

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 23, 2021

Findings Date: July 23, 2021

Project Analyst: Kim Meymandi

Team Leader: Lisa Pittman

Project ID #: B-12066-21

Facility: Margaret R. Pardee Memorial Hospital

FID #: 943324

County: Henderson

Applicant(s): Henderson County Hospital Corporation

Project: Develop inpatient dialysis services

### 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

Henderson County Hospital Corporation (hereinafter referred to as “the applicant”) proposes to develop inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital (Pardee) by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc. (TRC), a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. (Mountain Kidney) for medical management of the dialysis service. The applicant will serve as the lessee of equipment and DaVita, Inc. (parent company of TRC) will serve as the lessor. Pardee is located at 800 North Justice 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- (2) Repealed effective July 1, 1987.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 by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service. The applicant states that dialysis equipment along with staffing and operation of the equipment will be provided through a contract with DaVita, who will make available as many machines as needed to serve patients at the two dialysis stations and 12 dialysis-capable intensive care unit (ICU) rooms and medical management of the services will be provided through a contract with Mountain Kidney.

In Section C, page 31, the applicant states they propose to offer two methods of dialysis care. One method involves renovating vacant space in existing vacant ICU space to house two proposed inpatient stations which will provide dialysis treatment for chronic patients. The second method of proposed dialysis care involves creating access for critical or intensive care patients to receive dialysis care at their bedside and involves the installation of water access, drains and electrical receptacles in each of the 12 ICU rooms such that dialysis can be performed at the 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 33, 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, Polk, Rutherford, and Haywood. Facilities may also serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 33-34, the applicant provides the historical (FY2019) patient origin for acute care inpatient services at Pardee and the projected patient origin for the first three full fiscal years of operation (FY 2023-2025) of the proposed project, as shown in the following tables:

County	Inpatient Services		Inpatient Dialysis Services					
	Last Full FY 7/1/19-6/30/20		1 <sup>st</sup> Full FY 7/1/23-6/30/24		2 <sup>nd</sup> Full FY 7/1/24-6/30/25		3 <sup>rd</sup> Full FY 7/1/25-6/30/26	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Henderson	4,629	75.0%	222	75.0%	222	75.0%	222	75.0%
Buncombe	367	6.0%	18	6.0%	18	6.0%	18	6.0%
Polk	301	4.9%	14	4.9%	14	4.9%	14	4.9%
Transylvania	269	4.4%	13	4.4%	13	4.4%	13	4.4%
Rutherford	126	2.0%	6	2.0%	6	2.0%	6	2.0%
Haywood	81	1.3%	4	1.3%	4	1.3%	4	1.3%
South Carolina	75	1.2%	4	1.2%	4	1.2%	4	1.2%
Other*	320	5.2%	15	5.2%	15	5.2%	15	5.2%
Total	6,168	100.0%	296	100.0%	296	100.0%	296	100.0%

Other includes: Avery, Burke, Cabarrus, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Guilford, Jackson, Lenore, making, Madison, McDowell, Mecklenburg, Mitchell, New Hanover, Onslow, Pender, Person, Randolph, Robeson, Rowan, Swain, Union, Wake, Watauga, Wayne, Wilson, and Yancey counties in North Carolina and other states.

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

- The applicant uses patient origin information from its entire facility for general acute care inpatient services to project patient origin for inpatient dialysis services.
- The patients using inpatient acute care services are the most likely population to use inpatient dialysis services.

**Analysis of Need**

In Section C, pages 36-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

**Need for Inpatient Dialysis Care in Henderson County**

The applicant states that currently, only outpatient dialysis services are available in Henderson County and based on information from the 2021 License Renewal Application, as of December 31, 2019, this outpatient facility provided services for 94 patients. Due to the current lack of inpatient dialysis services in Henderson County, the applicant states that should one of these patients require acute inpatient care they would need to leave Henderson County. The closest facility to Henderson County with inpatient dialysis capabilities is Mission Hospital located in Buncombe County. The applicant states that in fiscal year (FY) 2020, a total of 378 patients

were either diverted by Emergency Medical Services (EMS) or transferred from Pardee to Mission Hospital due to the lack of inpatient dialysis services in Henderson County.

The applicant states that transferring patients requiring dialysis services to Mission Hospital is problematic due to many factors which include:

- The impact travel can have on dialysis patients who are medically fragile due to multiple chronic diseases that are often present
- Difficulties created for family members who are often elderly and fragile having to travel outside familiar territory
- Delays due to road construction in Henderson and Buncombe counties causing delays in transporting patients and can cause life-threatening situations
- Long wait times and backlogs at the Mission Hospital Emergency Department (ED) which can further delay treatment
- Decreased availability of Henderson County EMS due to time spent transporting and admitting patients in Buncombe County

The applicant also notes the common comorbidity of cardiovascular disease and chronic kidney disease and states that Pardee is the only hospital in Buncombe County that provides invasive cardiology services and this service would complement the proposed inpatient dialysis services.

#### Henderson County Demographics

The applicant provides data from the North Carolina Office of State Budget and Management (NC OSBM) showing the Henderson County population is expected to grow 1.2% over the next decade and by 2031 30.4% of the Henderson County population will be age 65 or older. The applicant also provides data from the State Center for Health Statistics showing that heart disease is the leading cause of death and accounted for 22.4% of total deaths in the 65 and over age cohort in Henderson County in 2019. The applicant notes that 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.

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

- Providing dialysis services during an inpatient stay will avoid potential life-threatening transportation issues and promote continuity of care at Pardee.
- There is a need for IP dialysis services at Pardee based on the growth of the population and ESRD patients in Henderson County.
- Given the common comorbidities for patients with chronic kidney disease, IP dialysis will serve to enhance other services already provided at Pardee.

#### Projected Utilization

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

- The applicant begins by providing data collected internally and by Henderson County EMS on dialysis patients transferred out of Henderson County to Mission Hospital for the time period FY 2018 through FY 2020 and for the purpose of projecting utilization, assumes these patients would be potential dialysis inpatients at Pardee. The data is shown in the table below.

	FY 2018	FY 2019	FY 2020	CAGR
EMS Diversions to Mission	91	107	110	9.9%
Transfers from Pardee ED to Mission	153	130	133	-6.8%
Pardee IPs transferred to Mission	163	135	135	-9.0%
Total Potential Dialysis Inpatients	407	372	378	-3.6%

- The applicant notes that in Project ID #B-12014-21, AdventHealth Hendersonville was approved to develop inpatient dialysis services and it is assumed that upon completion of the project, AdventHealth Hendersonville will serve 75% of the dialysis related patients diverted to Mission by Henderson County EMS. Given Pardee’s market share of general acute care inpatient admissions, which is calculated as 68% for FY 2020, the applicant assumes that should this project be approved, they will capture the remaining 25% of patients diverted to Mission by Henderson County EMS.
- The applicant conservatively assumes no annual growth and projects that beginning with FY 2024 they will serve a total of 296 dialysis inpatients each year. This is based on FY 2020 number of transfers from Pardee ED to Mission, IP transfers from Pardee to Mission and 25% of the EMS diversions to Mission  $[133 + 135 + (0.25 \times 110)]$ . The applicant projects serving a total of 148 dialysis inpatients in FY 2023 due to the start date of January 1, 2023 making it a partial year.
- The applicant projects the total number of dialysis treatments using DaVita’s historical average of three treatments per patient as illustrated in the table below.

Fiscal Year	Dialysis IP	Treatments per Patient	Treatments
2023	148	3.0	443
2024	296	3.0	887
2025	296	3.0	887
2026	296	3.0	887

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

- The applicant utilizes historical inpatient data as well as data from Henderson County EMS and market share percentages to base future utilization of inpatient dialysis service at Pardee.
- The applicant conservatively projects no growth for the first three project years, which is reasonable.

**Access to Medically Underserved Groups**

In Section C, page 46, the applicant states:

*“Pardee is committed to providing care to anyone in need and does not deny access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance. All area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, will have access to Pardee’s proposed inpatient dialysis services.”*

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 3<sup>rd</sup> Full FY</b>
Low income persons	Not available
Racial and Ethnic Minorities	5.5%
Women	60.5%
Persons with disabilities	Not available
Persons 65 and older	62.7%
Medicare beneficiaries	61.6%
Medicaid recipients	8.1%

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

- The applicant provides an estimate for each medically underserved group it proposes to serve.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

**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 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 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 by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

In Section E, pages 55-56 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.
- *Develop a different number of inpatient dialysis stations and/or bedside dialysis capable rooms* – The applicant states that developing the proposed two stations and upfitting each of the ICU rooms makes the most efficient use of existing space and will serve to provide patients safe and satisfactory outcomes.

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. Henderson County Hospital Corporation (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. The certificate holder shall develop inpatient dialysis services through service agreements with Total Renal Care, Inc. and Mountain Kidney and Hypertension Associates, PA.**
  - 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 sixth month. The first progress report shall be due on January 15, 2022. The second progress report shall be due on June 15, 2022 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 by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.



**Capital and Working Capital Costs**

In Section Q, Form F.1(a), the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$360,127
Miscellaneous Costs	\$58,865
<b>Total</b>	<b>\$418,992</b>

In Section Q, 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 information on projected capital costs provided by the applicant in Form F.1(a) and in the assumptions in Section Q of the application and the construction costs estimates in Exhibit F.1.

In Section F.3, pages 59-60, the applicant states it will not incur any start-up costs or initial operating expenses associated with this project, because it will enter into a Hospital Services Agreement with Total Renal Care (TRC), parent company to DaVita, for the provision of dialysis services to Pardee patients. The applicant states DaVita will provide the portable dialysis machines, all equipment supplies and staffing necessary to operate the machines.

**Availability of Funds**

In Section F.2, page 57, the applicant states that the capital cost will be funded as shown in the table below:

**Sources of Capital Cost Financing**

TYPE	HENDERSON COUNTY HOSPITAL CORPORATION	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$418,992	\$418,992
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$418,992</b>	<b>\$418,992</b>

\*OE = Owner's Equity

With regard to the working capital for the project, in Section F.3, page 59, the applicant states:

*“The proposed application involves the addition of inpatient dialysis services, which will be provided by a contracted vendor, to an existing acute care hospital. Any expenses associated with the addition of inpatient dialysis services will be covered by Pardee’s ongoing operations.”*

In Exhibit F.2-1, the applicant provides a letter from the Chief Financial Officer of Pardee UNC Health Care that confirms the applicant has sufficient cash reserves to fund the capital needs of the project and agrees to commit the necessary funds to the capital cost of the project. In Exhibit F.2-2 the applicant provides copies of the audited financial statements for Pardee, which indicate that as of June 30, 2020, Pardee had current assets totaling \$123 million and cash and cash equivalents totaling \$65 million.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on documentation provided in Exhibit F.2 as described above.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Forms F.2 and F.3, the applicant projects that revenues will exceed operating expenses in the first and second operating years of the project, as shown in the table below.

<b>Pardee Memorial Hospital</b>	<b>Partial FY 1/1/2023- 6/30/2023</b>	<b>1<sup>st</sup> Full FY 7/1/2023- 6/30/2024</b>	<b>2<sup>nd</sup> Full FY 7/1/2024- 6/30/2025</b>
Total Procedures	443	887	887
Total Gross Revenues (Charges)	\$479,275,357	\$994,891,678	\$1,028,581,198
Total Net Revenue	\$144,823,125	\$300,573,154	\$310,751,312
Average Net Revenue per procedure	\$326,914	\$338,865	\$350,340
Total Operating Expenses (Costs)	\$142,838,006	\$294,845,789	\$304,002,016
Average Operating Expense per procedure	\$326,915	\$332,408	\$342,731
Net Income	\$1,985,119	\$5,727,365	\$6,749,297

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant states that there are no separate dedicated charges and revenue for inpatient dialysis services. The charges and revenue for patients who receive inpatient dialysis services are paid on a total encounter basis with contract expenses factored into the total operating expenses. 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 and inflates these expenses 3% annually.
- 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 by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

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 33, 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, Polk, Rutherford, and Haywood. Facilities may also serve residents of counties not included in their service area.

In Section G, page 68, 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 that the closest inpatient dialysis services are provided by Mission Hospital in Buncombe County and travelling an extra 20 miles can have negative effects on an already fragile system and is also a barrier to the large percentage of dialysis patients who are low income. The applicant also states that although AdventHealth Hendersonville was recently approved to provide inpatient dialysis, the services proposed at Pardee are not duplicative because of the need to serve inpatients at Pardee, particularly those who need inpatient services such as interventional cardiology, which is not available at AdventHealth Hendersonville.

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 at Pardee requiring inpatient dialysis services.

- The other facility in Henderson County approved to provide inpatient dialysis services cannot serve patients admitted to Pardee for the services only offered at Pardee.

### **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 by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

In Section H, page 70, the applicant states it will not employ any staff directly attributable to the provision of inpatient dialysis services because all appropriate staff will be provided through contractual agreements with DaVita and Mountain Kidney. The assumptions and methodology used to project staffing for the hospital as a whole, exclusive of the provision of inpatient dialysis services, are provided in Section Q. Adequate costs for the health manpower and management positions are budgeted in Form F.3, Operating Costs. For informational purposes, the applicant describes the existing training and continuing education programs at Pardee.

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

- The applicant is contracting with a provider experienced in providing the proposed service.
- The applicant has experience providing sufficient manpower and management personnel for general inpatient acute care services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## C

The applicant proposes to provide inpatient dialysis services by renovating existing space for two dialysis stations and through contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

### **Ancillary and Support Services**

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 72-73, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1 and Exhibit I.1.

### **Coordination**

In Section I, pages 73-75, 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 information provided in Section I.2 and Exhibit I.2 as described above.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

- (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.

C

In Section K, page 77, the applicant states that the project involves renovating 3,167 square feet of existing space. Line drawings are provided in Exhibit C.1-2.

On pages 77-78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The renovation will be in the existing building space that has existing infrastructure.
- The location of the inpatient dialysis unit near the ICU will eliminate the need for duplicate space and support services.

On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The proposal involves the use of existing space and consolidation of services.
- The applicant states that providing inpatient dialysis services in Henderson County is expected to reduce the EMS transport and personal family support costs involved in traveling to another county.

On page 78, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **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.

(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

In section L, page 81, the applicant provides the historical payor mix during FY 2019 for the entire facility, as shown in the table below:

**Payor Mix 7/1/2019 to 6/30/2020**

<b>Payor Source</b>	<b>% of Patients</b>
Self-Pay	5.4%

Medicare	61.6%
Medicaid	8.1%
Insurance	21.9%
Other*	3.0%
<b>Total</b>	<b>100.0%</b>

\*Workers Comp and TRICARE

In Section L., page 82 the applicant provides the following comparison:

**Pardee Hospital**

	LAST FULL FY BEFORE SUBMISSION OF THE APPLICATION	
	PERCENTAGE OF TOTAL PATIENTS SERVED **	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	60.5%	52.0%
Male	39.5%	48.0%
Unknown	0.0%	0.0%
64 and Younger	37.3%	73.6%
65 and Older	62.7%	26.4%
American Indian	0.2%	0.7%
Asian	0.2%	1.3%
Black or African-American	2.7%	3.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	89.4%	92.5%
Other Race	2.4%	1.9%
Declined / Unavailable	5.1%	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 (Pardee Hospital) 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 83, the applicant states it has no such obligation.

In Section L, page 84, the applicant states that during the last 18 months immediately preceding the application deadline no patient civil rights access complaints have been filed against Pardee.

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

**Pardee Hospital Projected Payor Mix  
3<sup>rd</sup> Full FY 7/1/2025 to 6/30/2026**

<b>Payor Source</b>	<b>Percent of Total Patients</b>
Self-Pay	5.4%
Insurance*	21.9%
Medicare*	61.6%
Medicaid*	8.1%
Other^	3.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans

^ Workers Comp and TRICARE

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.4% of total services will be provided to self-pay patients, 61.6% to Medicare patients and 8.1% to Medicaid patients.

On page 84, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on FY 2020 payor mix for the entire facility.

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 86, 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 by renovating existing space for two dialysis stations and contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

In Section M, 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 in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 88 and Exhibit M.1 as described above.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 provide inpatient dialysis services by providing dedicated space for two dialysis stations and contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service.

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 33, 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, Polk, Rutherford, and Haywood. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 89, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to inpatient dialysis services as discussed in response to Section N.2 below.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 89, the applicant states:

*“...Pardee has reduced expenses by utilizing existing space and avoiding new construction and thus has proposed the most value-conscious alternative for the development of inpatient dialysis services.*

...

*In addition, the proposed project is expected to reduce the cost of EMS transfers outside Hendersonville County and the personal cost borne by patient families traveling to support inpatients admitted to hospitals outside Hendersonville County.*

...

*Further, Pardee, Hulu its relationship with the larger UNC health care system, benefits from significant saving measures through the consolidation of multiple services and large economies of scale.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 89-90, the applicant states:

*“Pardee believes that the project will promote safety and quality in the delivery of health care services. Pardee is dedicated to providing the highest quality care and as demonstrated below, is continually recognized for its commitment to delivering efficient, quality care. ...”*

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, pages 90-91, the applicant states:

*“Pardee historically has demonstrated a commitment to ensuring equitable access to all persons in need of medical care, regardless of race, creed, age, national origin, handicap, or ability to pay and will continue to provide such access upon completion of the proposed project.”*

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

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 22, 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 93, the applicant states that Pardee is the only facility located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 97, 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 Pardee. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care have occurred at Pardee. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at the facility, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective 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 by providing dedicated space for two dialysis stations and contractual agreements for the leasing of equipment and provision of supplies, staffing and medical management of the dialysis service. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.