ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: April 29, 2022
Findings Date: April 29, 2022

Project Analyst: Tanya M. Saporito
Co-Signer: Lisa Pittman

Project ID #: A-12175-22
Facility: Haywood Regional Medical Center
FID #: 933234
County: Cumberland
Applicant: DLP Haywood Regional Medical Center, LLC
Project: Develop no more than three permanent inpatient dialysis stations pursuant to Policy ESRD-3 that were previously approved pursuant to Executive Order 130

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

NA

DLP Haywood Regional Medical Center, LLC (HRMC or "the applicant") is a licensed acute care hospital located in Clyde, North Carolina in Haywood County that provides acute and psychiatric care as well as emergency and imaging services and operates several outpatient and urgent care clinics. Pursuant to Executive Order 130, signed by the Governor on April 8, 2020, HRMC was approved to temporarily develop three inpatient dialysis stations to provide dialysis services to the hospital's inpatient population. In this application, the applicant proposes to permanently develop the three previously approved inpatient dialysis stations.

The applicant submitted the application pursuant to Policy ESRD-3 in the 2022 SMFP; which states:

"Licensed acute care hospitals (see stipulations in G.S. 131E-77 (e1)) may apply for a certificate of need to develop or expand an existing Medicare-certified kidney

disease treatment center (outpatient dialysis facility) without regard to a county or facility need determination if all the following are true: [emphasis added]

1. *The hospital proposes to develop or expand the facility on any campus on its license where general acute beds are located.*
2. *The hospital must own the outpatient dialysis facility, but the hospital may contract with another legal entity to operate the facility.*
3. *The hospital must document that the patients it proposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus.*
4. *The hospital must establish a relationship with a community-based outpatient dialysis facility to assist in the transition of patients from the hospital outpatient dialysis facility to a community-based facility wherever possible…."*

The applicant does not currently own or operate a *"Medicare-certified kidney disease treatment center (outpatient dialysis facility)"*. The applicant was approved to temporarily provide dialysis treatments to its existing patients in the hospital, not to operate a Medicare-certified kidney disease treatment center/outpatient dialysis facility. On page 13 of its application, the applicant describes the proposal as follows:

"… DLP Haywood Regional Medical Center, LLC is currently operating three dialysis stations via Executive Order 130 Waiver Request granted in December 2021 which is valid through the COVID-19 Emergency Period, plus 30-days. Approval of this application will provide a permanent program at a rural hospital with a high-risk population."

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP);
- Acquire any medical equipment for which there is a need determination in the 2022 SMFP; or
- Offer a new institutional health service for which there are any policies in the 2022 SMFP

Therefore, Criterion (1) is not applicable to this review.

(2) Repealed effective January 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

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

N.C. Gen. Stat. §131E-176(16)(d) defines a *"new institutional health service"* as:

> *"the offering of dialysis services or home health services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility."*

The applicant is a hospital that has not offered dialysis services within the 12 months preceding application submission. The dialysis stations approved pursuant to Executive Order 130 began operation in February of 2022, according to the applicant on page 21 of its application. Even if the applicant had been providing dialysis services for a full 12 months prior to the application submission, the provision of those dialysis services pursuant to the Executive Order would not preclude the applicant from needing to file an application pursuant to N.C. Gen. Stat. §131E-176(16)(d), since the Executive Order permitted temporary provision of dialysis services as a direct result of the COVID-19 pandemic. Thus, this application is being reviewed as an application to offer a new institutional health service, dialysis services, by HRMC for its patients. The applicant states on pages 20-21 that DaVita, Inc. will provide dialysis management and clinical staff to HRMC's patients in need of dialysis. Additionally, the applicant states two of the three dialysis stations will be in existing patient rooms, one on the fifth floor and one on the intensive care unit on the fourth floor. The applicant states a nurse will transport the patient to the dialysis station where a trained DaVita nurse will supervise dialysis, and the HRMC nurse will transport the patient back to the hospital room. The third dialysis station will be portable, allowing provision of dialysis services to its observation and other in-patients. The applicant does not propose to offer dialysis services to any patients who are not hospital patients.

Patient Origin

In Section C, page 24, the applicant projects patient origin for the interim and first two project years, which are calendar years (CY) 2023-2024, as shown in the table below:

Projected Patient Origin, CY 2023-2024

COUNTY	PARTIAL YEAR 2022	CY 2023	CY 2024
Haywood	29.3	70.6	70.8
Jackson	1.6	3.9	3.9
Swain	1.0	2.3	2.3
Macon	0.5	1.1	1.1
Cherokee	0.4	0.9	0.9
Graham	0.3	0.8	0.8
Madison	0.2	0.4	0.5
Out of Area*	2.7	6.4	6.5
Total	**36.0**	**86.4**	**86.8**

Source: application page 25
*Applicant defines "out of area" as Buncombe, Clay, Henderson, Mecklenburg, Transylvania, Cleveland, Gaston, Mitchell and other NC counties, as well as other states.

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization, which it states is based on FY 2020 actual hospital-wide patient origin percentages by county.

The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant relies on its own internal historical patient origin data to project patient origin.
- The applicant relies on its acute care services data to project the patients who will use dialysis services while in the hospital.
- The applicant is an established regional medical center with consistent historical patient patterns, and it proposes to provide dialysis to its inpatients who need those services.

Analysis of Need

In Section C, pages 27-34, the applicant explains why it believes the population projected to utilize the proposed inpatient dialysis services needs the proposed services. On page 27, the applicant states:

> *"Adding inpatient dialysis machines at HRMC makes it possible for service area residents who are already receiving renal dialysis as outpatients, to receive inpatient care at HRMC, rather than traveling to Mission Hospital – the closest inpatient dialysis provider – or out of state."*

The applicant's demonstration of need is summarized as follows:

- Service area population growth – the applicant states that its proposed dialysis program would be the only hospital-based dialysis provider in the seven counties it proposes to serve based on its historical patient origin. Citing data from the North Carolina Office of State Budget and Management (OSBM) for the years 2021-2025, the applicant states the population in its service area is projected to grow by 2.5% overall, as shown in the following table:

HRMC Service Area Population Growth, 2021-2025

County	2022	2023	2024	2025	% Growth
Haywood	64,176	64,649	65,116	65,587	2.2%
Cherokee	30,021	30,248	30,544	30,803	2.6%
Graham	8,549	8,530	8,511	8,496	-0.6%
Jackson	44,972	45,375	45,776	46,172	2.7%
Macon	37,998	38,545	39,093	39,642	4.3%
Madison	22,697	22,841	22,986	23,130	1.9%
Swain	14,493	14,530	14,573	14,616	0.8%
Total	**222,906**	**224,754**	**226,754**	**228,446**	**2.5%**

Source: Application page 28

The applicant states the counties that comprise the service area also have a substantial tourist season, from which it is logical to conclude that hospital admissions could increase, as could the need for inpatient dialysis services. Tourist season notwithstanding, the applicant shows the population in the service area is projected to increase between 2021 and 2025 (pages 27-28).

- Population growth in the age 65 and older population – the applicant states the population of the 65 and over age group is projected to increase at a faster rate than younger population cohorts. The applicant states the 65 and older population is the primary user of ESRD services. See the following table, from page 28:

HRMC Service Area 65+ Population Growth, 2021-2025

COUNTY	2022	2023	2024	2025	% GROWTH
Haywood	17,058	17,386	17,668	17,960	5.3%
Cherokee	9,409	9,595	9,769	9,942	5.7%
Graham	2,204	2,217	2,230	2,259	2.5%
Jackson	9,358	9,498	9,663	9,870	5.5%
Macon	11,228	11,459	11,735	12,004	6.9%
Madison	5,565	5,702	5,819	5,938	6.7%
Swain	3,020	3,066	3,103	3,137	3.9%
Total	**57,842**	**58,923**	**59,987**	**61,110**	**5.6%**

Source: Application page 28

- ESRD patient need – the applicant describes the progression of Chronic Kidney Disease (CKD) to End Stage Renal Disease (ESRD), which requires regular dialysis treatments for survival. The applicant cites data from the United States Renal Data System that shows both the incidence and prevalence of ESRD was higher in North Carolina than in the United States for the time periods 2011-2014 and 2015-2018,

particularly for the over 65 age group. See the following tables from page 29 that illustrate the data:

ESRD Incidence and Prevalence Comparison

Time Period	Incidence		Prevalence	
	North Carolina	United States	North Carolina	United States
2011-2014	14,800	474,449	87,612	2,609,956
2015-2018	16,559	517,387	100,214	3,001,719
CAGR*	2.8%	2.2%	3.4%	3.6%
% Growth	11.9%	9.1%	14.4%	15.0%

*Compound annual growth rate
Source: application page 29

ESRD Incidence and Prevalence Comparison by Age

Age Group	Incidence				Prevalence			
	2011-2014	2015-2018	CAGR	% Growth	2011-2014	2015-2018	CAGR	% Growth
0-17	121	134	2.6%	10.7%	711	739	1.0%	3.9%
18-44	2,055	2,243	2.2%	9.1%	15,101	15,763	1.1%	4.4%
45-64	6,224	6,774	2.1%	8.8%	40,600	44,991	2.6%	10.8%
65+	**6,400**	**7,408**	**3.7%**	**15.8%**	**31,200**	**38,721**	**5.5%**	**24.1%**
Total	14,800	16,559	2.8%	11.9%	87,612	100,214	3.4%	14.4%

Source: application page 29

The applicant states on page 30 that the same trend in both incidence and prevalence of ESRD exists in the service area, as shown in the table below. The applicant states analyzing prevalence is critical in projecting need, since it anticipates it will serve chronic patients as well as those newly diagnosed while inpatients at HRMC.

ESRD Incidence and Prevalence Comparison in HRMC Service Area

County	Incidence				Prevalence			
	2011-2014	2015-2018	CAGR	% Growth	2011-2014	2015-2018	CAGR	% Growth
Haywood	77	88	3.4%	14.3%	411	457	2.7%	11.8%
Cherokee	32	42	7.0%	31.3%	156	184	4.2%	17.9%
Graham	13	12	-2.0%	-7.7%	63	70	2.7%	11.1%
Jackson	28	39	8.6%	39.3%	161	177	2.4%	9.9%
Macon	34	47	8.4%	38.2%	161	182	3.1%	13.0%
Madison	19	21	2.5%	10.5%	93	105	3.1%	12.9%
Swain	41	46	2.9%	12.2%	217	238	2.3%	9.7%
Total SA	**244**	**295**	**4.9%**	**20.9%**	**1,262**	**1,413**	**2.9%**	**12.0%**

Source: application page 30

- Common co-morbidities in people with Chronic Kidney Disease – the applicant states that, according to the National Institute of Diabetes and Kidney Disease, the two most common causes of CKD are diabetes and high blood pressure, both of which are prevalent in the HRMC service area (page 31).

- Social determinants of health in the service area – the applicant states that the co-morbidities noted above are prevalent in the service area and in the state; however, the applicant states that data accounts for those who already are diagnosed with diabetes or high blood pressure. In fact, the applicant states research suggests that certain persons are at risk of developing one or more of those co-morbidities if they are obese, smokers, sedentary, or consume large quantities of alcohol. The applicant states age and other demographic risk factors also tend to increase a person's risk of developing one or more of the co-morbidities and then either CKD or ESRD. The applicant states the data in the state and the service area help to demonstrate a clear need for inpatient ESRD services at HRMC (pages 30-34).

The information is reasonable and adequately supported based on the following:

- The applicant relies on its own internal historical inpatient data to show a need for providing inpatient dialysis services.

- The applicant cites national and regional data to illustrate the projected growth in the populations most likely to utilize the inpatient dialysis services.

- The applicant documents data that illustrate the prevalence of CKD and ESRD, as well as risk factors that lead to both, in the service area.

Projected Utilization

In Section Q Form C the applicant provides the projected utilization for the interim and project years (PY), as illustrated in the following tables:

Projected Utilization

FORM C UTILIZATION	INTERIM PY 2/1/22-8/5/22	PARTIAL PY 8/6/22-12/31/22	1ST PY CY 2023	2ND PY CY 2024
Average # of Patients during the Year	43	36	86	87
# of Treatments / Patient / Year	2.5	2.5	2.5	2.5
Total # of Treatments	**108**	**90**	**213**	**217**

In Section Q, in its assumptions following Form C, pages 85-93, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- Step 1: the applicant identified the historical acute care service area by county, based on its own internal data and data reported to DHSR on the annual license renewal applications.

- Step 2: the applicant identified the number of hemodialysis and peritoneal dialysis patients from the seven-county service area from the 2018 – 2021 SMFPs, which reported data from 2017-2020. See the following table that illustrates the dialysis population in those counties:

Historical ESRD Patients in HRMC Service Area

LOCATION	DEC. 2017	DEC. 2018	DEC. 2019	DEC. 2020
Home	56	60	68	71
In-center	198	215	191	184
Total	254	275	259	255

- Step 3: the applicant projected the number of dialysis patients to be served by HRMC using three separate methods: linear trending, annual growth calculations, and projected growth in the population of residents age 65 and over.

    - Linear Trending – using a linear trend analysis, the applicant projected the following dialysis patients to be served at HRMC:

Projected ESRD Patients in HRMC Service Area Using Linear Trend

LOCATION	2021	2022	2023	2024
Home	72	77	82	88
In-center	187	181	174	167
Total	259	258	256	255

Note: applicant provides graphs and key on application page 86

    - Annual Growth Calculations – using the information from Step 2, the applicant calculated a four-year average annual growth rate of total HRMC service area dialysis patients from 2017-2020:

Projected ESRD Patients in HRMC Service Area Using Annual Growth

	2017	2018	2019	2020	AVERAGE
Number of Patients	254	275	259	255	--
Annual Growth Rate	--	8.3%	-5.8%	-1.5%	0.3%

Source: application page 87

The applicant states that the high risk factors and co-morbidities support the reasonableness of applying a 0.3% growth rate, despite some decrease in the number of patients. See the following table that illustrates the growth in patients:

Projected ESRD Patients in HRMC Service Area Using Linear Trend

	2021	2022	2023	2024
Total Patients	256	257	257	258

Source: application page 87

    - Over Age 65 Calculations – the applicant states the primary users of dialysis services for ESRD is the over 65 age group, citing data from the American Society of Nephrology. The applicant used the population data described earlier in these findings to project growth in that population group specifically:

Projected Service Area Residents Age 65 +

	2017	2018	2019	2020	AVERAGE
Number of Patients	56,704	57,842	58,923	59,987	
Annual Growth Rate	--	2.0%	1.9%	1.8%	1.9%

Source: application page 87

The applicant applied the average growth rate of the over 65 population (1.9%) to project dialysis patients for all three project years:

Projected Service Area Patients Age 65 +

	2021	2022	2023	2024
Patients	260	265	270	275

Source: application page 88

The following table illustrates the three utilization projections methods utilized by the applicant:

Projected Service Area Patients Age 65 +

	2021	2022	2023	2024
Linear Trend	259	258	256	255
Average Annual Growth	256	257	257	258
Average Growth 65+	260	265	270	275

Source: application page 88

The applicant states on page 88 that the *Average Annual Growth* method is the most conservative and the method chosen by the applicant to project utilization.

- Step 4: calculate HRMC service area peritoneal and hemodialysis patient ratio – the applicant examined historical data to determine which percent of total dialysis patients have historically been peritoneal or hemo dialysis, as shown in the following table:

Percent of Peritoneal and Hemodialysis Patients, 2017-2020

	2017	20118	2019	2020	TOTAL	% OF TOTAL
Home (Peritoneal)	56	60	68	71	255	24.4%
In-Center	198	215	191	184	788	75.6%
Total	**254**	**275**	**259**	**255**	**1,043**	**100.0%**

Source: application page 88

The applicant applied the percentages to its projections:

Projected Peritoneal and Hemodialysis Patients

	2021	2022	2023	2024
Total Dialysis Patients	256	257	257	258
Peritoneal Dialysis	63	63	63	63
Hemodialysis	193	194	194	195

Source: application page 89

- Step 5: determine average number of inpatient admissions per dialysis patient per year – the applicant reviewed 2018 data from the USRDS to determine average inpatient admissions per dialysis patients in the HRMC service area. The applicant states the average for the service area is 1.2 admissions per dialysis patient, with some counties suppressing data due to inadequate sample sizes. See the following table:

Inpatient Admissions per Dialysis Patient, 2018

COUNTY	RATE
Haywood	1.2
Jackson	1.3
Swain	1.1
Cherokee	--
Macon	1.2
Graham	--
Madison	--
Average SA	**1.2**

Source: application page 89

The applicant states its observation patients may require dialysis treatments as outpatients while on the hospital campus. To determine how many patients this entails, the applicant examined its historical data to determine how many of its patients have been observation patients, as shown in the following table:

Ratio of Observation to Inpatient Beds, 2018-2021

	2018	2019	2020	2021	4 YEAR TOTAL
Inpatient	4,735	4,794	4,750	4,034	18,313
Observation	2,210	1,746	2,127	1,889	7,972
Ratio	**0.5**	**0.4**	**0.4**	**0.5**	**0.4**

Source: application page 89

Based on that data, the applicant provides the following table to illustrate the number of inpatient admissions per dialysis patient in the HRMC service area:

Ratio of Observation to Inpatient Beds, 2018-2021

Inpatient Admissions per Patient	1.2
Outpatient Admissions per Patient	0.4
Total Admissions per Patient	**1.6**

Source: application page 90

- Step 6: Calculate the number of HRMC service area dialysis patients by type of dialysis – the applicant applied the data derived from the foregoing steps to project the number of ESRD inpatient admissions, by type, in the HRMC service area:

Service Area ESRD Inpatient Admissions by Type

	2021	2022	2023	2024
Peritoneal Admissions	102	103	103	103
Hemodialysis Admissions	316	317	318	319
Total Admissions	**418**	**420**	**421**	**422**

Source: application page 90

- Step 7: Forecast utilization – the applicant states it does not project it will capture all of the dialysis patients projected to need dialysis services in the service area. The applicant calculated a market share by examining the historical percentage of acute care admissions by HRMC in the service area for fiscal years (FY) 2017-2020. The applicant determined it has historically captured an average of 20.6% of the acute care admissions in the seven-county service area See the following table:

HRMC Market Share of Acute Care Inpatients by County, FY 2017-FY 2020

COUNTY	FY 2017	FY 2018	FY 2019	FY 2020	4 YEAR TOTAL
Haywood	53.5%	54.54%	53.6%	51.9%	53.4%
Cherokee	1.9%	2.9%	3.2%	2.6%	2.6%
Graham	3.1%	6.7%	5.35	5.8%	5.2%
Jackson	5.9%	7.5%	6.8%	5.6%	6.5%
Macon	1.3%	1.9%	1.4%	1.8%	1.6%
Madison	1.1%	1.4%	1.5%	0.9%	1.2%
Swain	4.0%	5.7%	6.1%	5.7%	5.4%
Total SA Patients	**20.9%**	**21.2%**	**20.7%**	**19.4%**	**20.6%**

Source: application page 91

- Step 8: Calculate the number of inpatient dialysis admissions at HRMC – the applicant projected the number of inpatient dialysis admissions to be served by HRMC, 2021-2024:

Projected Dialysis Patients by Type, 2021-2024

	2021	2022	2023	2024
Peritoneal Admissions	21	21	21	21
Hemodialysis Admissions	65	65	65	65
Total Admissions	**86**	**86**	**86**	**86**

Source: application page 91

- Step 9: Determine annual hospital days per dialysis patient – using USRDS data from 2018 (the most recent data available), the applicant calculated the average number of hospital days per dialysis patient per year in the service area:

Hospital Days per Dialysis Patient Per Year

COUNTY	RATE
Haywood	6.8
Jackson	4.7
Swain	6.9
Cherokee	--
Macon	7.4
Graham	--
Madison	--
Average SA	**6.5**

Source: application page 92

The applicant states suppressed counties (those with insufficient data) behave like the averages of reported counties.

The applicant next determined the hospital days per patient admission by dividing the hospital days per year by the number of admissions per patient per year (Steps 9 and 5, respectfully). The applicant determined the average number of hospital days per admission is 3.9:

Average Hospital Days per Patient Admission

Hospital Admissions per Patient (Step 9)	6.5
Admissions per Patient (Step 5)	1.6
Hospital Days per Admission	**3.9**

Source: application page 92

- Step 10: Calculate the number of dialysis treatments per patient admission – the applicant assumes three dialysis treatments per patient per week, or per seven days, based on information from DaVita, Inc., the dialysis provider who will staff the stations. The applicant states that, according to Step 9, each dialysis patient admission is projected to last 3.9 days; therefore, each admission is projected to need 2.5 treatments. Assuming 2.5 treatments per admission, the applicant projects the following number of treatments:

Projected Dialysis Treatments, 2021-2024

	2021	2022	2023	2024
Peritoneal Treatments (Step 7 x 2.5)	53	53	53	53
Hemodialysis Treatments (Step 7 x 2.5)	162	163	163	164
Total Treatments	**215**	**216**	**216**	**217**

Source: application page 91

Projected utilization is reasonable and adequately supported based on the following:

- The applicant uses historical inpatient data from HRMC in the seven counties that comprise its service area to calculate patient growth.

- The applicant utilizes a conservative growth rate to calculate inpatient admissions, ratios of admissions to dialysis patients, and the growth in dialysis treatments.

- The applicant projects a conservative market share of dialysis patients based on verifiable data.

Access to Medically Underserved Groups

In Section C.6, page 37, the applicant states:

"HRMC accepts patients regardless of gender, gender preference, race, ethnicity, age, income, or disability status. … HRMC has Medicare and Medicaid certification, and provides services to both populations."

On pages 37-38, the applicant describes the provision of care to the underserved groups listed in the table below. On page 38 the applicant provides the estimated percentage for each medically underserved group it will serve during the second project year, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	11.1%
Racial and ethnic minorities	10.5%
Women	42.0%
Persons with disabilities	100.0%
Persons 65 and older	56.0%
Medicare beneficiaries	56.0%
Medicaid recipients	10.1%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides an estimate for each medically underserved group it proposes to serve.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.
- The applicant demonstrates that HRMC has historically provided care to all persons in need of services, including underserved persons.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.

- Projected utilization is reasonable and adequately supported.

- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

(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

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

(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

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

In Section E, page 46, the applicant states it considered no alternative to permanently developing the three inpatient dialysis stations authorized pursuant to Executive Order 130. The applicant states it must turn inpatients in need of dialysis services away, and that is unacceptable for the patients.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming or conditionally conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **DLP Haywood Regional Medical Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall develop inpatient dialysis services through service agreements with DaVita, Inc.**

3. **Progress Reports:**
   a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**
   b. **The certificate holder shall complete all sections of the Progress Report form.**
   c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
   d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on September1, 2022. The second progress report shall be due on December 1, 2022 and so forth.**

4. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

Capital and Working Capital Costs

In Section F.1, page 48, the applicant states there is no capital cost associated with this project since the renovation cost necessary to make the proposed dialysis stations permanent had previously been incurred when the applicant received approval to temporarily develop the

dialysis stations. The applicant included a $150,000 cost for the project to cover any contingency that may arise.

In Section Q, the applicant provides the assumptions used to project the contingency cost and includes a January 10, 2022 letter signed by the Chief Financial Officer of HRMC that confirms the availability of the possible contingency amount and commits those funds to the project if necessary. In Section F.3, page 50, the applicant states it will enter into a hospital services agreement with DaVita, Inc. to provide all the necessary equipment and clinical staff to provide dialysis services.

Financial Feasibility

In Section Q, the applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first two full fiscal years of operation following completion of the proposed project, as shown in the table below:

HRMC	1ST FULL PY CY 2023	2ND FULL PY CY 2024
Total Treatments	216	217
Total Gross Revenue (HRMC)	$2,270,435	$2,391,106
Total Net Revenue	$501,040	$512,970
Average Net Revenue per Treatment	$2,320	$2,364
Total Operating Expenses (HRMC)	$322,085	$342,750
Average Operating Expense per Treatment	$1,491	$1,579
Net Income	$178,955	$170,220

The applicant states in Section Q page 97 that the inpatient dialysis services will be a*"'loss leader'"* for the hospital, but states the entire inpatient admission, of which the provision of dialysis services will be a part, will result in a positive net income for the hospital.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on the historical hospital operations projected forward.
- The applicant accounts for total hospital admissions in calculating the revenue for the provision of inpatient dialysis services.
- FTEs and salaries are based on current staffing.
- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

(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

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

N.C.G.S. §131E-176(24a) states: "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*" The 2022 SMFP does not define a service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the service area for inpatient dialysis services. In Section C, page 23, the applicant defines the service area for the proposed project as Haywood, Jackson, Swain, Macon, Cherokee, Graham and Madison counties. Facilities may also serve residents of counties not included in their service area.

In Section G, page 54, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in the proposed service area. The applicant states the only dialysis center in Haywood County is Waynesville Dialysis Center, and HRMC will be the only provider of hospital-based inpatient dialysis services in the seven counties that comprise its service area. On page 55 the applicant states it serves patients who are admitted to the hospital for reasons other than renal disease, but who need dialysis during their stay; the temporary allowance granted to provide those dialysis services to its inpatients will continue to permanently serve its patients with this proposal. The applicant states it has already begun to work with community dialysis centers to provide continued dialysis services for its patients upon discharge from the hospital.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The proposal is necessary to accommodate dialysis patients admitted to HRMC who also require inpatient dialysis services.
- The existing dialysis facility in Haywood County is unable to accommodate or care for the patients who are admitted to HRMC for acute hospital services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(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 applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) positions for the proposed dialysis services, as shown in the following table:

HRMC Projected Dialysis Services Staffing

POSITION	INTERIM AND 2022	OY1	OY2
RN	1.00	1.00	1.13
CNA	1.00	1.00	1.10
Housekeeping	0.20	0.20	0.20
Administration	0.20	0.20	0.20
Total	**[2.00] 2.40**	**[2.40] 2.40**	**[3.00] 2.60**

Source: Section Q Form H

The applicant appears to have made mathematical errors in the table in Form H, shown by the numbers in brackets in the table above. The errors do not impact the analysis or reasonableness of the application.

In Section H, page 56, the applicant states the hospital is a major employer in the county and will easily fill necessary positions. The applicant states DaVita, Inc. will provide the staff necessary for dialysis. The assumptions and methodology used to project staffing for the hospital as a whole, exclusive of inpatient dialysis services staff, are provided in Section Q. Adequate costs for the health manpower and management positions are budgeted in Form F.3, Operating Costs. For informational purposes, the applicant describes the existing training and continuing education programs at HRMC on page 57.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant is contracting with a provider experienced in providing the proposed service.

- The applicant has experience providing sufficient manpower and management personnel for general inpatient acute care services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

Ancillary and Support Services

In Section I, page 58, the applicant identifies the necessary ancillary and support services for the proposed services and the hospital and explains how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1 and Exhibit I.1 as described above.

Coordination

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2 and Exhibit I.2 as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective January 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

In Section K, page 62, the applicant states there is no construction or renovation associated with the proposed project, because HRMC renovated the space for the dialysis stations after Executive Order 130 granted a waiver for the applicant to temporarily provide inpatient dialysis. Therefore, Criterion (12) is not applicable to this review.

(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 L, page 66, the applicant states the application is filed to permanently develop three inpatient dialysis stations that had been approved pursuant to Executive Order 130. As such, the applicant does not have historical dialysis data to provide.

In Section L, page 67, the applicant provides the following comparison of FY 2021 acute care discharge data and the service area population:

HRMC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE HOSPITAL, FY 2021	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	55.9%	51.7%
Male	44.1%	48.3%
Unknown	--	--
64 and Younger	54.8%	75.0%
65 and Older	45.2%	25.0%
American Indian	1.3%	0.7%
Asian	--%	0.6%
Black or African-American	1.9%	1.4%
Native Hawaiian or Pacific Islander	0.1%	--%
White or Caucasian	93.4%	95.9%
Other Race	3.4%	1.4%
Declined / Unavailable	--	--

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 68, the applicant states that, as a certified hospital, HRMC is subject to EMTALA rules. The applicant states it is in full compliance with CMS certification rules and thus the EMTALA rules.

In Section L, page 69, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility identified in Section A, Question 4.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.3(a), page 69, the applicant projects payor mix for the proposed services during the second full fiscal year of operation following project completion, as summarized in the table below:

HRMC Projected Payor Mix (CY 2024)

PRIMARY PAYOR SOURCE AT ADMISSION	INPATIENT DIALYSIS	
	# PTS.	% OF TOTAL
Self-Pay	3	4.0%
Insurance*	2	2.5%
Medicare*	49	56.0%
Medicaid*	9	10.0%
Other (Misc., includes VA)	24	27.4%
Total	**87**	**100.0%**

*Includes any managed care plans
Numbers may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.0% of IC dialysis services will be provided to self-pay patients, 56.0% to Medicare recipients and 10.0% to Medicaid recipients.

On page 69, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on FY 2021 payor mix for the hospital.

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(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 L.5, page 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have and will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides access to the hospital for applicable clinical and health professional training programs in the area.

- The applicant will continue to provide applicable health professional training programs in the area with access to the hospital.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming 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

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

N.C.G.S. §131E-176(24a) states: "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services*

from a health service facility." The 2022 SMFP does not define a service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the service area for inpatient dialysis services. In Section C, page 23, the applicant defines the service area for the proposed project as Haywood, Jackson, Swain, Macon, Cherokee, Graham and Madison counties. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 74, the applicant states:

> *"HRMC expects development of hospital-based inpatient and outpatient dialysis services to have a positive impact on competition in the service area.*
>
> *Currently, neither Haywood, nor any of the other six service area counties provide inpatient dialysis services. With the development of inpatient dialysis services at HRMC, service area residents receiving outpatient dialysis treatments will have access to inpatient care within the area."*

In its application, on pages 13 and 55, the applicant indicates that observation patients classify as "outpatients".

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

> *"The inpatient dialysis service is a very cost-effective service for dialysis patients and their families. Service area residents, especially those in Haywood County, will no longer have to travel to Mission Hospital or out of state for inpatient services that would require dialysis treatment. ... Patients will be closer to family and support networks which improves patient outcomes. HRMC notes that some patients already live an hour or more from its hospital in Clyde. Mission is another hour away in difficult traffic."*

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 75, the applicant states:

> *"To assure quality of the inpatient dialysis service at HRMC, DaVita Inc. will provide the dialysis service through a Hospital Service Agreement. DaVita currently operates 67 dialysis stations in the service area.*
>
> *Additionally, HRMC has developed quality policies for the proposed program* [in Exhibit N.2]*."*

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 75, the applicant states:

"*Access to inpatient dialysis is available only through an order of a nephrologist or physician authorized by HRMC. All persons will have access to the proposed services. HRMC does not discriminate based on income, gender, nationality, race, creed, or any other unmentioned group."*

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(19) Repealed effective January 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 proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital.

In Section O, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred at two related facilities, Maria Parham Medical Center and Central Carolina Medical Center. Each facility is back in compliance and neither lost accreditation. According to the files in the Acute Care and

Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care have occurred at HRMC. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at the facility, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective January 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.

NA

The applicant proposes to develop no more than three permanent dialysis stations that were temporarily approved pursuant to Executive Order 130, to provide inpatient dialysis services at the hospital by providing dedicated space for three dialysis stations and contractual agreements with DaVita, Inc. for staffing and medical management of the dialysis service. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.