REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: May 13, 2021
Findings Date: May 13, 2021

Project Analyst: Ena Lightbourne
Team Leader: Gloria C. Hale

Project ID #: B-12013-21
Facility: Mission Hospital
FID #: 943349
County: Buncombe
Applicant(s): MH Mission Hospital, LLLP
Project: Develop a hospital-based, outpatient dialysis center with no more than 4 stations pursuant to Policy ESRD-3

REVIEW CRITERIA

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

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

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MH Mission Hospital, LLLP (the applicant) proposes to develop a hospital-based outpatient dialysis center to be located at Mission Hospital ("Mission"), an existing acute care hospital, with a total of no more than four dialysis stations pursuant to Policy ESRD-3. The patients proposed to be served do not include home hemodialysis or peritoneal dialysis patients.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2021 SMFP, on pages 21-22, which is applicable to this review: *Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus* 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:*
>
> 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 hospital shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare and Medicaid Services (CMS). Certificate of need will impose a condition requiring the hospital to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.*
>
> *The performance standards in 10A NCAC 14C .2203 do not apply to a proposal submitted by a hospital pursuant to this policy."*

In Section B.6, pages 18-19, the applicant explains why it believes its application is consistent with Policy ESRD-3. On pages 18-19, the applicant states the following:

- The proposed project involves the development of an outpatient dialysis facility located on the campus of Mission Hospital, an acute care facility with general acute care beds.

- The applicant certifies that the proposed outpatient dialysis facility will be owned by Mission Hospital.

- The applicant documents that the patients proposed to be served are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus. On page 19, the applicant defines these patients as:

  "
  - *Patients with no payor source*
  - *Patients with behavioral health issues*

- *Patients who regularly receive care at other existing outpatient dialysis centers but are being discharged from inpatient care and cannot make their scheduled outpatient dialysis appointment*
- *Patients who missed a scheduled appointment at their regular dialysis center*
- *Patients requiring emergency dialysis outside of their regular clinic's operating hours*
- *Patients referred by their provider for complications*
- *Patients who need to initiate dialysis treatment and receive their first few treatments in a controlled, outpatient setting at a hospital before moving to receive care in a community dialysis center*
- *Patients who present to the hospital requiring dialysis and must be admitted as an observation or inpatient to be dialyzed by the inpatient dialysis program when inpatient dialysis is not medically necessary."*

In Section C, pages 35-37, applicant cites several actual scenarios of patients who fall under these groups.

- The applicant documents its relationship with DaVita Kidney Care, the only provider of outpatient community dialysis in the service area. Exhibit B-6 contains a letter from the Medical Director of Mission's existing inpatient dialysis unit, who is also a nephrologist with Mountain Kidney Associates, confirming Mission's relationship with DaVita Kidney Care to transition patients to community providers in the area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion. The applicant adequately demonstrates that the proposal is consistent with Policy ESRD-3 based on the following:

- The applicant adequately demonstrates a plan to develop an outpatient dialysis facility located at an acute care facility with general acute care beds.
- The applicant adequately demonstrates it will own the outpatient dialysis facility.
- The applicant adequately demonstrates that the patients proposed to be served are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus.
- The applicant adequately demonstrates its relationship with the only provider of outpatient community dialysis in the service area and their support in transitioning patients to community providers in the area.

(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, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

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The applicant proposes to develop a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 22, the applicant states that the proposed project involves the development of a new facility, therefore, there is no historical patient origin to report. In supplemental information, the applicant provides a corrected table that illustrates projected patient origin. The table includes Yancey County in the primary service area.

Mission Hospital Outpatient Dialysis Center Projected Patient Origin		
County	**2nd FFY 10/01/2022-09/30/2023 (FY 2023)**	
	# of Patients	**% of Total**
Buncombe	400	47.65%
Henderson	62	7.42%
Haywood	55	6.57%
McDowell	46	5.47%
Madison	37	4.39%
Macon	30	3.51%
Transylvania	29	3.49%
Yancey	27	3.22%
PSA Subtotal	**686**	**81.72%**
Jackson	25	2.96%
Swain	21	2.47%
Rutherford	16	1.85%
Mitchell	15	1.79%
Burke	11	1.32%
Cherokee	8	0.93%
Polk	7	0.84%
Graham	7	0.78%
Avery	4	0.43%
Caldwell	3	0.33%
Clay	2	0.26%
SSA Subtotal	**117**	**13.97%**
Other: North Carolina	10	1.18%
Out of State	26	3.13%
Total	**840**	**100.00%**

Note: **PSA** (Primary Service Area); **SSA** (Secondary Service Area)

In Section C, page 22, and in supplemental information, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant based its projected patient origin on the FY 2019 actual hospital-wide patient origin percentages at Mission by county.
- As Mission has the only existing inpatient dialysis program and is proposing the first hospital-based outpatient dialysis center in the service area, the applicant assumes that the patient origin percentages will mirror that of its existing inpatient dialysis operations.

Analysis of Need

In Section C, pages 25-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

To demonstrate the need for the proposed project, the applicant begins by identifying the proposed service area for the new outpatient dialysis center. On page 25, the applicant states that Mission is the only provider of inpatient dialysis in western North Carolina. Based on its historical patient origin, Mission serves a 19-county service area, which includes a primary service area and a secondary service area, as shown in the table below.

Mission Hospital Service Area Definition	
PSA	**SSA**
Buncombe	Jackson
Henderson	Swain
Haywood	Rutherford
McDowell	Mitchell
Madison	Burke
Macon	Cherokee
Transylvania	Polk
Yancey	Graham
	Avery
	Caldwell
	Clay

Source: Section C, page 25

Service Area Population (pages 27-30)

The applicant used data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth trends in the service area. The applicant states that between 2020 and 2025, the primary service area is projected to grow steadily from 574,937 to 603,708, a 5 percent growth. The applicant states that the entire service area is projected to grow by 4.1 percent over the same time period, as shown in the tables below.

2020 Service Area Population

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	49,481	92,059	70,130	55,376	267,046
Henderson	21,919	33,515	31,461	32,837	119,730
Haywood	11,379	18,182	17,705	16,547	63,813
McDowell	9,018	14,667	13,140	10,080	46,905
Madison	3,958	7,193	6,325	5,367	22,843
Transylvania	5,680	9,796	8,779	11,551	35,806
Yancey	3,353	5,730	4,944	4,767	18,794
PSA	**104,786**	**181,142**	**152,484**	**136,525**	**574,937**
Macon	6,755	10,226	9,135	10,781	36,897
Jackson	7,483	18,538	9,870	8,957	44,848
Swain	3,252	4,400	3,505	2,951	14,108
Rutherford	13,646	21,703	18,665	15,091	69,105
Mitchell	2,741	4,887	3,952	3,678	15,258
Burke	17,869	29,660	25,260	19,145	91,934
Cherokee	4,894	7,822	8,114	9,142	29,972
Polk	3,360	5,874	5,963	6,655	21,852
Graham	1,728	2,604	2,164	2,190	8,686
Avery	2,687	6,106	5,185	4,057	18,035
Caldwell	16,108	26,720	23,965	16,910	83,703
Clay	2,071	3,160	3,147	3,680	12,058
SSA	**82,594**	**141,700**	**118,925**	**103,237**	**446,456**
Total	**187,380**	**322,842**	**271,409**	**239,762**	**1,021,393**

Source: Section C, page 28; 2019 NCOSBM

2025 Service Area Population

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	49,359	96,417	72,654	63,574	282,004
Henderson	21,939	35,659	31,892	36,793	126,283
Haywood	11,758	19,082	17,323	18,083	66,246
McDowell	8,910	15,031	12,871	11,387	48,199
Madison	4,085	7,465	6,368	6,129	24,047
Transylvania	5,841	9,944	8,880	12,622	37,287
Yancey	3,471	6,203	4,849	5,119	19,642
PSA	**105,363**	**189,801**	**154,837**	**153,707**	**603,708**
Macon	7,111	11,084	8,950	11,734	38,879
Jackson	7,639	19,872	9,901	10,009	47,421
Swain	3,143	4,271	3,155	3,031	13,600
Rutherford	13,707	22,227	18,238	16,572	70,744
Mitchell	2,787	5,041	3,646	3,826	15,300
Burke	17,736	30,871	23,699	21,293	93,599
Cherokee	4,922	8,286	8,045	10,217	31,470
Polk	3,372	6,313	5,525	7,394	22,604
Graham	1,636	2,750	2,016	2,284	8,686
Avery	2,647	5,888	5,056	4,439	18,030
Caldwell	16,084	27,823	23,203	18,805	85,915
Clay	2,159	3,478	3,154	4,177	12,968
SSA	**82,943**	**147,907**	**114,588**	**113,781**	**459,216**
Total	**188,306**	**337,705**	**269,425**	**267,488**	**1,062,924**

Source: Section C, page 29; 2019 NCOSBM

The applicant states that the 65+ population is showing the highest growth projections which is significant due to their higher use of health care resources. The applicant states that ESRD is common among the middle-aged and elderly, therefore the use rates for dialysis services will increase as this population grows. Based on data from the NCOSBM, the table below demonstrates the percentage of growth by age group and county in the proposed service area, across a five-year period.

Population Growth 2020 to 2025

	Age 0-17	Age 18-44	Age 45-64	Age 65+	Total
Buncombe	-0.25%	4.73%	3.60%	14.80%	5.60%
Henderson	0.10%	6.40%	1.37%	12.05%	5.47%
Haywood	3.33%	4.95%	-2.16%	9.28%	3.81%
McDowell	-1.20%	2.48%	-2.05%	12.97%	2.76%
Madison	3.21%	3.78%	0.68%	14.20%	5.27%
Transylvania	2.83%	1.51%	1.15%	9.27%	4.14%
Yancey	3.52%	8.25%	-1.92%	7.38%	4.51%
PSA	**0.55%**	**4.78%**	**1.54%**	**12.59%**	**5.00%**
Macon	5.27%	8.39%	-2.03%	8.84%	5.37%
Jackson	2.08%	7.20%	0.31%	11.75%	5.74%
Swain	-3.35%	-2.93%	-9.99%	2.71%	-3.60%
Rutherford	0.45%	2.41%	-2.29%	9.81%	2.37%
Mitchell	1.68%	3.15%	-7.74%	4.02%	0.28%
Burke	-0.74%	4.08%	-6.18%	11.22%	1.81%
Cherokee	0.57%	5.93%	-0.85%	11.76%	5.00%
Polk	0.36%	7.47%	-7.35%	11.10%	3.44%
Graham	-5.32%	5.61%	-6.84%	4.29%	0.00%
Avery	-1.49%	-3.57%	-2.49%	9.42%	-0.03%
Caldwell	-0.15%	4.13%	-3.18%	11.21%	2.64%
Clay	4.25%	10.06%	0.22%	13.51%	7.55%
SSA	**0.42%**	**4.38%**	**-3.65%**	**10.21%**	**2.86%**
Total	**0.49%**	**4.60%**	**-0.73%**	**11.56%**	**4.07%**

Source: Section C, page 30; 2019 NCOSBM

Growing Needs of ESRD Patients (pages 30-35)

To demonstrate the need for the proposed project, the applicant refers to the growing needs of ESRD patients. The applicant cites the president's 2019 executive order to improved health services for ESRD patients and combat the growing amount of at-risk patients suffering from chronic kidney disease progressing to late-stage kidney failure. The applicant also cites data from The United States Renal Data System (USRDS) to demonstrate the nationwide incidence and the prevalence of ESRD. The applicant states that according to data from USRDS, the ESRD incidence count increased nationally by 7.07 percent from 2014 to 2017. During the same period of time, the number of persons living with ESRD increased nationally by 14.51 percent. The applicant also refers to the growth in the incidence count in North Carolina among the population age 65 and older, which was higher than other age cohorts. The following tables illustrate these growth trends.

Nationwide Incidence and Prevalence of ESRD		
Year	**Incidence Count**	**Prevalence Count**
2010-2013	463,836	2,500,270
2014-2017	496,619	2,863,153
% Growth	7.07%	14.51%
CAGR	1.72%	3.45%

Source: Section C, page 31

Incidence and Prevalence of ESRD by Age in North Carolina								
	Incidence Count				Prevalence Count			
Age	**2010-2013**	**2014-2017**	**% Growth**	**CAGR**	**2010-2013**	**2014-2017**	**% Growth**	**CAGR**
0-17	115	109	-5.22%	-1.33%	702	708	0.85%	0.21%
18-44	1,907	2,056	7.81%	1.90%	14,416	14,456	3.05%	0.75%
45-64	6,078	6,435	5.87%	1.44%	38,102	42,312	11.05%	2.65%
65+	6,296	6,934	10.13%	2.44%	28,547	35,613	24.75%	5.68%
Total	**14,396**	**15,534**	**7.90%**	**1.92%**	**81,767**	**93,489**	**14.34%**	**3.41%**

Source: Section C, page 31

The applicant refers to the incidence count and prevalence of ESRD in North Carolina and the growing need of ESRD patients in the proposed service area. The applicant states that the growth in North Carolina is mirrored in Mission's 19-county service area. According to data from USRDS, incidence of ESRD in Mission's service area from 2014 to 2017 saw 1,212 new patients diagnosed with ESRD. The prevalence of ESRD in Mission's service area demonstrated an overall growth of 11.46 percent and an annual growth rate of 2.75 percent across two 4-year time periods; 2010-2013 and 2014-2017. The applicant projects that the prevalence of ESRD in the proposed service area will continue to grow at a similar rate. The applicant also refers to the number of ESRD patients using in-center dialysis services at a community dialysis center in the service area where the proposed outpatient dialysis center will be located. The following tables illustrate the growth trends stated above.

Incidence of ESRD in Mission's Service Area	
Service Area	**Incidence Count**
PSA	603
SSA	609
Total	**1,212**

Source: Section C, page 32; 2013-2017 USRDS Incidence Count

Prevalence of ESRD in Mission's Service Area				
Service Area	**2010-2013**	**2014-2017**	**% Growth**	**CAGR**
PSA	3,235	3,590	10.97%	2.64%
SSA	2,732	3,061	12.04%	2.88%
Total	**5,967**	**6,651**	**11.46%**	**2.75%**

Source: Section C, page 33; 2013-2017 USRDS Prevalence Count

Number of ESRD Patients using In-Center Dialysis Services	
Service Area	**# of Patients**
PSA	484
SSA	484
Total	**968**

Source: Section C, page 34

Needs of the Defined Patient Population (pages 35-38)

The applicant states that the proposed hospital-based outpatient dialysis center will serve patients who are inappropriate for treatment in the community setting, or who otherwise are unable to receive treatment in a community setting. The applicant states that individuals who fall under this group may include patients who have behavioral issues or have no payor source, patients who missed treatment at the community dialysis center due to emergency room treatment or hospital admission, or patients referred by their community provider due to complications. The applicant states that these patients tend to have unequal or sporadic access to dialysis treatment and would have been better served in the proposed outpatient dialysis center.

The applicant states that Mission will provide dialysis for patients in the appropriate outpatient setting when they do not require an admission. This will reduce the length of time a patient remains in the emergency department and avoid subsequent admission for patient dialysis. The applicant states that this will open up space, free up hospital beds and alleviate any capacity restraints in the inpatient dialysis unit.

The applicant states that the proposed project will support high quality, integrated care for patients with ESRD by serving patients in a convenient and comfortable setting, equipped with state-of-the-art equipment and technologies. In addition, the proposed center will allow patients to be served in an outpatient setting at a lower cost as opposed to its inpatient unit.

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

- The applicant provides data showing the population growth in the service area, particular those 65 and over who tend to utilize more health resources, including ESRD services.
- The applicant's proposal is in response to ESRD patients who are inappropriate for treatment, or unable to receive treatment, in a community setting.
- The applicant relies on growth trends and historical utilization of its existing inpatient dialysis unit to justify the need.

Projected Utilization

In Section C, page 42, the applicant provides historical and projected utilization, as illustrated in the following table.

Mission Hospital Outpatient Dialysis Center Projected Utilization			
	2020 YTD	1st FY FY 2022	2nd FY FY 2023
Projected Patients	796	818	840
Growth Rate		2.75%	2.75%
Treatments per Patient	1.62	1.62	1.62
Projected Treatments	1,290	1,326	1,362
Dialysis Slots Available*	1,976	1,976	1,976
Percent Utilization of 4 Stations	65.3%	67.1%	68.9%

*Assume four hours per treatment but due to the irregular nature of these patient treatment schedules, it was assumed that the average would be 1.5 treatment per day. Two slots on weekdays, and each Saturday and Sunday.

In Section C, pages 39-42, and in supplemental information, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The following table illustrates the applicant's assumption of hours of operation:

Mission's Outpatient Dialysis Center Assumptions for Hours of Operation	
8	Hours per Day
6	Days (½-day Saturday, ½-day Sunday)
48	Hour[s] per Week
52	Weeks
312	Equivalent Days per Year

Source: Section C, page 42

Step 1: Determine the Number of Patients Served by the Inpatient Unit that are Appropriate for Hospital Based Outpatient Dialysis

The applicant reviewed data from January through November 2020 of its existing inpatient dialysis unit to determine the number of patients appropriate for hospital based outpatient dialysis and their total number of treatments, as illustrated in the table below.

Mission Dialysis Patients by Scenarios Jan-Nov 2020		
Dialysis Patient Scenarios	**Patient Episodes**	**Treatment Days**
Outpatients Receiving Dialysis	96	128
Inpatient with Short Average Length of Stay (ALOS)	58	106
Long Stay inpatients that Could be Discharged Sooner	487	731
Behavioral Health/Substance Abuse Patients	17	44
Patients without Funding Source	27	130
Total Current Mission Patients	**685**	**1,139**

Source: Section C, page 40; Mission's internal data through November 2020

In supplemental information, the applicant states that its calendar year estimate of 2020 (Jan. – Nov. 2020) is the basis for its projections.

Step 2: Estimate the Number of Patients that will Need Planned Starts in a Controlled Environment Before Shifting to the Community Setting

The applicant estimates the number of patients that will need planned starts in an outpatient dialysis setting as opposed to a community setting based on a review of national data, input from Mission's nephrologists, and Mission's inpatient dialysis experience. The applicant projects that 15 percent of the estimated 2020 new patient ESRD incidence will start in the proposed facility, calculated and summarized as follows:

Estimated New Patient Starts as Mission Outpatient	
Service Area 2014-2017 ESRD Patient Incidence	1,212
Average Annual ESRD Incidence 2014-2017	303
Historical CAGR of Service Area Incidence ESRD Patients	1.9%
Estimated 2020 new Patient ESRD Incidence	321
Percent Best Started in Hospital Setting	15%
Projected 2020 New Starts	**48**

Source: Section C, page 40; United States Renal Data System Database

Step 3: Total Estimated 2020 Potential Outpatient Volume

The applicant combined the annualized data from Step 1 with the estimated new patients starts from Step 2 to calculate average treatments per patient. The applicant states that that while patients in a scheduled environment receive dialysis three times a week, the proposed center will fill in gaps of care. The applicant projects an average of 1.62 treatment days per patient for the first two project years.

Mission Dialysis Patients by Scenarios 2020 Annualized		
Dialysis Patient Scenarios	**Patient Episodes**	**Treatment Days**
Outpatients Receiving Dialysis*	96	128
Inpatient with Short Average Length of Stay (ALOS)	58	106
Long Stay inpatients that Could be Discharged Sooner**	487	731
Behavioral Health/Substance Abuse Patients	17	44
Patients without Funding Source	27	130
Total Current Mission Patients Jan. - Nov. 2020	**685**	**1,139**
2020 YTD Data Annualized	747	1,242
15% Inpatients than Can Start in a Hospital Outpatient Dialysis Station and Transition to Community Care***	48	48
Total	**796**	**1,290**
Average Treatment Days per Patient		**1.62**

Source: Section C, page 41; Mission's internal data
*Include 36.5% patients arriving in the ED
**Assumes 1.5 day of long ALOS could be shifted to outpatient treatment
***15% of community based treatment is started in hospital supported environment at Mission

In supplemental information, the applicant states that patient episodes and treatment days were annualized by dividing January through November data by 11 months and multiplying by 12 months. The applicant then adds a calendar year estimate of 2020 patient starts in community

dialysis that would start in the controlled hospital environment and then transition to community care.

Annualized 2020 current Mission patients equals 685 ÷ 11 x 12 = 747 + 48 = 796
Annualized 2020 current Mission treatments equals 1,139 ÷ 11 x 12 = 1,242 + 48 = 1,290

Step 4: Determine Mission's Projected Utilization

The applicant assumes a 2.75 percent growth rate in the number of patients to be served, which is equivalent to the growth of the prevalence in ESRD in Mission's service area across two 4-year time periods; 2010-2013 and 2014-2017. The applicant states that this is a reasonable assumption since Mission experienced a 3.5 percent growth between 2019 and 2020. In supplemental information, the applicant states that the first full year for the project starts nine months after the calendar year estimates of 2020. The applicant states:

> *"Mission did not include data for the first 9 months of 2021 and will only initiate services in October of 2021. Mission conservatively chose to hold potential volume constant from CY 2020 annualized until the start of the program on October 1, 2021."*

The applicant projects a 67.1 percent utilization or 1,326 projected treatments in Year 1 and 68.9 percent in utilization or 1,362 projected treatments in Year 2.

Mission Hospital
Outpatient Dialysis Center
Projected Utilization

	2020 YTD	1st FY FY 2022	2nd FY FY 2023
Projected Patients	796	818	840
Growth Rate		2.75%	2.75%
Treatments per Patient	1.62	1.62	1.62
Projected Treatments	1,290	1,326	1,362
Dialysis Slots Available*	1,976	1,976	1,976
Percent Utilization of 4 Stations	65.3%	67.1%	68.9%

*Assume four hours per treatment but due to the irregular nature of these patient treatment schedules, it was assumed that the average would be 1.5 treatment per day. Two slots on weekdays, and each Saturday and Sunday.

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

- The applicant's utilization projections are supported by the historical utilization of ESRD patients determined to be inappropriately served at the Mission's existing inpatient dialysis unit.
- The applicant provided adequate support for the growing trends in utilization based on prevalence of ESRD in North Carolina and the service area.
- The applicant provides adequate support for the increase in incremental projections.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

> *"Historically at Mission Hospital, women have had equal access to all services…Handicapped persons and the elderly population have always been accommodated through design of the facility…Mission does not discriminate against any persons, including racial and ethnic minorities…Mission also has a long history of meeting the needs of low-income individuals."*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients during the 2nd FFY
Low income persons	13.31%
Racial and ethnic minorities	10.00%
Women	43.00%
Persons with disabilities	100.00%
Persons 65 and older	65.00%
Medicare beneficiaries	73.23%
Medicaid recipients	11.31%

Section C, page 45

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 Mission's experience with its inpatient dialysis program and the demographic makeup of the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

(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, … persons [with disabilities], 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.

C

The applicant proposes to develop a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

In Section E, pages 54-55 the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo-The applicant currently serves dialysis patients through its 10-station inpatient dialysis unit. The applicant states that maintaining the status quo would not allow Mission to serve patients in a lower-cost setting, support patients with gaps in dialysis, or receive any reimbursement for patients with pending payor sources. In addition, the proposed project will address the issue of emergency department patients unnecessarily admitted or served in an inappropriate setting while missing a regularly scheduled dialysis treatment at their community dialysis center.

Expand the Inpatient Dialysis Program-The applicant states that this alternative was rejected because it does not address the unnecessary use of inpatient services for patients who do not medically require it.

On page 55, the applicant states that its proposal is the most effective alternative because it would better serve ESRD patients that are inappropriate for treatment in a community setting who do not require inpatient dialysis. The applicant states that less patients will seek treatment through the emergency department and more patients will experience reduced lengths of stay by utilizing the outpatient dialysis center instead of the inpatient unit.

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 proposed project will reduce emergency department visits and avoid patients being served in inappropriate settings.
- Patients will be served in a low-cost setting and support patients with gaps in dialysis services.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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. **MH Mission Hospital, LLLP (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**

2. **Pursuant to Policy ESRD-3, the certificate holder shall develop a new Medicare-certified kidney disease treatment center (outpatient dialysis facility) with no more than four in-center dialysis stations at Mission Hospital upon project completion.**

3. **Pursuant to Policy ESRD-3, the certificate holder shall document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.**

4. **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 August 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**

5. **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 a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

Capital and Working Capital Costs

In Section Q, page 91, the applicant projects the total capital cost of the project, as shown in the table below.

Mission Hospital (Outpatient Dialysis Center) Capital Costs	
Medical Equipment	$189,400
Non-Medical (IT Cost)	$12,527
Furniture	$12,796
Consultant Fees (CON Consultants)	$40,000
Other (Contingency)	$21,472
Total	**$276,195**

In Section Q, page 91, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Documented quotes for furniture and IT software/equipment
- A contingency of 10 percent for medical equipment, IT costs and furniture.

In Section F, page 58, the applicant states that there will be no start-up or initial operating costs because the proposed project will be part of Mission's existing hospital-based services.

Availability of Funds

In Section F, page 56, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	MH Mission Hospital, LLLP	Total
Loans	$0	$0
Accumulated reserves or OE *	$276,195	$276,195
Bonds	$0	$0
Other (Specify)	$0	$0
Total Financing	$276,195	$276,195

* OE = Owner's Equity

Exhibit F-2.1 contains a letter dated January 15, 2021 from the Chief Financial Officer of the North Carolina Division of HCA Healthcare, parent company of Mission Hospital, documenting its intention to provide funding for the project through an inter-company loan. The letter states that as of December 31, 2019, HCA Healthcare (HCA) generated $7.6 billion of cash flow from operating activities and has revolving credit facilities totaling $5.7 billion. Exhibit F-2.2 contains the audited consolidated financial statements of HCA, which show that as of December 31, 2019, HCA had $621 million in cash and cash equivalents, $45,058 million in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the applicant's documentation of HCA's accumulated funds and their willingness to fund the project.

Financial Feasibility

The applicant provided 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 the first two full fiscal years following completion of the project, as shown in the table below.

Mission Hospital Outpatient Dialysis Center	1st FFY FY 2022	2nd FY FY 2023
Total Treatments	1,326	1,362
Total Gross Revenues (Charges)	$1,335,282	$1,412,680
Total Net Revenue	$439,660	$465,144
Average Net Revenue per Treatment	$331.56	$341.51
Total Operating Expenses (Costs)	$303,675	$311,338
Average Operating Expense per Treatment	$229.01	$228.58
Net Income	$135.985	$153,806

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 92-94. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Gross revenue projections include a 3 percent inflation rate.
- Bad debts, charity care, and payor mix are based on Mission's existing inpatient dialysis unit.
- 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.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to develop a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Buncombe County as of December 31, 2019, as illustrated in Table 9A of the 2021 SMFP.

Buncombe County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station
Arden Dialysis	0	0	0.00%	0.0
Asheville Kidney Center	52	189	90.87%	3.6
Swannanoa Dialysis Center	10	0	0.00%	0.0
Weaverville Dialysis	20	52	65.00%	2.6
Total	**82**	**241**	73.48%	

Source: 2021 SMFP, Table 9A, page 119

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Buncombe County. The applicant states:

> *"Mission's proposed project will be the first hospital-based outpatient dialysis center in the region and will serve to provide access to patients with special circumstances that would be inappropriate or unable to receive treatment in a community dialysis center setting."*

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 would not result in an increase in hospital-based outpatient dialysis centers or community-based dialysis centers.
- The applicant is proposing the only hospital-based outpatient dialysis center in Buncombe County.
- The applicant adequately demonstrates that the proposed dialysis services are needed in addition to the existing or approved dialysis services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

In Section Q, page 97, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	1st FFY FY2022	2nd FFY FY2023
Registered Nurses (RNs)	2.4	2.4
TOTAL	**2.4**	**2.4**

The assumptions and methodology used to project staffing are provided in Section Q, page 97. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 66-67, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- Mission has a long history of recruiting and retaining clinical and non-clinical personnel.
- Mission has an established orientation and training program specific to each position.
- Mission requires clinical staff members to maintain current licensure and certification and to annually provide evidence of competency.
- Mission requires clinical staff members to attend continuing education programs and receive annual in-services on HIPPA, Medicare Compliance, and OSHA.

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 all the reasons described 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 a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed services. On page 68, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on Mission's existing clinical ancillary and support services that are already in place to support everyday functioning of the facility.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides 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 following:

- As the only quaternary and tertiary health care provider and operator of the only inpatient dialysis unit in the service area, Mission has a long history of receiving patient referrals from hospitals in the region.
- Mission has an existing transfer agreement with the Western North Carolina Network, which allows the transfer of a patient to a member's facility for the purpose of continuity of patient treatment and care.
- Mission has an existing inpatient agreement with DaVita Kidney Care for patient dialysis care.

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 all the reasons described above.

(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 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

The applicant does not propose to construct any new space, renovate any existing space nor make minor renovations to existing space.

(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 … persons [with disabilities], 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;

NA

Neither the applicant nor any related entities own, operate or manage an existing outpatient dialysis facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

(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 77, the applicant states:

> *"Mission is not obligated to provide uncompensated care, community service, or access by minorities and persons with disabilities."*

In Section L, page 77, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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, page 78, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Mission Hospital Projected Payor Mix, FFY 2023		
Primary Payor Source at Admission	**# of Patients**	**In-Center Dialysis Services as Percent of Total**
Self-Pay	18	2.20%
Insurance*	65	7.73%
Medicare*	615	73.23%
Medicaid*	95	11.31%
Other^	46	5.53%
Total	**840**	**100.00%**

Source: Section L, page 78
^Other federal and state governmental
*Including managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.20% of total services will be provided to self-pay patients, 73.23% to Medicare patients and 11.31% to Medicaid patients.

On page 78, 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 based on the following:

- Projected payor mix for the proposed outpatient dialysis center is based on the most recent and actual experience of Mission's inpatient dialysis program.
- The projected payor source for the entire facility is based on percent of projected revenue by payor source.

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.

(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, page 80, 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 a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

In Section M, pages 81-82, the applicant describes the extent to which health professional training programs in the area 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:

- A proposed Internal Medicine residency program to support training and care for renal patients
- Mission's partnership with the Mountain Area Health Education Center (MAHEC) whose purpose is to improve training and retention of healthcare professionals

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 all the reasons described above.

(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 a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Buncombe County as of December 31, 2019, as illustrated in Table 9A of the 2021 SMFP.

Buncombe County Dialysis Facilities

Facility Name	Certified Stations as of 12/31/2019	# of IC Patients as of 12/31/2019	Utilization by Percent as of 12/31/2019	Patients Per Station
Arden Dialysis	0	0	0.00%	0.0
Asheville Kidney Center	52	189	90.87%	3.6
Swannanoa Dialysis Center	10	0	0.00%	0.0
Weaverville Dialysis	20	52	65.00%	2.6
Total	**82**	**241**	73.48%	

Source: 2021 SMFP, Table 9A, page 119

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

> *"The proposed project will not negatively impact competition in the proposed service area. Instead, introduction of a hospital-based outpatient dialysis center on Mission's campus will serve to expand access to ESRD patients who would be inappropriate for treatment in a community setting."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

> *"Mission currently serves patients seeking emergency dialysis services through its inpatient unit, regardless of its ability to collect reimbursement for those services. Instead, with the proposed project, it can send these patients to the outpatient setting, at a lower cost to patients and payors. Mission will also reduce expensive inpatient care by discharging patients sooner serving them in the outpatient center before transitioning to a routine schedule at community dialysis centers."*

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

Regarding the impact of the proposal on quality, in Section N, page 84, the applicant states:

> *"The proposed project will enhance the quality of care for patients who currently have a gap in dialysis care. Many of the patients that Mission proposes to serve currently either do not have access to a community center, have missed an appointment at their regular center, or are in the process of being discharged from Mission. For each of these cases, the proposed center will ensure that patients have access to the right level of care and will guarantee that they will not miss a dialysis session, all while having access to a full range of resources and support services from the hospital."*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, the applicant states:

> *"…the proposed project will expand access to groups not currently being served by the community setting. The proposed project will also expand cost-effective options for patients that are currently being dialyzed in Mission's inpatient dialysis program due to lack of options."*

See also Section L and C 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 adequately 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
- Information publicly available during the review and used by the Agency

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

(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

In Section Q, page 98, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 87, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred in this facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in this facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at this facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop a hospital-based, outpatient dialysis center with no more than four stations pursuant Policy ESRD-3. There are no administrative rules that are applicable to proposals for a hospital-based, outpatient dialysis center pursuant Policy ESRD-3.