

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 4, 2019

Findings Date: October 4, 2019

Project Analyst: Julie M. Faenza

Team Leader: Fatimah Wilson

Project ID #: J-11758-19

Facility: Hope Valley Dialysis

FID #: 180368

County: Durham

Applicant: Renal Treatment Centers – Mid-Atlantic, Inc.

Project: Cost overrun for Project I.D. #J-11544-18 (develop a new 10-station dialysis facility)

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 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

Renal Treatment Centers – Mid-Atlantic, Inc. (referred to as RTC or “the applicant”) proposes a cost overrun for Project I.D. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

A certificate of need was issued on November 27, 2018 for Project I.D. #J-11544-18 and authorized a capital cost of \$2,275,057. The current application proposes a capital cost increase of \$571,881 over the previously approved capital cost for a total combined capital cost of \$2,846,938. The cost overrun application is necessary due to increased costs for development as the result of a site change from the location originally proposed in Project I.D. #J-11544-18. There is no material change in scope from the originally approved project in this application.

### Need Determination

There were no need determinations in the 2018 State Medical Facilities Plan (SMFP) applicable to Project I.D. #J-11544-18 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 2019 SMFP. Therefore, there are no need determinations applicable to this review.

### Policies

Project I.D. #J-11544-18 was found to be consistent with Policy ESRD-2 and Policy GEN-4 as published in the 2018 SMFP. The applicant proposes no changes in the current application which would affect that determination. There are no policies in the 2019 SMFP that are applicable to this review.

### Conclusion

Project I.D. #J-11544-18 was previously approved to develop a new 10-station dialysis facility. 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, handicapped persons, 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. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

A certificate of need was issued on November 27, 2018 for Project I.D. #J-11544-18, to develop Hope Valley Dialysis (HVD), and authorized a capital cost of \$2,275,057. The current application proposes a capital cost increase of \$571,881 over the previously approved capital cost for a total combined capital cost of \$2,846,938. The cost overrun application is necessary due to increased costs for development as the result of a site change from the location originally proposed in Project I.D. #J-11544-18. There is no material change in scope from the originally approved project in this application.

In Project I.D. #J-11544-18, the applicant proposed to develop HVD on a parcel of land, identified in the application by its PIN number, near Fayetteville Road in Durham. On April

12, 2019, the Agency determined that the applicant’s request to change the site of the proposed facility from the previously approved site to 101 West Woodcroft Parkway in Durham was in material compliance with the representations made in the application for Project I.D. #J-11544-18. The applicant stated in its request that the new site was three miles from the primary site approved in Project I.D. #J-11544-18.

In Section C, page 22, the applicant states:

*“The two sites identified in the CON application for Project ID# J-11544-18 were not available and/or suitable for development once the Certificate of Need was issued. A new site was selected and Material Compliance approval for this change of site was approved by the Agency.... After completing a new site survey and receiving bids for developing the project on the new site, the project manager reported that the capital expenditure would be greater than in the previously approved application.”*

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

The application for Project I.D. #J-11544-18 adequately identified the current and projected patient origin for the facility at the time of the application. No changes are proposed in this application which would affect that determination.

Analysis of Need

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

<b>HVD – Previously Approved and Proposed Capital Cost</b>			
	<b>Previously Approved Cost (J-11544-18)</b>	<b>Additional Costs Projected (J-11758-19)</b>	<b>Total</b>
Site Preparation	\$115,680	\$67,586	\$183,266
Construction/Renovation Contract(s)	\$1,448,303	\$470,097	\$1,918,400
Architect/Engineering Fees	\$123,000	\$18,804	\$141,804
Medical Equipment	\$165,360	\$0	\$165,360
Non-Medical Equipment	\$285,182	\$6,943	\$292,125
Furniture	\$103,910	\$0	\$103,910
Interest During Construction	\$33,622	\$8,451	\$42,073
<b>Total Capital Costs</b>	<b>\$2,275,057</b>	<b>\$571,881</b>	<b>\$2,846,938</b>

In Section C, page 22, the applicant states the increase in capital expenditure is necessary due to increased costs for development as the result of a site change from the location originally proposed in Project I.D. #J-11544-18.

The applicant's representations regarding the need for an additional capital expenditure to develop the proposed facility are reasonable and adequately supported for the following reasons:

- The applicant adequately explains the necessity of the increased capital expenditure to develop the project as approved in Project I.D. #J-11544-18.
- 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

The application for Project I.D. #J-11544-18 adequately demonstrated projected utilization was based on reasonable and adequately supported assumptions regarding continued growth in the patient population that utilized the services proposed in the application. The applicant proposes no changes in the current application which would affect that determination.

#### Access

The application for Project I.D. #J-11544-18 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 I.D. #J-11544-18 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 increased capital expenditure 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. #J-11544-18 and there are no changes proposed in this application which would affect that determination.
  - The application for Project I.D. #J-11544-18 adequately identified the extent to which all residents, including underserved groups, would have access to the proposed services (payer mix), 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes a cost overrun for Project I.D. #J-11544-18. 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 cost overrun for Project I.D. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

In Section E, page 25, the applicant states the only other alternative to the one proposed in this application was to maintain the status quo, and states it was not considered an effective

alternative because the additional capital costs are required to develop the facility approved in Project I.D. #J-11544-18.

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

- The applicant proposes to develop the project as approved in Project I.D. #J-11544-18.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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. Renal Treatment Centers – Mid-Atlantic, Inc. shall materially comply with the representations in this application and representations in Project I.D. #J-11544-18. Where representations conflict, Renal Treatment Centers – Mid-Atlantic, Inc. shall materially comply with the last made representation.**
- 2. Pursuant to Policy ESRD-2, Renal Treatment Centers - Mid-Atlantic, Inc. shall develop a new kidney disease treatment center to be known as Hope Valley Dialysis by relocating no more than six dialysis stations from Southpoint Dialysis and no more than four dialysis stations from Durham West Dialysis.**
- 3. The total combined capital expenditure for both projects is \$2,846,938, an increase of \$571,881 over the capital expenditure of \$2,275,057 previously approved in Project I.D. #J-11544-18.**
- 4. Renal Treatment Centers – Mid-Atlantic, Inc. shall take the necessary steps to decertify six dialysis stations at Southpoint Dialysis for a total of no more than 16 dialysis stations at Southpoint Dialysis upon completion of this project and Project I.D. #J-11600-18 (add six stations).**

5. Upon completion of this project, Renal Treatment Centers - Mid-Atlantic, Inc. shall take the necessary steps to decertify four dialysis stations at Durham West Dialysis for a total of no more than 21 dialysis stations at Durham West Dialysis.
  6. Renal Treatment Centers - Mid-Atlantic, Inc. shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any isolation stations.
  7. Renal Treatment Centers - Mid-Atlantic, Inc. 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. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

Capital and Working Capital Costs

The applicant projects the total capital cost to develop the new 10-station dialysis facility approved in Project I.D. #J-11544-18 will be \$2,846,938, an increase of \$571,881 over the previously approved capital expenditure of \$2,275,057. The applicant states the increase in capital costs is necessary due to increased costs for development as the result of a site change from the location originally proposed in Project I.D. #J-11544-18. The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

<b>HVD – Previously Approved and Proposed Capital Cost</b>			
	<b>Previously Approved Cost (J-11544-18)</b>	<b>Additional Costs Projected (J-11758-19)</b>	<b>Total</b>
Site Preparation	\$115,680	\$67,586	\$183,266
Construction/Renovation Contract(s)	\$1,448,303	\$470,097	\$1,918,400
Architect/Engineering Fees	\$123,000	\$18,804	\$141,804
Medical Equipment	\$165,360	\$0	\$165,360
Non-Medical Equipment	\$285,182	\$6,943	\$292,125
Furniture	\$103,910	\$0	\$103,910
Interest During Construction	\$33,622	\$8,451	\$42,073
<b>Total Capital Costs</b>	<b>\$2,275,057</b>	<b>\$571,881</b>	<b>\$2,846,938</b>

In Section F, pages 29-30, the applicant does not propose any changes to the start-up expenses or initial operating expenses approved in Project I.D. #J-11544-18.

### Availability of Funds

In Section F, page 27, the applicant states it will fund the entire capital expenditure to develop new facility with accumulated reserves. In Exhibit F, the applicant provides a letter from the Chief Accounting Officer of DaVita, Inc. (DaVita), the parent company of the applicant, which states DaVita will make accumulated reserves in the amount of the proposed capital expenditure available to develop HVD, and further states DaVita will make available any other funds necessary to develop the project. Exhibit F-2 contains DaVita's Form 10-K for the year ending December 31, 2018. The Form 10-K indicates that as of December 31, 2018, DaVita had adequate assets to fund the proposed capital expenditure. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

### Financial Feasibility

In Project I.D. #J-11544-18, the applicant projected revenues would exceed operating expenses in the first two full fiscal years of operation following project completion, and the applicant projects no changes in this application to those projections.

### 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 the increased capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the increased capital needs of the proposal.
- The applicant projects no changes to the assumptions and methodology in Project I.D. #J-11544-18 which demonstrated projected capital costs were reasonable and adequately supported and which adequately demonstrated the availability of sufficient funds for the working capital costs.
- The applicant projects no changes to the assumptions and methodology in Project I.D. #J-11544-18 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. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

Project I.D. #J-11544-18 adequately demonstrated that the project would not result in unnecessary duplication of existing or approved services in the service area and no changes are proposed 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.

- (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. #J-11544-18. That application adequately demonstrated the availability of sufficient 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 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.

- (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

Project I.D. #J-11544-18 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.

The application for Project I.D. #J-11544-18 was found 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.

- (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. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

A certificate of need was issued on November 27, 2018 for Project I.D. #J-11544-18 and authorized a capital cost of \$2,275,057. The current application proposes a capital cost increase of \$571,881 over the previously approved capital cost for a total combined capital cost of \$2,846,938. The cost overrun application is necessary due to increased costs for development as the result of a site change from the originally proposed location. There is no material change in scope from the originally approved project in this application.

In Project I.D. #J-11544-18, the applicant proposed to develop HVD on a parcel of land, identified in the application by its PIN number, near Fayetteville Road in Durham. On April 12, 2019, the Agency determined that the applicant's request to change the site of the proposed facility from the previously approved site to 101 West Woodcroft Parkway in Durham was in material compliance with the representations made in the application for Project I.D. #J-11544-18. The applicant stated in its request that the new site was three miles from the primary site approved in Project I.D. #J-11544-18.

In Section C, page 22, the applicant states:

*“The two sites identified in the CON application for Project ID# J-11544-18 were not available and/or suitable for development once the Certificate of Need was issued. A new site was selected and Material Compliance approval for this change of site was approved by the Agency.... After completing a new site survey and receiving bids for developing the project on the new site, the project manager reported that the capital expenditure would be greater than in the previously approved application.”*

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

<b>HVD – Previously Approved and Proposed Capital Cost</b>			
	<b>Previously Approved Cost (J-11544-18)</b>	<b>Additional Costs Projected (J-11758-19)</b>	<b>Total</b>
Site Preparation	\$115,680	\$67,586	\$183,266
Construction/Renovation Contract(s)	\$1,448,303	\$470,097	\$1,918,400
Architect/Engineering Fees	\$123,000	\$18,804	\$141,804
Medical Equipment	\$165,360	\$0	\$165,360
Non-Medical Equipment	\$285,182	\$6,943	\$292,125
Furniture	\$103,910	\$0	\$103,910
Interest During Construction	\$33,622	\$8,451	\$42,073
<b>Total Capital Costs</b>	<b>\$2,275,057</b>	<b>\$571,881</b>	<b>\$2,846,938</b>

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. The applicant adequately demonstrates 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.

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.

- (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 handicapped persons, 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 I.D. #J-11544-18 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 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.

- (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

Project I.D. #J-11544-18 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 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.

- (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 I.D. #J-11544-18 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 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.

- (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 I.D. #J-11544-18 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 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.

- (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

Project I.D. #J-11544-18 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 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.

- (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. #J-11544-18 (develop a new 10-station facility by relocating four stations from Durham West Dialysis and six stations from Southpoint Dialysis).

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

The applicant proposes a cost overrun for Project I.D. #J-11544-18. 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 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.

- (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

On Form A in Section Q, 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 107 dialysis facilities located in North Carolina.

In Section O, pages 43-44, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were incidents related to quality of care resulting in an immediate jeopardy violation that occurred in two of these facilities. The applicant states both facilities are back in compliance and provides supporting documentation in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 107 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.
- (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

Project I.D. #J-11544-18 was found 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 this application which would affect that determination. Consequently, the application is conforming to the performance standards in this rule.