

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 25, 2022

Findings Date: April 25, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala Mitchell

Project ID #: G-12190-22

Facility: Highland Oaks Dialysis Center of Wake Forest University

FID #: 200885

County: Mecklenburg

Applicant: Wake Forest University Health Sciences

Project: Cost overrun for Project ID# G-11989-20 (develop a new PD training facility)

### 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.

C

Wake Forest University Health Sciences (hereinafter referred to as “the applicant”) proposes a cost overrun (COR) for Project I.D. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. 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
- offer a new institutional health service for which there are any policies in the 2022 SMFP

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

- (2) Repealed effective July 1, 1987.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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. 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 24, the applicant describes the project as follows:

*“This CON is filed due to a cost-overrun resulting from a mid-renovation building inspection. The building inspector required upgrades to the wiring and plumbing that were previously unknown as well as other unanticipated plant improvements. The cost of the improvements escalated due to the pandemic and supply and demand for goods.”*

### **Patient Origin**

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility is Forsyth County. Facilities may serve residents of counties not included in their service area.

In Project I.D. #G-11989-20, the Agency determined the applicant had adequately identified the population to be served by the proposed project at that time. The applicant proposes no

changes in the current application which would change the projected patient origin from the previous project, or which would otherwise affect the Agency's determination in that project.

### **Analysis of Need**

The following table compares the previously approved capital cost and the proposed capital cost for Highland Oaks Dialysis Center of Wake Forest University, as reported by the applicant in Section Q, Form F.1(b):

<b>HIGHLAND OAKS DIALYSIS CENTER – PREVIOUSLY APPROVED &amp; PROPOSED CAPITAL COST</b>			
	<b>PREVIOUSLY APPROVED (G-11989-20)</b>	<b>PROJECTED CHANGES TO CAPITAL COST (G-12190-22)</b>	<b>NEW TOTAL PROJECTED CAPITAL COST</b>
Construction/Renovation Contract	\$287,890	\$219,092	\$506,982
Medical Equipment	\$100,110	\$0	\$100,110
<b>Total Capital Cost</b>	<b>\$388,000</b>	<b>\$219,092</b>	<b>\$607,092</b>

In Section Q, Form F.1(b), page 62, the applicant explains why the proposed capital cost increase is necessary to develop the proposed project:

*“Prior to the original CON submission, the contractor did a walk-through of the property to assess the cost to renovate it. That initial cost was reported to be \$287,890. After the CON was approved, the contractor and architect updated the original estimate based upon the required work and the estimated cost of goods and services at that time. ...*

*Work on the project continued and during a mid-renovation inspection, the building inspector determined that a vast amount of additional work would be required to the plumbing, electrical, and HVAC to bring the location up to code for a dialysis unit.”*

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.
- The applicant provides supporting documentation for its statements in Exhibits C-8(c).
- 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 I.D. #G-11989-20, 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 24, 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**

In Project I.D. #G-11989-20, 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 I.D. #G-11989-20 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 I.D. #G-11989-20 and there are no changes proposed in this application which would affect that determination.
- The application for Project I.D. #G-11989-20 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. #G-11989-20, 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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. 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 E, page 30, the applicant states there are no alternatives other than the alternative proposed in this application to meet the need. The applicant states, *“This CON is filed due to a cost-overrun resulting from a mid-renovation building inspection. The building inspector required upgrades to the wiring and plumbing that were previously unknown as well as other unanticipated plant improvements. The cost of the improvements escalated due to the pandemic and supply and demand for goods to more than 115% of the originally approved project cost, requiring this CON.”*

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. #G-11989-20.
- 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. Wake Forest University Health Sciences (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project I.D. #G-11989-20. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
  - 2. The total combined capital expenditure for both projects is \$607,092, an increase of \$219,092 over the capital expenditure of \$388,000 previously approved in Project I.D. #G-11989-20.**
  - 3. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on September 1, 2022. The second progress report shall be due on December 1, 2022 and so forth.**
  - 4. The certificate holder shall not acquire as part of this project any equipment that is not included in this project's and Project I.D. #G-11989-20's combined 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 a cost overrun for Project I.D. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

### **Capital and Working Capital Costs**

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. 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 Highland Oaks Dialysis Center of Wake Forest University, as reported by the applicant in Section Q, Form F.1(b):

<b>HIGHLAND OAKS DIALYSIS CENTER – PREVIOUSLY APPROVED &amp; PROPOSED CAPITAL COST</b>			
	<b>PREVIOUSLY APPROVED (G-11989-20)</b>	<b>PROJECTED CHANGES TO CAPITAL COST (G-12190-22)</b>	<b>NEW TOTAL PROJECTED CAPITAL COST</b>
Construction/Renovation Contract	\$287,890	\$219,092	\$506,982
Medical Equipment	\$100,110	\$0	\$100,110
<b>Total Capital Cost</b>	<b>\$388,000</b>	<b>\$219,092</b>	<b>\$607,092</b>

In Section F.5, page 37, the applicant states there is no change to the previously approved working capital. In Project I.D. #G-11989-20, the Agency determined the applicant had demonstrated the projected capital and working capital costs were based on reasonable and adequately supported assumptions. There are no changes proposed in this application which would affect that determination.

In Section Q, page 62, the applicant explains the need for the proposed increase in projected capital costs. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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 previously demonstrated to the Agency in Project I.D. #G-11989-20 that the projected capital costs were based on reasonable and adequately supported assumptions, and there are no changes proposed in this application which would affect that determination.
- 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(c).

### **Availability of Funds**

In Project I.D. #G-11989-20, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital needs of the project in the amount of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a combined total capital cost of \$607,092.

In Section F, page 36, the applicant states the increase in projected capital costs will be funded through the accumulated reserves of the applicant.

Exhibit F-5 contains a letter dated February 15, 2021 from the Chief Executive Officer of Atrium Health Wake Forest Baptist, the ultimate parent company of Highland Oaks Dialysis Center, committing the funds necessary for the projected increase in capital costs.

Exhibit F-5(2)(c) contains the Consolidated Financial Statements for Wake Forest University. As of June 30, 2021, Wake Forest University had \$2 billion in total assets and \$177 million in cash and cash equivalents.

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

- The applicant provides a letter from an appropriate company officer confirming the applicant's commitment to use that funding accordingly.
- The applicant provides adequate documentation of the availability of sufficient funds to for the project's capital needs.

### **Financial Feasibility**

In Project I.D. #G-11989-20, the applicant projected revenues would exceed operating expenses during each of the first three full fiscal years of operation following project completion. The Agency determined Project I.D. #G-11989-20 demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges. The applicant projects no changes in this application to those projections and no changes which would otherwise affect the Agency's previous 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 applicant adequately demonstrates that the increased capital cost is 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 and working capital costs of the proposal for all the reasons described above.
  - The applicant projects no changes to the assumptions and methodology in Project I.D. #G-11989-20 which demonstrated sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal was 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 a cost overrun for Project I.D. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility is Forsyth County. Facilities may serve residents of counties not included in their service area.

In Project I.D. #G-11989-20, 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 the Agency’s determination in that project.

### **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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Project I.D. #G-11989-20, 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 the Agency's determination in that project.

### **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 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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

In Project I.D. #G-11989-20, 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 the Agency's determination in that project.

### **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:
- would be available under a contract of at least 5 years duration;
  - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - would cost no more than if the services were provided by the HMO; and
  - 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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. 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 Highland Oaks Dialysis Center of Wake Forest University, as reported by the applicant in Section Q, Form F.1(b):

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Construction/Renovation Contract	\$287,890	\$219,092	\$506,982
Medical Equipment	\$100,110	\$0	\$100,110
<b>Total Capital Cost</b>	<b>\$388,000</b>	<b>\$219,092</b>	<b>\$607,092</b>

In Section K.5, page 49, the applicant states that the project involves renovation of existing space as previously approved in Project ID#G-11890-20. The applicant states this COR application follows a mid-renovation building inspection that revealed upgrades to wiring and plumbing are necessary and were unknown at the time the originally approved application was filed. Line drawings are provided in Exhibit K-5(2).

In Sections K.5 and Exhibit C-8(c), the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on pages 49-51 of the application.

In Section K.5, 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 information and representations made by the applicant on pages 49-51 of the application.

On page 51, 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. #G-11989-20, 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 the Agency's determination in that project.

### **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. #G-11989-20, 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. #G-11989-20, the Agency determined the applicant adequately demonstrated the elderly and the medically underserved groups identified in this subdivision would be served by the applicant's proposed services and the extent to which each of these groups would be expected to utilize the proposed services. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

**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. #G-11989-20, 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 the Agency's determination in that project.

**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. #G-11989-20, the Agency determined the applicant adequately demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect the Agency's determination in that project.

**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. #G-11989-20, which approved the development of a new dialysis facility consisting of five (5) peritoneal dialysis training rooms dedicated to providing peritoneal dialysis training and support services.

A certificate of need was issued on March 12, 2021 for Project I.D. #G-11989-20 and authorized a capital cost of \$388,000. The current application proposes a capital cost increase of \$219,092 over the previously approved capital cost for a total combined capital cost of \$607,092. The COR application is necessary due to increased construction costs and increased costs of goods and services since the original project was approved.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility is Forsyth County. Facilities may serve residents of counties not included in their service area.

In Project I.D. #G-11989-20, 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 competition 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 the Agency’s determination in that project.

**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 the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 20 of this type of facility located in North Carolina.



In Section O, page 59, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in four of these facilities. The applicant states that all the problems have been corrected and all facilities are back in compliance. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in four of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all the applicant's facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

In Project I.D. #G-11989-20, the Agency determined the application was conforming to all applicable Criteria and Standards for End-Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, which were in effect at that time. The applicant proposes no changes in this application which would affect that determination. Therefore, there are no Criteria and Standards applicable to this review.