

REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: November 22, 2022

Findings Date: November 22, 2022

Project Analyst: Donna Donihi

Co-Signer: Gloria C. Hale

Project ID #: B-12254-22

Facility: Margaret R. Pardee Memorial Hospital

FID #: 943324

County: Henderson

Applicant: Henderson County Hospital Corporation

Project: Cost overrun for Project ID #B-12066-21 (Develop inpatient dialysis services)

REVIEW CRITERIA

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

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

NA

Henderson County Hospital Corporation (hereinafter referred to as “the applicant” proposes a cost overrun (COR) for Project I.D. #B-12066-21, which approved the development of 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., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on August 24, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost

increase of \$109,842 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2022 SMFP,
- acquire any medical equipment for which there is a need determination in the 2022 SMFP, or
- offer a new institutional health service for which there are any applicable policies in the 2022 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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on August 24, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

In Section C.8, page 38, the applicant describes the project as follows:

The applicant states that this CON is filed as a cost-overrun due to changes required in the design and construction of the proposed project. In addition, the applicant states:

“In its communications with the Construction Section, Pardee learned that the clinical use and type of occupancy of the dialysis stations would require fire separation from the ICU. In other words, Pardee would not be able to convert the

vacant “wedge” space in the existing ICU to the dialysis stations, as previously planned, without a redesign that created the code-required firewall between the stations and the ICU. Based on this new information, Pardee proceeded to work with its architect and contractor to redesign the project and estimate the new costs. Cost estimates for the redesign of the wedge space within the ICU were estimated to be around \$800,000, nearly double the previously approved cost. Rather than move forward with that design alternative, Pardee decided to explore other physical alternatives that were less expensive.”

...

“...Pardee determined that renovating Rooms 101 and 102, directly across the hall from the ICU would be the best alternative.”

...

“The dialysis equipment room had already been planned for space occupied by a waiting area that is across the hall from the ICU. Rooms 101 and 102 are immediately adjacent to this space, making the renovation area more concise than with the previously approved design.”

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 2022 SMFP does not define a service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the services for inpatient dialysis services.

In Project I.D. #B-12066-21, the Agency determined the applicant had adequately identified the population to be served by the proposed project. The applicant proposes no changes in the current application which would affect that determination.

Analysis of Need

The following table compares the previously approved capital cost and the proposed capital cost for Margaret R. Pardee Memorial Hospital as reported by the applicant in Section Q, Form F.1(b):

Margaret R. Pardee Memorial Hospital – Previously Approved & Proposed Capital Cost			
	Previously Approved (B-12066-21)	Projected Changes to Capital Cost (B-12254-22)	New Total Projected Capital Cost
Construction/Renovation Contract	\$360,127	\$90,035	\$450,162
Architect / Engineering Fees	\$55,000	\$20,807	\$75,807
Non-Medical Equipment	\$1,000	-\$1,000	\$0
Consultant Fees	\$2,865	\$0	\$2,865
Total Capital Cost	\$418,992	\$109,842	\$528,834

In Section C page 38, the applicant explains why the proposed capital cost increase is necessary to develop the proposed project:

Prior to the original CON submission, the applicant planned on renovating a different space of the property and assessed the cost. The initial cost was reported to be \$418,992. After the CON was approved, they learned that the existing space cost would increase to \$800,000 due to the need to install a fire suppression wall. Since the increase in cost was significant, the applicant chose to then change the location of the project within the same building. The new location of the rooms is adjacent to the space that was previously proposed. A new cost estimate was devised by the contractor and architect based upon the new location and required work.

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

- The applicant adequately explains the reasons the additional costs are necessary to develop the proposed project and why the other location was not viable.
- The applicant provides supporting documentation for its statements in Exhibits C.8-1.
- The applicant does not propose to change the scope of services offered or to change the patients projected to be served by the proposed project.

Projected Utilization

In Project ID #B-12066-21, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. In this application, in Section C page 41, the applicant states it proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency's determination in that project.

Access to Medically Underserved Groups

In Project ID #B-12066-21, the Agency determined the applicant had adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

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 application for Project ID #B-12066-21 adequately identified the population to be served and there are no changes proposed in this application which would affect that determination.
- The applicant adequately explains why the proposed increase in projected capital cost is necessary to provide the population to be served with the services proposed in this application.
- Projected utilization was deemed reasonable and adequately supported in Project ID #B-12066-21 and there are no changes proposed in this application which would affect that determination.
- The application for Project ID #B-12066-21 adequately identified the extent to which all residents, including underserved groups, were likely to have access to the proposed services, and there are no changes proposed in this application which would affect that determination.

- (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

In Project I.D. #B-12066-21, Criterion (3a) was not applicable to that review. There are no changes proposed in this application which would affect that determination. 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 a cost overrun for Project I.D. # B-12066-21, which approved the development of inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on August 24, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to change in room remodel, increased construction costs and increased costs of goods and services since the original project was approved.

In Section E, page 48, 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 alternative's considered were:

- Cease development of the project – The applicant states that residents of Henderson County have historically been forced to travel to another hospital for inpatient care if they required dialysis services while hospitalized. Failure to develop this project would require Pardee patients to be transferred elsewhere for inpatient care. Therefore, this alternative is less effective.
- Develop the project in the same physical space originally proposed and submit a cost overrun application. - As discussed in Section C.8, developing the project in the location proposed in the previously approved application, with the required fire separation, would have nearly doubled the cost of the project. Therefore, this alternative is more costly.
- Develop the project at an alternate location within the hospital - Each of the other locations in the hospital considered by Pardee were not as effective as remaining near the ICU. Therefore, this alternative is less effective.

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

- The applicant does not propose to change the scope services or patients to be served from the previously approved Project I.D. #B-12066-21.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Henderson County Hospital Corporation (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. #B-12066-21. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop inpatient dialysis services through service agreements with Total Renal Care, Inc. and Mountain Kidney and Hypertension Associates, PA for no more than two dialysis stations.**
- 3. The approved combined capital expenditure for both Project ID # B-12066-21 and this project is \$528,834, an increase of \$109,842 over the capital expenditure of \$418,992 previously approved in Project I.D. #B-12066-21.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on March 1, 2023.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in this project and Project I.D. #B-12066-21's combined proposed**

capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

- 6. 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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

Capital and Working Capital Costs

A certificate of need was issued on August 24, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,8422 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

The following table compares the previously approved capital cost and the proposed capital cost for Margaret R. Pardee Memorial Hospital, as reported by the applicant in Section Q, Form F.1(b):

PREVIOUSLY APPROVED & PROPOSED CAPITAL COST			
	PREVIOUSLY APPROVED Capital Cost Project ID #B-12066- 21	PROJECTED CHANGES TO CAPITAL COST Project ID #B-12254- 22	NEW TOTAL PROJECTED CAPITAL COST
Construction/Renovation Contract	\$360,127	\$90,035	\$450,162
Architect / Engineering Fees	\$55,000	\$20,807	\$75,807
Non-Medical Equipment	\$1,000	-\$1,000	\$0
Consultant Fees	\$2,865	\$0	\$2,865
Total Capital Cost	\$418,992	\$109,842	\$528,834

In Section F.5, 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, Inc., 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.

In Section Q, Forms F.1a and F.1b., page 62, the applicant provides the assumptions used to project the capital costs. The applicant adequately demonstrates that the proposed increase in the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains the need for the different costs that make up the combined total increase in capital cost for this COR application and the explanations are reasonable and adequately supported.
- The applicant provides supporting documentation for the need for the proposed capital cost increase and the assumptions regarding the proposed capital cost increase in Exhibit C-8.

Availability of Funds

In Project I.D. #B-12066-21, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a combined total capital cost of \$528,834.

In Section F, page 59, the applicant states the increase in projected capital costs will be funded through the accumulated reserves of the applicant as shown in the table below.

Sources of Capital Cost Financing

TYPE	HENDERSON COUNTY HOSPITAL CORPORATION	TOTAL
Accumulated reserves or OE*	\$109,842	\$109,842
Total Financing	\$109,842	\$109,842

*OE = Owner's Equity

In Exhibit F.2-1 the applicant provides a letter dated August 15, 2022, 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, 2021, Pardee had current assets totaling \$226 million and cash and cash equivalents totaling \$42 million.

The applicant adequately demonstrates the availability of sufficient funds for the proposed increase in the projected capital cost based on the following:

- In Exhibit F.2-2, the applicant provides a copy of Henderson County Hospital Corporation's Financial Statements for the years ended June 30, 2021, and 2020 which shows it has sufficient funds for the project's capital needs.
- The applicant provides a letter from an appropriate company officer confirming the applicant's commitment to use that funding accordingly.

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.2b and F.3b, 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.

Pardee Memorial Hospital	1 st Full Year 7/1/2023- 6/30/2024	2 nd Full FY 7/1/2024- 6/30/2025	3 rd Full FY 7/1/2025- 6/30/2026
Total Procedures	887	887	887
Total Gross Revenues (Charges)	\$1,216,930,101	\$1,259,705,194	\$1,303,983,831
Total Net Revenue	\$354,038,998	\$366,483,469	\$379,365,363
Average Net Revenue per procedure	\$339,142	\$413,172	\$427,695
Total Operating Expenses (Costs)	\$349,977,910	\$360,950,382	\$372,268,696
Average Operating Expense per procedure	\$394,563	\$406,934	\$419,694
Net Income	\$4,061,088	\$5,533,087	\$7,096,667

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 increased capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the increased capital cost of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on March 12, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a total combined capital

cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the service area for inpatient dialysis services. The applicant indicates there are no changes to the service area from the prior project.

In Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated that the project would not result in unnecessary duplication of existing or approved services in the service area. The applicant proposes no changes in the current application which would affect that determination.

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 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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

In Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated the availability of sufficient health manpower and management personnel to provide the proposed services. The applicant proposes no changes in the current application which would affect that determination.

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 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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient (IP) dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

In Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated the availability of the ancillary and support services necessary to provide the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system. The applicant proposes no changes in the current application which would affect that determination.

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 stated above.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration.
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO.
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on August 24, 2021, for Project ID # B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

The following table compares the previously approved capital cost and the proposed capital cost for Margaret R. Pardee Memorial Hospital, as reported by the applicant in Section Q, Form F.1(b):

PREVIOUSLY APPROVED & PROPOSED CAPITAL COST			
	PREVIOUSLY APPROVED Capital Cost Project ID # B-12066- 21	PROJECTED CHANGES TO CAPITAL COST Project ID #B-12254- 22	NEW TOTAL PROJECTED CAPITAL COST
Construction/Renovation Contract	\$360,127	\$90,035	\$450,162
Architect / Engineering Fees	\$55,000	\$20,807	\$75,807
Non-Medical Equipment	\$1,000	-\$1,000	\$0
Consultant Fees	\$2,865	\$0	\$2,865
Total Capital Cost	\$418,992	\$109,842	\$528,834

In Section K.5, pages 72-73, the applicant states that the project involves renovation of 1,120 square feet of existing space which is less than the 3,167 square feet of space it had proposed to renovate in Project I.D. #B-12066-21. In Section C.8, page 39, the applicant states this COR application follows a mid-renovation building inspection that revealed the previously planned space would require a code-required firewall between the dialysis stations and the required re-design would nearly double the previously approved cost. The applicant identified space in rooms 101 and 102, across the hall from the ICU, that would be appropriate and much less costly since it would not require a firewall. Line drawings are provided in Exhibit C.8-(2).

In Sections C.8., pages 39-40, and E.2, page 48, 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 which will not require the fire separation that the original wedge space required. Thus, it will be less expensive to renovate.
- The location of the inpatient dialysis unit is across the hall from the ICU which will eliminate the need for duplicate space and support services.

In Section K.5, page 73, 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 73, 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 all the reasons described 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 Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated 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. The applicant proposes no changes in the current application which would affect that determination.

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.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or

access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant.

C

In Project I.D. #B-12066-21, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

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 Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated 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. The applicant proposes no changes in the current application which would affect that determination.

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.

- (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 Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect that determination.

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.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated that the proposed health services would accommodate the clinical needs of health professionals training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

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 a cost overrun for Project I.D. #B-12066-21, which approved the development of inpatient dialysis services at Margaret R. Pardee Memorial Hospital by providing dedicated space for two dialysis stations and through service agreements with Total Renal Care, Inc., a subsidiary of DaVita, Inc. for the leasing of equipment, provision of supplies and staffing and Mountain Kidney & Hypertension Associates, P.A. for medical management of the dialysis service.

A certificate of need was issued on March 12, 2021, for Project I.D. #B-12066-21 and authorized a capital cost of \$418,992. The current application proposes a capital cost increase of \$109,842 over the previously approved capital cost for a total combined capital cost of \$528,834. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define a service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the service area for inpatient dialysis, nor are there any applicable rules adopted by the Department that define the services for inpatient dialysis services.

In Project I.D. #B-12066-21, the Agency determined the applicant adequately demonstrated the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competitions would have a positive impact upon the cost effectiveness, quality, and access to the services proposed. The applicant proposes no changes in the current application which would affect that determination.

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.

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

C

In Section Q, Form, O, the applicant identifies Pardee as the only facility located in North Carolina owned, operated or managed by the applicant or a related entity. However, the applicant does not own or operate any facilities that provide dialysis services in North Carolina.

In Section O, pages 87-88, 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.