

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 16, 2022

Findings Date: May 16, 2022

Project Analyst: Kim Meymandi

Co-Signer: Micheala Mitchell

Project ID #: J-12181-22

Facility: Fresenius Medical Care Rock Quarry

FID #: 160555

County: Wake

Applicant(s): Fresenius Medical Care Rock Quarry, LLC

Project: Cost overrun for Project ID# J-11271-16 (develop a new 10-station dialysis facility)

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.

C

Fresenius Medical Care Rock Quarry, LLC (hereinafter referred to as “the applicant” or “FMCRQ”), proposes a cost overrun (COR) for Project ID# J-11271-16 (develop a new 10-station dialysis facility by relocating six stations from FMC New Hope Dialysis (FMC New Hope) and four stations from Wake Dialysis Clinic (WDC). This application proposes no material change in scope from the originally approved project.

Need Determination

The original project did not involve a need determination in the 2016 State Medical Facilities Plan (SMFP) applicable to Project ID# J-11271-16 and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire

equipment for which there is a need determination in the 2022 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

Project ID# J-11271-16 was found to be consistent with *Policy ESRD-2: Relocation of Dialysis Stations* as published in the 2016 SMFP. The applicant proposes no changes in the current application which would affect that determination. There are no policies in the 2022 SMFP that are applicable to this review.

Conclusion

In Project ID# J-11271-16, the applicant was previously approved to relocate 10 stations pursuant to Policy ESRD-2, for a total of 10 stations at FMCRQ upon project completion. In the original review, the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination. Therefore, the application is conforming to this criterion.

- (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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

A certificate of need was issued on May 9, 2017 for Project ID# J-11271-16 and authorized a capital cost of \$1,608,166. The current application proposes a capital cost increase of \$1,136,118 over the previously approved capital cost for a total combined capital cost of \$2,744,284. The cost overrun application is necessary due to increased construction, materials and equipment costs due to current market conditions compared to the estimated costs in 2016 when the original application was submitted. The application proposes no material change in scope from the originally approved project.

Patient Origin

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

In Project ID# J-11271-16, the Agency determined the applicant had adequately identified the projected patient origin for the facility. The applicant proposes no changes in the current application which would affect that determination.

Analysis of Need

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project ID# J-11271-16, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Fresenius Medical Care Rock Quarry – Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11271-16)	New Total Projected Capital Cost	Projected Changes to Capital Cost (J-12181-22)
Construction/Renovation Contract(s)	\$1,040,955	\$1,629,619	\$588,664
Architect/Engineering Fees	\$93,686	\$163,125	\$69,439
Non-Medical Equipment	\$210,000	\$275,000	\$65,000
Furniture	\$206,793	\$245,991	\$39,198
Other (Construction Contingency)	\$56,732	\$181,069	\$124,337
Other (Project Contingency)	\$0	\$249,480	\$249,480
Total Capital Cost	\$1,608,166	\$2,744,284	\$1,136,118

In Section C, page 33, the applicant explains why it believes the proposed increase in capital cost is necessary to develop the proposed project:

- Increased Construction Contract Costs: Following the issuance of the Certificate of Need for Project ID# J-11271-16, delays in the planning and zoning approvals, inflation and the COVID-19 pandemic caused the cost of construction and materials to increase.
- Increased Architect & Engineering Fees: The applicant states that these fees have increased due to the increase in construction costs upon which they are based.
- Increased Non-Medical Equipment and Furniture: The applicant states these expenses have increased due to delays in project development.
- Increased Construction and Project Contingency: The applicant states both of these have increased due to the increased cost of materials resulting from the delays in project development.

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

- The applicant adequately explains the reasons additional costs are necessary to develop the proposed project.
- 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# J-11271-16, the Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. The applicant

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

The application for Project ID# J-11271-16 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
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The application for Project ID# J-11271-16 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# J-11271-16 and there are no changes proposed in this application which would affect that determination.
- The application for Project ID# J-11271-16 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.

C

The applicant proposes a cost overrun for Project ID# J-11271-16. That application adequately demonstrated that the needs of the population currently using the services to be relocated would

be adequately met and the project would not adversely impact the ability of underserved groups to access these services. The applicant does not propose changes in this application which would affect that determination.

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.

- (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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

In Section E, page 38, 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:

- *Not developing FMCRQ* – the applicant states this alternative is less effective because it would prevent patients from receiving much needed treatment within close proximity to their homes.
- *Develop FMCRQ at a new location* – the applicant states this alternative would result in patients having to commute a further distance for treatment.

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 of the previously approved Project ID# J-11271-16.
- 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
- Information publicly available during the review and used by the Agency

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

- 1. Fresenius Medical Care Rock Quarry, LLC (hereinafter certificate holder) shall materially comply with the representations in this application, and the representations in Project ID# J-11271-16. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop a new 10-station dialysis facility by relocating no more than six dialysis stations from FMC New Hope Dialysis and no more than four dialysis stations from Wake Dialysis Clinic.**
- 3. Upon completion of the project, the certificate holder shall take the necessary steps to decertify six in-center stations at FMC New Hope Dialysis and decertify four in-center stations at Wake Dialysis Clinic.**
- 4. The approved combined capital expenditure for both Project ID# J-11271-16 and this project is \$2,744,284, an increase of \$1,136,118 over the previously approved capital expenditure of \$1,608,166 in Project ID# J-11271-16.**
- 5. 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 November 1, 2022.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project ID #J-11271-16, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

Fresenius Medical Care Rock Quarry – Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11271-16)	New Total Projected Capital Cost	Projected Changes to Capital Cost (J-12181-22)
Construction/Renovation Contract(s)	\$1,040,955	\$1,629,619	\$588,664
Architect/Engineering Fees	\$93,686	\$163,125	\$69,439
Non-Medical Equipment	\$210,000	\$275,000	\$65,000
Furniture	\$206,793	\$245,991	\$39,198
Other (Construction Contingency)	\$56,732	\$181,069	\$124,337
Other (Project Contingency)	\$0	\$249,480	\$249,480
Total Capital Cost	\$1,608,166	\$2,744,284	\$1,136,118

In Section C, page 33, and immediately following Form F.1b 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 following:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant has knowledge and experience in calculating costs related to the construction of ESRD facilities.

In Project ID# J-11271-16, the applicant stated start-up costs will be \$149,773 and initial operating expenses will be \$1,255,503 for a total working capital of \$1,405,276. The Agency determined Project ID# J-11271-16 was conforming to this criterion. In Section F, pages 45-46, the applicant states there are no changes to the start-up expenses or initial operating expenses approved in Project ID# J-11271-16.

Availability of Funds

In Project ID # J-11271-16, the Agency determined that the applicant adequately demonstrated it had sufficient funds available for the capital and working capital needs of the project in the amount of \$1,608,166 and \$1,405,276, respectively. The current application proposes a capital cost increase of \$1,136,118 over the previously approved capital cost.

In Section F.5, page 44, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing	
Type	Fresenius Medical Care Rock Quarry, LLC
Loans	\$0
Accumulated reserves or OE *	\$1,136,118
Bonds	\$0
Other	\$0
Total Financing	\$1,136,118

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F-2 contains a letter dated February 15, 2022, from Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., parent company to Bio-Medical Applications of North Carolina, Inc., authorizing the use of accumulated reserves for the capital needs of the project.
- The applicant documents that it has adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

In Project ID# J-11271-16, the applicant projected revenues would exceed operating expenses during the first two operating years of the project following project completion. The Agency determined Project ID# J-11271-16 had demonstrated the financial feasibility of the proposal was based on reasonable projections of costs and charges. The applicant is not proposing any changes that would affect that determination.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working 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 capital and working capital needs 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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

Project ID #J-11271-16 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

The application for Project ID #J-11271-16 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed services and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

The application for Project ID #J-11271-16 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

- (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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

In Section K, page 57, the applicant states that the project involves constructing a total of 7,250 square feet of new space which is more than what was proposed in Project ID# J-11271-16. The applicant states that the square footage amount proposed in Project ID# J-11271-16 only included the square footage for the treatment area because this was what was requested at the time of the original application. The current COR proposal provides a total square footage amount for the entire facility and includes the treatment area and other non-treatment area. The applicant provides line drawings in Exhibit K-2.

A certificate of need was issued on May 9, 2017, for Project I.D. #J-8618-10 and authorized a capital cost of \$1,608,166. The current application proposes a capital cost increase of \$1,136,118 over the previously approved capital cost for a total combined capital cost of

\$2,744,284. The cost overrun application is necessary due to increased construction, architect and engineering fees, equipment costs and construction and project contingency fees due to current market conditions compared to the estimated costs in 2016 when the original application was submitted. This application proposes no material change in scope from the originally approved project.

The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

Fresenius Medical Care Rock Quarry – Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11271-16)	New Total Projected Capital Cost	Projected Changes to Capital Cost (J-12181-22)
Construction/Renovation Contract(s)	\$1,040,955	\$1,629,619	\$588,664
Architect/Engineering Fees	\$93,686	\$163,125	\$69,439
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Furniture	\$206,793	\$245,991	\$39,198
Other (Construction Contingency)	\$56,732	\$181,069	\$124,337
Other (Project Contingency)	\$0	\$249,480	\$249,480
Total Capital Cost	\$1,608,166	\$2,744,284	\$1,136,118

The discussion regarding the need for the increased capital expenditure found in Criterion (3) is incorporated herein by reference. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. In Project ID# J-11271-16, the applicant adequately demonstrated that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services and no changes are proposed in this application which would affect that determination.

On pages 58-59, the applicant identifies describes 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

Project ID# J-11271-16 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Project ID# J-11271-16 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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

Project ID# J-11271-16 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Project ID# J-11271-16 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

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 a COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

The application for Project ID# J-11271-16 adequately demonstrated that the proposed health services will accommodate the clinical needs of health professional 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 COR for Project ID# J-11271-16 (develop a new 10-station dialysis facility).

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

The applicant proposes a cost overrun for Project ID# J-11271-16. That application adequately demonstrated the expected effects of the proposed services on competition and how any enhanced competition would have a positive impact on cost-effectiveness, quality, and access to the services proposed. The applicant proposes no changes in this application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, pages 87-90, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.4, page 70, the applicant states that, during the 18 months immediately preceding submission of the application, incidents of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all related facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

In Project ID #J-11271-16, 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, and the applicant proposes no changes in the current application which would affect that determination. Consequently, the application is conforming to the performance standards in this rule.