

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 14, 2021

Findings Date: April 14, 2021

Project Analyst: Kim Meymandi

Team Leader: Fatimah Wilson

Project ID #: B-12014-21

Facility: AdventHealth Hendersonville

FID #: 943388

County: Henderson

Applicant(s): Fletcher Hospital, Inc.

Project: Develop inpatient dialysis services through a service agreement with Total Renal Care, Inc. with no more than two portable inpatient dialysis units upon project completion

### 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.

NA

Fletcher Hospital, Inc. (hereinafter referred to as “the applicant”) proposes to develop inpatient (IP) dialysis services at AdventHealth Hendersonville through a service agreement with Total Renal Care, Inc. (TRC), a subsidiary of DaVita, Inc. utilizing no more than two portable inpatient dialysis units upon project completion. The applicant will serve as the lessee of equipment and DaVita, Inc. (parent company of TRC) will serve as the lessor. AdventHealth Hendersonville is located at 100 Hospital Drive in Hendersonville, Henderson County.

### **Conclusion**

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP);
- Acquire any medical equipment for which there is a need determination in the 2021 SMFP; or
- Offer a new institutional health service for which there are any policies in the 2021 SMFP

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

- (2) Repealed effective July 1, 1987.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.

## C

The applicant proposes to provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

In Section C, page 26, the applicant states that no renovations to AdventHealth Hendersonville are necessary to start inpatient dialysis services at the facility. The proposed equipment and supplies will be stored in a room located on the third floor of AdventHealth Hendersonville with inpatient dialysis services being performed at a patient's bedside.

### **Patient Origin**

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 2021 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 28, the applicant defines the service area for the proposed project. The primary service area is Henderson County and the secondary service area includes the surrounding counties of Buncombe, Transylvania and Polk. Facilities may also serve residents of counties not included in their service area.

In Section C, page 27, the applicant states that AdventHealth Hendersonville does not currently provide inpatient dialysis services. Therefore, there is no historical patient origin information to report. In Section C, page 28, the applicant projects patient origin based on general acute care inpatient services as reported on the 2021 Hospital License Renewal Application (LRA) data for AdventHealth Hendersonville. The following table illustrates projected patient origin and the LRA basis for arriving at such.

County	2021 Hospital LRA		2 <sup>nd</sup> Full FY 10/01/2022 to 9/30/2023	
	Admissions	% of 4-County Service Area	Inpatient Dialysis Patients	% of Total IP Dialysis Patients
Henderson	1,567	62.3%	99	62.3%
Buncombe	757	30.1%	48	30.1%
Transylvania	99	3.9%	6	3.9%
Polk	93	3.7%	6	3.7%
<b>Total</b>	<b>2,516</b>	<b>100.0%</b>	<b>159</b>	<b>100.0%</b>

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

- The applicant uses patient origin information from the most recent LRA
- The patients using inpatient acute care services are the most likely population to use inpatient dialysis services

**Analysis of Need**

In Section C, pages 30-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

**Dialysis Patient Transfers**

Currently, inpatient dialysis services are not offered at the two hospitals in Henderson County, AdventHealth Hendersonville and Pardee Memorial Hospital. On page 30 the applicant states:

*“As a result, patients admitted for acute care services in Henderson County do not have access to this life-saving treatment and must be transferred out-of-county.”*

During the period December 2019 to November 2020, the applicant states that 12 admitted patients and 41 emergency department (ED) patients had to be transferred to a hospital providing IP dialysis and 120 patients being transported by EMS bypassed AdventHealth Hendersonville for a hospital providing IP dialysis.

**Henderson County Population Growth**

On page 31, the applicant discusses Henderson County population growth using projections from the North Carolina State Budget and Management (NCOSBM). The applicant states that from 2016 to 2021, the population of Henderson County grew by 6.3 percent. By demographics, the 45-64 population grew by 2.9 percent and the 65+ population grew by 15.4 percent. The applicant states that the NCOSBM projects the 45-64 population will increase by 1.3 percent from 2021 to 2026 and the 65+ population will increase by 11.3 percent from 2021 to 2026 to become 29.4 percent of Henderson County’s population. The applicant assumes with the

increase in the Henderson County population, particularly the 65 + population, there will be an increase in patients with chronic kidney disease and related deaths.

#### Extended Service Area Population Growth

On page 32, the applicant discusses the population growth of the extended service area, which includes Buncombe, Polk and Transylvania counties using projections from the NCOSBM. The applicant states from 2016 to 2021, the population of the extended service area grew by 5.0 percent. By demographics, the 45-64 population decreased by 0.1 percent and the 65+ population grew by 16.9 percent. The applicant states that the NCOSBM projects the 45-64 population will increase by 3.5 percent from 2021 to 2026 and the 65+ population will increase by 12.9 percent from 2021 to 2026 to become 24.8 percent of the extended service area's total population. The applicant assumes with the increase in the extended service area population, particularly the 65 + population, there will be an increase in patients with chronic kidney disease and related deaths.

#### Henderson County ESRD Growth

On page 33, the applicant discusses the number of patients receiving dialysis services in Henderson County and references data from the July 2017 NC Semiannual Dialysis Reports (SDR) through the July 2019 SDR. The applicant states that based on this data, Henderson County has experienced a 3-year average of 89 end stage renal disease (ESRD) patients receiving in-center hemodialysis and a 3-year average of 119 total ESRD patients. The applicant assumes with the increase in patients receiving dialysis services in Henderson County, more patients will require some level of care as an inpatient at AdventHealth Hendersonville during the period that they are receiving ESRD treatments.

#### Common Co-morbidities

On pages 33-38, the applicant discusses the common comorbidities in people with chronic kidney disease. These comorbidities include diabetes, high blood pressure, cardiovascular disease and congestive heart disease. Referencing the North Carolina Trend Report, February 2019, the applicant reports that in 2018 three of the five leading causes of death in persons age 65+ is related to these comorbidities. The applicant states that based on the data, the population of Henderson County is more likely to be hospitalized for conditions related to chronic kidney disease. The applicant states that as the population ages and these comorbidities become more prevalent in Henderson County, the more likely these patients will need access to dialysis services.

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

- Providing dialysis services during an inpatient stay will avoid transportation expenses without interrupting patient care at AdventHealth Hendersonville.
- There is a need for IP dialysis services at AdventHealth Hendersonville based on the growth of the population and ESRD patients in Henderson County.
- There is a need for IP dialysis services based on the increased need for IP services for common comorbidities for patients with chronic kidney disease.

Projected Utilization

In Form C in Section Q and a response to a request for clarifying information, the applicant provides the assumptions and methodology used to project inpatient dialysis utilization, which is summarized below.

- Using population growth data from NCOSBM, the applicant calculates a 6-year CAGR for the 65+ population of Henderson County and the extended service area for 2016 through 2021  $[(109,401-93,964)^{(1/5)}-1=3.09]$ .
- Using population growth data from NCOSBM, the applicant calculates a 6-year CAGR for the 65+ population of Henderson County and the extended service area for 2021 through 2026  $[(122,954-109,401)^{(1/5)}-1=2.36]$ .
- The applicant identifies during the period of December 2019 through November 2020 the dialysis patients that were: 1) admitted to the hospital but transferred due to needing dialysis (12) 2) treated in the ED but transferred due to needing dialysis (41) or 3) being transported by local EMS and bypassed AdventHealth Hendersonville due to the need for IP dialysis services (120).
- The applicant projects the number of dialysis patients for the 10-month period of December 2020 through September 2021 by multiplying the prior 12-month period (12/19-11/20) by the CAGR of 3.09% calculated in Step 1 multiplied by 10/12 (3.09% x 10/12 = 2.58%).
- The applicant then projects the number of dialysis patients for the 1<sup>st</sup> Full FY and 2<sup>nd</sup> Full FY by multiplying the previous year dialysis patients by the CAGR of 2.36% calculated in Step 2.
- The applicant assumes a capture rate of 100% for both IP Transfers and ED Transfers with a 75% capture rate for EMS Transport Bypasses to account for patients who are treated at other local hospitals providing IP dialysis.
- Assuming an average length of stay of 3.5 days, the applicant projects patients would require two dialysis treatments and multiplies the projections of patients in the first and second full fiscal years by two, providing the total projected number of dialysis treatments.

The table below summarizes calculations and projections made by the applicant for AdventHealth Hendersonville and the utilization of IP dialysis services.

	<b>1<sup>st</sup> Full FY 10/21-9/22</b>	<b>2<sup>nd</sup> Full FY 10/22-9/23</b>	<b>Capture Rate</b>	<b>1<sup>st</sup> Full FY 10/21-9/22</b>	<b>2<sup>nd</sup> Full FY 10/22-9/23</b>
IP Transfers	13	13	100.0%	13	13
ED Transfers	44	46	100.0%	43	44
EMS Transfer Bypasses	129	134	75.0%	95	97
<b>Total Dialysis Patients</b>	<b>182</b>	<b>186</b>		<b>151</b>	<b>154</b>
<b>Total Projected IP Dialysis Treatments</b>				<b>302</b>	<b>308</b>

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

- Projected growth of inpatient dialysis care is adequately supported by projected population growth of Henderson County and the extended service area.
- The applicant projects the number of patients remaining at AdventHealth Hendersonville for inpatient dialysis care will grow at the same rate as the population, which is reasonable.

**Access to Medically Underserved Groups**

In Section C, page 41, the applicant discusses access to services at AdventHealth Hendersonville. The applicant states:

*“AdventHealth Hendersonville will provide services to all persons regardless of race, sex, age religion, creed, disability, national origin, or ability to pay because AdventHealth facilities and programs do not discriminate against any persons, or other medically underserved persons, regardless of their ability to pay. Services are available to all area residents including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved, including the medically indigent referred by their attending physicians.”*

On page 41, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Group</b>	<b>Percentage of Patients in 2<sup>nd</sup> Full FY</b>
Low income persons	7.3%
Racial and Ethnic Minorities	15.0%
Women	60.0%
Persons with disabilities	0.8%
Persons 65 and older	58.5%
Medicare beneficiaries	58.5%
Medicaid recipients	7.3%

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.

**Conclusion**

The Agency reviewed the:

- Application

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

Based on the 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 projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately support their 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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce or 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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

In Section E, pages 51-52 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 states that maintaining the status quo is not an effective alternative because transferring patients needing inpatient dialysis to another facility creates additional costs, inconveniences and an interruption in care for the patients.
- *Operate an inpatient dialysis service without a Hospital Service Agreement* – The applicant states this alternative would involve the acquisition and maintenance of equipment and specialized staff trained to operate and repair the equipment. The applicant states that the offering of inpatient dialysis treatments will not generate sufficient volume to justify the expense.

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

- The application is 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. Fletcher Hospital, Inc. (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. The certificate holder shall develop inpatient dialysis services through a service agreement with Total Renal Care, Inc. with no more than two portable inpatient dialysis units upon project completion.**
- 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 third month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

**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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

**Capital and Working Capital Costs**

In Section F.1, page 53, the applicant states that AdventHealth Hendersonville is not projecting any capital costs for this project.

In Section F.3, page 55, the applicant states that this project will not involve start-up or initial operating expenses because the hospital will establish a Hospital Services Agreement with Total Renal Care to provide the inpatient dialysis service.

**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 after an inpatient contribution margin (net income per inpatient by x number of dialysis inpatients) is added, revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

<b>AdventHealth Hendersonville</b>	<b>1<sup>st</sup> Full FY 10/1/2021- 9/30/2022</b>	<b>2<sup>nd</sup> Full FY 10/1/2022- 9/30/2023</b>
Total Procedures	302	308
Total Gross Revenues (Charges)	\$230,275	\$234,850
Total Net Revenue	\$111,683	\$113,902
Average Net Revenue per procedure	\$302	\$370
Total Operating Expenses (Costs)	\$192,322	\$196,143
Average Operating Expense per procedure	\$637	\$637
Net Income (loss)	(\$80,638)	(\$82,241)
Inpatient Contribution Margin	\$264,099	\$269,346
Net Income	\$183,461	\$187,105

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

- The applicant accounts for projected operating expenses, such as the hospital service agreement, program maintenance fees and salaries, consistent with projections elsewhere in the application.
- 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 for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and 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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

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 2021 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 28, the applicant defines the service area for the proposed project. The primary service area is Henderson County and the secondary service area includes the surrounding counties of Buncombe, Transylvania and Polk. Providers may serve residents of counties not included in their service area.

In Section G, page 60, the applicant states that Mission Hospital in Asheville, Buncombe County is the only facility in the service area that provides inpatient dialysis. On its 2020

Hospital License Renewal Application, Mission Hospital reports operating 10 inpatient dialysis stations.

In Section G, page 61, 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:

*“As previously stated, Mission Hospital in Asheville provides inpatient dialysis services. However, this requires AdventHealth Hendersonville patients receiving outpatient dialysis treatments who require an inpatient admission to travel to or be transported to Mission Hospital for their inpatient admission.*

*Pardee Memorial Hospital in Henderson County does not provide inpatient dialysis services, so it is not possible for this project to result in an unnecessary duplication of health services in Henderson County.”*

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

- The proposal is necessary to accommodate dialysis patients in Henderson County requiring inpatient dialysis services.
- There are no existing or approved facilities that provide inpatient dialysis services in Henderson County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

In Section Q, Form H, the applicant provides a table showing projected staffing in full-time equivalent (FTE) positions for the proposed services, as illustrated below. There are no current staffing needs for the proposed services as they are not yet offered.

**AdventHealth Hendersonville Projected Staffing**

Position	Current FTE Staff	Projected FTE Staff	Projected FTE Staff
		1 <sup>st</sup> FY 10/1/2021 to 9/30/2022	2 <sup>nd</sup> FY 10/1/2022 to 9/30/2023
Administrator	0	0.1	0.1
Medical Records	0	0.1	0.1
Housekeeping	0	0.1	0.1
Administration/Business Office	0	0.1	0.1
<b>TOTAL</b>	<b>0</b>	<b>0.4</b>	<b>0.4</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, Operating Costs. In Section H, page 63, the applicant states AdventHealth Hendersonville will contract with Total Renal Care to provide staffing for the inpatient dialysis staffing. The applicant also describes the existing training and continuing education programs at AdventHealth Hendersonville.

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 projects an increase in the FTE staffing positions necessary to accommodate the proposed increase in health services proposed at AdventHealth Hendersonville.

**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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

**Ancillary and Support Services**

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On page 66, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the necessary ancillary and support services for dialysis patients admitted to AdventHealth Hendersonville and how these will be made available.

**Coordination**

In Section I, page 67 , the applicant describes their 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 following:

- The applicant has existing relationships with local healthcare providers in the area including but not limited to Mission Hospital

**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.

- (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

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 ... 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;

C

This is an application for the provision of a new service. Therefore, historical payor mix data for the proposed service does not exist. In a response to a request for clarifying information, the applicant provided the payor mix for ED transfers between December 2019 and November 2020 as shown in the table below.

**ED Payor Mix (12/2019-11/2020)**

Payor Source	# of Patients	% of Patients
Self-Pay	3	7.3%
Insurance	11	26.8%
Medicare	24	58.5%
Medicaid	3	7.3%
<b>Total</b>	<b>41</b>	<b>100.0%</b>

In Section L., page 75 the applicant provides the following comparison:

**AdventHealth Hendersonville**

	LAST FULL FY BEFORE SUBMISSION OF THE APPLICATION	
	PERCENTAGE OF TOTAL PATIENTS SERVED **	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	67.8%	52.0%
Male	32.2%	48.0%
Unknown	0.0%	0.0%
64 and Younger	53.4%	73.6%
65 and Older	46.6%	26.4%
American Indian	0.2%	0.7%
Asian	0.7%	1.3%
Black or African-American	3.7%	3.4%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	89.2%	92.5%
Other Race	3.2%	1.9%
Declined / Unavailable	2.9%	0.0%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

\*\*Percentage of Total Patients Served by AdventHealth Hendersonville in Henderson County, NC.

**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 applicant adequately documents the extent to which medically underserved populations currently use the applicant's (AdventHealth Hendersonville) existing services in comparison to the percentage of the population in the applicants' 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 76, the applicant states it has no such obligation.

In Section L, page 76, the applicant states that during the last 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against AdventHealth Hendersonville.

**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.

- (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 77, 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.

**AdventHealth Hendersonville Payor Mix  
2<sup>nd</sup> Full FY 10/1/2022 to 9/30/2023**

Payor Source	Percent of Total Patients
Self-Pay	7.3%

Insurance*	26.9%
Medicare*	58.5%
Medicaid*	7.3%
Other	0.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.3% of total services will be provided to self-pay patients, 9.8%, 58.5% to Medicare patients and 7.3% to Medicaid patients.

On page 77, 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 Emergency Department transfers between December 2019 and November 2020.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, pages 79, 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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

In clarifying information, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on a documented offer to an area program to access the facility for training.

- (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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

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 2021 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 28, the applicant defines the service area for the proposed project. The primary service area is Henderson County and the secondary service area includes the surrounding counties of Buncombe, Transylvania and Polk. Providers may serve residents of counties not included in their service area.

In Section G, page 60, the applicant states that Mission Hospital in Asheville, Buncombe County is the only facility in the service area that provides inpatient dialysis. On its 2020 Hospital License Renewal Application, Mission Hospital reports operating 10 inpatient dialysis stations.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states that currently inpatient dialysis services are not provided in Henderson County. The development of inpatient dialysis services at AdventHealth Hendersonville will allow outpatient dialysis patients residing in Henderson, Polk and Transylvania counties to have access to inpatient care in Henderson County.

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

*“....the project will require minimal initial capital from AdventHealth Hendersonville, and it will not require AdventHealth Hendersonville to hire additional staff.*

...

*Henderson County residents will no longer have to travel outside of Henderson County for inpatient services that would require a dialysis treatment, saving transportation costs for both the patients and the medical transport provider, especially emergency medical services. Patients will be closer to family and support networks, which has been shown to improve patient outcomes.”*

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 AdventHealth Hendersonville will utilize performance metrics that will be monitored on a monthly basis.

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:

*“AdventHealth Hendersonville will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay. Services are available to all area residents including low-income persons, racial and ethnic minorities, women handicapped persons, the elderly, and other underserved persons, including the medically indigent referred by their attending physicians.*

*AdventHealth facilities and programs do not discriminate against any persons, or other medically underserved persons, regardless of their ability to pay.”*

See also Sections 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 which was 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 the reasons stated 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 A, page 14, the applicant states there are no dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. In Section O, page 86, the applicant states that AdventHealth Hendersonville is the only facility located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 86, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred at AdventHealth Hendersonville. 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, incidents related to quality of care have not occurred at AdventHealth Hendersonville. 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 all 12 facilities, 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 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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion. There are no administrative rules that are applicable to proposals adding inpatient dialysis services to a hospital through a service agreement with an outside dialysis provider