-14 (add 2 stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center (WRDC) proposes to add 3 dialysis stations for a total of 24 stations upon completion of this project and Project I.D. #D-10244-14 (add 2 stations).

Need Determination

The 2014 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology to determine need for additional dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), there is a need for seven 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 July 2014 SDR is 3.68 patients per station. This utilization rate was calculated based on 70 in-center dialysis patients and 19 certified stations. However, in Project I.D. #D-

10244-14, WRDC was approved to add 2 stations for a total of 21 dialysis stations. Application of the facility need methodology indicates that seven additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		92.1%
Certified Stations		19
Pending Stations		2
Total Existing and Pending Stations		21
In-Center Patients as of 12/31/13 (July 2014 SDR) (SDR2)		70
In-Center Patients as of 6/30/13 (January 2014 SDR) (SDR1)		62
Step	Description	
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change.	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/13	0.2581
(ii)	Divide the result of Step (i) by 12	0.0215
(iii)	Multiply the result of Step (ii) by 12 (the number of months between 12/31/12 and 12/31/13).	0.2581
(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	88.0645
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.5202
	and subtract the number of certified and pending stations as recorded in SDR2 [21 stations] to determine the number of stations needed	7

As shown in the table above, based on the facility need methodology for dialysis stations there are potentially seven stations needed at WRDC. Step 2(C) of the facility need methodology states: “*The facility may apply to expand to meet the need established in (2)(B)(v), up to a maximum of ten stations.*” The applicant proposes to add three new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

Policy GEN-3: Basic Principles in the 2014 State Medical Facilities Plan is applicable to this review and is discussed below.

Policy GEN-3: Basic Principles

This policy 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 – The applicant describes how it believes the proposed project would promote safety and quality in Section II.1, pages 11-12; Section II.3, pages 15-16; Section V.7, pages 32-33; Sections VII.3 and VII.5, page 40; Section XI.6(g), page 57, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section II.3, pages 16-17; Section V.7, pages 32-33; Section VI, pages 34-38; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section II.3, page 17; Section III.9, page 26; Section V.7, pages 32-33; Section XI.6(d), page 56; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the need identified in the July 2014 SDR and the 2014 SMFP. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that its proposal to develop three dialysis stations is consistent with the facility need determination in the July 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.

C

WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center (WRDC) proposes to add 3 dialysis stations for a total of 24 stations upon completion of this project and Project I.D. #D-10244-14 (add 2 stations).

Population to be Served

In Section IV.1, page 27, the applicant identifies the population currently served at WRDC, as shown below:

Patient Origin – WRDC (as of 6/30/13)		
County of Residence	# In-Center Pts.	% of Total
Wilkes	59	95.2%
Ashe	2	3.2%
Alexander	1	1.6%
Total	62	100.0%

In supplemental information, the applicant also provides a table to illustrate the population to be served following the addition of three dialysis stations, as shown below:

Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as Percent of Totals	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Wilkes	73	4	76	5	93.9%	95.3%
Ashe	4	0	3	0	4.9%	3.5%
Alexander	1	0	1	0	1.2%	1.2%
Total	78	4	80	5	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant states that need for the proposed expansion is based on the following factors:

- Utilization at WRDC is at 92.11 percent as of the publication of the July 2014 SDR, which contains data from December 31, 2013. See Table A in the July 2014 SDR and page 19 of the application. Additionally, in the previous reporting period (the January 2014 SDR, containing data from June 30, 2013), utilization at WRDC was at 81.58 percent. See Table A in the January 2014 SDR and page 19 of the application.
- End Stage Renal Disease (ESRD) rates for Wilkes County and North Carolina continue to increase due to the high prevalence of diseases that contribute to ESRD. Assuming a 4.9 percent average annual change rate (AACR) as published in the July 2014 SDR through the end of CY 2015 and an annual rate of 4.0 percent from January 2016 through the end of Operating Year Three, the projected number of ESRD patients supports the proposed three station expansion.
- Using the facility need methodology in the July 2014 SDR and the 2014 SMFP, the applicant could add up to seven additional dialysis stations to WRDC. The discussion

regarding the facility need determination found in Criterion (1) is incorporated herein by reference.

- The applicant projects that WRDC will have 78 in-center patients at the end of Operating Year One (ending December 31, 2016), which is a utilization rate of 81.25 percent. See page 23 of the application.

Projected Utilization

The applicant provides information on the historical utilization of WRDC, as shown in the table below:

Historical Wilkes County Population			
	12/31/2012	12/31/2013	12/31/2014
Total Wilkes County ESRD Patients*	83	98	103
Wilkes County Population**	69,710	69,774	69,817
ESRD Patients/1000 Population	1.19	1.40	1.47

*Source: July 2014 SDR

**Source: Annual Population Totals 2012-2014, NC Office of Budget and Management

Projected Wilkes County Population					
	Projected	Projected	OY1	OY2	OY3
	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Total Projected Wilkes County ESRD Patients*	103	108	112	117	121
Home Dialysis Patients	12	16	17	18	19
In-Center Patients	90	92	95	99	102
Market Share Estimate for WRDC	76.74%	76.74%	76.74%	76.74%	76.74%
Wilkes County In-Center Patients at WRDC	69	70	73	76	79
Wilkes County Percent of WRDC Patient Origin	94.29%	94.29%	94.29%	94.29%	94.29%
Projected Number of Patients at WRDC	74	75	78	80	83
ESRD Stations Needed at 3.2 Patients per Station	23.01	23.32	24.25	25.09	26.02
Total Currently Available Stations at WRDC	19	21	21	21	21
Additional Dialysis Stations Needed	NA	2.32	3.25	4.09	5.02

*Projections for 2015 are calculated by using a 4.9% annual growth rate assumption as published in the July 2014 SDR and for 2016-2018 using a 4.0% annual growth rate assumption.

Note: While some of the numbers in this table were rounded improperly by the applicant, when the rounding is done accurately, it further supports the applicant's calculations.

As shown in the table above, at the end of Operating Year 1, the applicant projects to serve 78 in-center dialysis patients on 24 certified dialysis stations, or 3.25 patients per station per week, which is a utilization rate of 81.25 percent [$78 / 24 = 3.25$; $3.25 / 4 = 0.8125$]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Assumptions and Methodology Used

In Section III.2, pages 21-23, the applicant states that it used the following assumptions to project utilization.

- Operating Year One = January 1, 2016 through December 31, 2016
- Operating Year Two = January 1, 2017 through December 31, 2017
- Operating Year Three = January 1, 2018 through December 31, 2018
- The Wilkes County ESRD patient population is projected to increase at the 4.9 percent five year average annual change rate (AACR) published in the July 2014 SDR for the year ending on December 31, 2015.
- The Wilkes County ESRD patient population is projected to increase by 4.0 percent annually through the third operating year following completion of the project.
- The number of Wilkes County ESRD patients that are projected to dialyze at home is 15 percent of the overall Wilkes County ESRD patients. This percentage is higher than the 12.2 percent published in the July 2014 SDR because WRDC intends to implement a home peritoneal dialysis program instead of sending the home dialysis patients to Statesville Dialysis and Piedmont Dialysis Centers (see Exhibit 12).
- WRDC's market share is projected to be 76.74 percent of all Wilkes County in-center patients which is the same as the current market share calculated from data published in the July 2014 SDR.
- Wilkes County ESRD patients are projected to make up 94.29 percent of the patient population served by WRDC. This assumption is based on historical WRDC patient origin data and calculations based on information reported in the July 2014 SDR.

The applicant states that it then applied the assumptions to the stated methodology, as shown in the table below:

WRDC – In-Center Patient Projections				
Step*	12/31/2015	OY1	OY2	OY3
1. Calculate projected Wilkes County ESRD patients using 4.9% for the year ending 12/31/2015 and 4.0% for OY1-3	$103 \times 1.049 = 108$	$108 \times 1.04 = 112$	$112 \times 1.04 = 117$	$117 \times 1.04 = 121$
2. Calculate projected Wilkes County home dialysis patients at 15% of total patients	$108 \times 0.15 = 16$	$112 \times 0.15 = 17$	$117 \times 0.15 = 18$	$121 \times 0.15 = 19$
3. Calculate total projected Wilkes County in-center patients (Step 1 – Step 2)	$108 - 16 = 92$	$112 - 17 = 95$	$117 - 18 = 99$	$121 - 19 = 102$
4. Apply 76.74% WRDC market share to total Wilkes County in-center patients	$92 \times 0.7674 = 70$	$95 \times 0.7674 = 73$	$99 \times 0.7674 = 76$	$102 \times 0.7674 = 79$
5. Calculate total WRDC in-center patients by applying 94.29% Wilkes County patient origin	$70 / 0.9429 = 75$	$73 / 0.9429 = 78$	$76 / 0.9429 = 80$	$79 / 0.9429 = 83$
6. Calculate total stations needed by applying standard of 3.2 patients per station	$75 / 3.2 = 23.32$	$78 / 3.2 = 24.25$	$80 / 3.2 = 25.09$	$83 / 3.2 = 26.02$
7. Calculate additional stations needed (Step 6 - existing stations)	$23.32 - 21 = 2.32$	$24.25 - 21 = 3.25$	$25.09 - 21 = 4.09$	$26.02 - 21 = 5.02$

*The step numbers listed in this table do not correspond with the step numbers given by the applicant in Section III.2. This table was prepared by the Project Analyst to demonstrate the methodology and the step numbers correspond to the order that the calculations were made.

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

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth at WRDC. The applicant adequately demonstrates the need that this population has for the services proposed.

Access to Services

In Sections VI.1(b) and VI.1(c), pages 34-35, the applicant provides the current and projected payor mix for the proposed services at WRDC, as shown in the table below. The applicant projects no change from the current payor mix upon project completion:

WRDC	
Current / Projected Payor Mix	
Payor Source	% Gross Revenue
Private Pay	0.61%
Commercial Insurance	6.06%
Medicare	90.52%
Medicaid	2.82%
Total	100.00%

The applicant adequately demonstrates 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 proposed services.

Conclusion

In summary, the applicant adequately:

- Identifies the population it proposes to serve.

- Demonstrates the need that this population has for the proposed services.
- Demonstrates 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 proposed services.

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 26, the applicant identified the alternatives considered and the reasons the applicant concluded they were not the least costly or most effective alternative, as described below:

1. Maintain the Status Quo – the applicant states this option is not an effective alternative because utilization is greater than the required 3.2 patients per station. Additionally, there is a waiting list for patients wishing to change their schedule, and the current capacity of the facility does not allow much flexibility, which may lead to treatment delays for patients in the future.
2. Relocate and Expand the Facility – the applicant states this option is not an effective alternative because it would be costly and unnecessary when the current facility has room to expand and is already located near the hospital and in the center of the county.

The applicant states that adding three stations is the most effective alternative because the facility has room to expand, the upgrades can be completed during evenings and weekends to minimize disruptions, the necessary utilities can be upgraded to handle the additional volume without major changes or purchases, and adding the three stations will only require one additional FTE staff member.

The applicant adequately demonstrates the need for three additional stations based on the number of in-center patients it projects to serve. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference.

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

The applicant adequately demonstrates that the proposal to add three dialysis stations is its 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 any supplemental information provided. In those instances where representations conflict, the certificate holder 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 3 additional dialysis stations for a total of no more than 24 certified stations upon completion of this project and Project I.D. #D-10244-14 (add 2 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 3 additional dialysis stations for a total of no more than 24 certified stations upon completion of this project and Project I.D. #D-10244-14 (add 2 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 Agency 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.

C

In Section VIII.1, page 45, the applicant projects a capital cost of \$397,130 for the proposed project, funded through accumulated cash and reserves. In Section IX, page 48, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

In Section VIII.2, page 45, and Section VIII.5, page 46, the applicant states the entire capital cost of the project will be funded with accumulated reserves of WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center (WRMC). Exhibit 30 contains a letter dated

September 27, 2014, signed by the Chief Financial Officer of WRMC, which states that WRMC is authorizing the use of \$400,000 from cash reserves to add three stations to WRDC.

In Exhibit 31, the applicant provides the audited financial statements for WRMC for the fiscal years that ended on September 30, 2013 and September 30, 2012. As of September 30, 2013, WRMC had \$2,180,415 in cash and cash equivalents, \$82,570,253 in total assets, and \$42,752,322 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 49, the applicant provides the allowable charges per treatment for each payor source for WRDC as follows:

WRDC	
Payor Source	Allowable Charge Per In-Center Treatment
Private Pay	\$1,260.00
Medicare	\$234.00
Medicaid	\$137.29
BCBS and Commercial	\$1,260.00
VA	\$193.00

On page 50, the applicant documents its assumptions for each source of revenue used to project revenue in Operating Years One and Two. The applicant states that it calculated its assumptions for average reimbursement per treatment based on WRDC historical experience and expected future reimbursement.

In Sections X.2, page 49, and X.4, page 51, the applicant projects revenues and expenses for WRDC as follows:

WRDC		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$2,204,415	\$2,260,938
Total Expenses	\$1,875,620	\$1,910,763
Net Profit	\$328,795	\$350,175

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 formas, including the number of projected treatments, are reasonable and adequately supported. See Section X.3, page 50, and supplemental information for the applicant's assumptions regarding revenue calculations.

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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.

C

WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center (WRDC) proposes to add 3 dialysis stations for a total of 24 stations upon completion of this project and Project I.D. #D-10244-14 (add 2 stations). The applicant does not propose to establish a new facility.

The applicant operates the only existing dialysis facility located in Wilkes County and there are no approved facilities. As of December 31, 2013, WRDC was serving 70 patients weekly on 19 stations, which is 3.68 patients per station or 92.1 percent of capacity. At the end of Operating Year Two, WRDC projects that utilization will be 3.3 in-center patients per station (80 patients / 24 dialysis stations = 3.3) or 82.5 percent of capacity. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the need to develop three additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve. Consequently, the applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities and 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.

C

The following table illustrates current and projected staffing for WRDC, as provided by the applicant in Section VII.1, page 39:

WRDC Current and Projected Staffing			
Position	Current FTEs	# of FTE Positions to be Added*	Total FTE Positions
RN	3.0	1.0	4.0
LPN	1.0	0.0	1.0
Tech	7.0	2.0	9.0
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	16.7	3.0	19.7

*Positions to be added are current vacant positions that will be filled, except for one new Tech position.

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 32, 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 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 the proposed 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 29, 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 Exhibit 23 contains 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;

C

In Section VI.1(b), page 34, the applicant reports that 93.34 percent 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 payor mix for the facility:

WRDC In-Center Patients	
Payor Source	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 provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. 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	19.5%	8.7%	19.1%
Statewide	16.5%	6.7%	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 services offered by dialysis facilities. In fact, in 2013 only 6.6 percent of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

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

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender, and race, which show that 65.4 percent were white, 28.0 percent were African American, 15.0 percent were Hispanic, 4.7 percent were Asian, and 1.2 percent were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31 percent since 2000 and by 48 percent 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 *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%20%20Annual%20Report.pdf>

²www.usrds.org/adr.aspx

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%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race, and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

The applicant demonstrates that medically underserved populations have adequate access to the services provided at WRDC. Therefore, the application is conforming to this criterion.

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

C

³<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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 36, the applicant states that WRDC has no Hill-Burton obligations to fulfill.

In Section VI.6, page 37, the applicant states there have been no patient civil rights access complaints filed in 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), pages 34-35, the applicant provides the projected payor mix for the proposed services at WRDC, as shown in the table below. The applicant projects no change from the current payor mix upon project completion.

WRDC Projected Payor Mix	
Payor Source	Percentage
Medicare	90.52%
Medicaid	2.82%
Commercial Insurance	6.06%
Private Pay	0.61%
Total	100.00%

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 37, 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 offers 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 31, 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) and referenced exhibits 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

WRMC Hospital Operating Corporation d/b/a Wilkes Regional Medical Center d/b/a Wilkes Regional Dialysis Center (WRDC) proposes to add 3 dialysis stations for a total of 24 stations upon completion of this project and Project I.D. #D-10244-14 (add 2 stations).

The applicant operates the only existing dialysis facility located in Wilkes County and there are no approved facilities. As of December 31, 2013, WRDC was serving 70 patients weekly on 19 stations, which is 3.68 patients per station or 92.1 percent of capacity. At the end of Operating Year Two, WRDC projects that utilization will be 3.3 in-center patients per station (80 patients / 24 dialysis stations = 3.3) or 82.5 percent of capacity. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section V.7, pages 32-33, 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 applicant adequately demonstrates that any enhanced competition will have a positive impact on the cost-effectiveness, quality, and access to the proposed services based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed services and that the proposed project is a cost-effective alternative to meet the need for additional dialysis services. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant adequately demonstrates it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

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

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
 - (1) *Utilization rates;*
 - C- See Section III.2, page 18, which documents WRDC had a 92.11 percent utilization rate as of December 31, 2013.
 - (2) *Mortality rates;*
 - C- In Section IV.2, page 27, the applicant reports 2010, 2011, 2012, and 2013 facility mortality rates of 25.6 percent, 39.3 percent, 35.2 percent, and 20.6 percent, respectively.

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

-C- In Section IV.3, page 28, 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 28, the applicant states WRDC referred six 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 28, the applicant states WRDC has six 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 28, the applicant reports a total of 156 hospital admissions in 2013; 119 (78 percent) were non-dialysis related and 37 (22 percent) were dialysis related.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section IV.7, page 28, 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 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 39, Section XI.6(g), page 57, 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 supplemental information, WRDC provides projected patient origin based on historical experience for the first two years of operation following completion of the project, as presented in the following table:

Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as Percent of Totals	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Wilkes	73	4	76	5	93.9%	95.3%
Ashe	4	0	3	0	4.9%	3.5%
Alexander	1	0	1	0	1.2%	1.2%
Total	78	4	80	5	100.0%	100.0%

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

(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 rate 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.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- 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 supplemental information, the applicant projects to serve 78 in-center patients by the end of Operating Year One, which is 3.25 patients per station ($78 / 24 = 3.25$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected, in Section II.1, pages 12-13, and Section III.2, pages 18-24.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (2) *maintenance dialysis;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (3) *accessible self-care training;*
- C- WRDC does not currently offer a home dialysis program. The applicant currently refers patients who need self-care training to Piedmont Dialysis Center or Statesville Dialysis Center. See Section V.1, page 29. In Section II.2, page 15, and Exhibit 12, WRDC states it will be offering home peritoneal dialysis training and support services.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- WRDC does not currently offer a home dialysis program. The applicant currently refers patients who need self-care training to Piedmont Dialysis Center or Statesville Dialysis Center. See Section V.1, page 29. In Section II.2, page 15, and Exhibit 12, WRDC states it will be offering home peritoneal dialysis training and support services.
- (5) *x-ray services;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (6) *laboratory services;*

- C- These services are provided by Meridian Lab, Wake Forest University Baptist Medical Center, and WRMC. See Section V.1, page 29.
- (7) *blood bank services;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (8) *emergency care;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (9) *acute dialysis in an acute care setting;*
- C- These services are provided by WRMC. See Section V.1, page 29.
- (10) *vascular surgery for dialysis treatment patients;*
- C- These services are provided by surgeons at WRMC, Lake Norman Regional Hospital, and Wake Forest University Baptist Medical Center. See Section V.1, page 29.
- (11) *transplantation services;*
- C- These services are provided by Wake Forest University Baptist Medical Center, Carolinas Medical Center, Duke University Medical Center, UNC Hospitals, and VA Pittsburgh. See Section V.1, page 29.
- (12) *vocational rehabilitation counseling and services; and*
- C- These services are provided by the NC Division of Vocational Rehabilitation in North Wilkesboro and others. See Section V.1, page 29.
- (13) *transportation.*
- C- This service is provided by Wilkes Transportation Association and Carolina Mobility. See Section V.1, page 29.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 [494].*
- C- In Section VII.1, page 39, the applicant provides the proposed staffing. In Section VII.2, page 39, and Exhibit 26, the applicant states that staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

- (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 40, and Exhibit 19 for documentation of ongoing training for staff at WRDC.