# **ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

#### **FINDINGS**

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

| Decision Date:<br>Findings Date: | May 25, 2018<br>May 25, 2018   |
|----------------------------------|--|
| Project Analyst:<br>Team Leader: | Jane Rhoe-Jones<br>Fatimah Wilson  |
| Project ID #:                    | R-11454-18   |
| Facility:                        | Perquimans County Dialysis   |
| FID #:                           | 140091   |
| County:                          | Perquimans   |
| Applicant:                       | DVA Healthcare Renal Care, Inc.  |
| Project:                         | Change of site and cost overrun for Project I.D. #R-10264-14 (develop a new 10-<br>station dialysis facility in Hertford by relocating six dialysis stations from Elizabeth<br>City Dialysis Center and four dialysis stations from Edenton Dialysis Center and<br>provide peritoneal dialysis training and support) |

## **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.

## NA

The applicant, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Perquimans County Dialysis proposes a cost overrun for Project I.D. #R-10264-14 (develop a new 10-station dialysis facility in Hertford by relocating six stations from Elizabeth City Dialysis Center and four stations from Edenton Dialysis Center and provide peritoneal dialysis training and support).

The certificate of need was issued on July 29, 2014 for Project I.D. #R-10264-14 and authorized a capital cost of \$1,386,766. The current application is for a cost overrun of \$435,232 due to the following changes listed by the applicant in Section C.14(b), page 17:

- A site change because the sites identified in the original application were no long available when project development began.
- A change in capital cost for the project results in the cost overrun.
- The original capital cost was approved for a ground up build (new construction), however, there will be a build out (reconfiguration of existing space) which accounts for an increase in capital cost.

In Project I.D. #R-10264-14, the applicant projected occupancy and offering of services by September 1, 2018. In this cost overrun application, the applicant projects occupancy and offering of services by December 1, 2018. There is no material change in scope from the originally approved project in this application.

# **Need 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 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review.

# **Policies**

Project I.D. # R-10264-14 was found to be consistent with Policy ESRD-2 in the original review. The applicant proposes no changes in the current application that would affect the determination in the previous application. There are no other policies in the 2018 SMFP that are applicable to this review.

## **Conclusion**

In summary, in Project I.D. # R-10264-14, the applicant was approved to develop a new 10station dialysis facility in Perquimans County by relocating six dialysis stations from Elizabeth City Dialysis (Pasquotank County) and four dialysis stations from Edenton Dialysis Center (Chowan County) and provide peritoneal dialysis training and support. In that review, the application was conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Therefore, this criterion 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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The applicant proposes a change of site and cost overrun for Project I.D. # R-10264-14 (develop a new 10-station dialysis facility in Hertford by relocating six dialysis stations from Elizabeth City Dialysis Center and four dialysis stations from Edenton Dialysis Center and provide peritoneal dialysis training and support). A certificate of need was issued on July 29, 2014 for Project I.D. #R-10264-14 as described above. The original approved capital expenditure was \$1,386,766. The current application is for a cost overrun of \$435,232, and the applicant now projects a total capital cost of \$1,821,998.

# Patient Origin

On page 365, the 2018 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." Perquimans County Dialysis is located in Perquimans County; thus, the service area for this facility consists of Perquimans County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #R-10264-14, the applicant defined its primary service area as Perquimans County. The current application is a change of site and cost overrun for that project. In Project I.D. #R-10264-14, the applicant adequately identified the population to be served and no changes are proposed in this application that affect that determination.

## Analysis of Need

In Section C.14(b), page 17, the applicant describes the reasons for the change of site and cost overrun application, as summarized below:

- The original primary and secondary sites were no longer available when project development began, so it was necessary to select a new site.
- In the original application, the applicant proposed ground up construction for the building, however, in this cost overrun application, the applicant proposes a build out for the new facility, which increases the construction costs.
- The \$435,233 cost overrun includes \$408,313 for construction costs, \$33,660 for dialysis machines, \$40,360 for water treatment equipment and \$26,926 for interest during construction.
- The applicant was able to reduce cost for equipment/furniture (\$67,026) and architect/engineering fees (\$7,000) in this application.

The following table compares the previously approved capital cost for Project I.D. #R-10264-14 and the proposed capital cost in this application, as reported in Section F.1, page 21.

| PERQUIMANS COUNTY DIALYSIS<br>Previously Approved vs. Proposed Capital Expenditures |  |                                     |               |  |  |  |
|---|--|-------------------------------------|---------------|--|--|--|
| Item/Category   | Previously Approved Cost<br>R-10264-14 | Total Additional Cost<br>R-11454-18 | Total Overrun |  |  |  |
| Construction Contract   | \$780,500                              | \$408,313                           | \$1,188,813   |  |  |  |
| Dialysis Machines   | \$131,700                              | \$33,660                            | \$165,360     |  |  |  |
| (RO) Water Treatment<br>Equipment   | \$90,000                               | \$40,360                            | \$130,360     |  |  |  |
| Equipment/Furniture   | \$294,566                              | \$(67,026)                          | \$227,540     |  |  |  |
| Architect/Engineering Fees  | \$90,000                               | \$(7,000)                           | \$83,000      |  |  |  |
| Interest During Construction  | \$0                                    | \$26,926                            | \$26,926      |  |  |  |
| Total   | \$1,386,766                            | \$435,233                           | \$1,821,999   |  |  |  |

The project scope, the population to be served, and access by underserved groups as demonstrated in the original application will not change as a result of this application. The applicant's representations regarding the need for a change of site and additional capital expenditure to offer in-center dialysis and peritoneal dialysis training and support are reasonable and adequately supported.

## Projected Utilization

In Section C.15, page 17, the applicant provides the projected utilization for Perquimans County Dialysis and states that there are no changes to its projected utilization from those projections provided as part of Project I.D. #R-10264-14.

In Project I.D. #R-10264-14, the applicant adequately demonstrated that projected utilization was based on reasonable and adequately supported assumptions regarding continued growth in the patient population that requires dialysis services. The applicant proposes no changes in the current application that would affect that determination.

## Access

In Project I.D. #R-10264-14, the applicant adequately demonstrated the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. The applicant proposes no changes in the current application that would affect that determination.

# **Conclusion**

In the previously approved application, Project I.D. #R-10264-14, the applicant adequately identified the population to be served, demonstrated the need for the proposed 10-station dialysis facility, and demonstrated the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. The applicant proposes no change in this application that would affect that determination. In this application, the applicant adequately demonstrates the need for the change in site and the proposed cost overrun. Consequently, the application is conforming to this criterion.

(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.

### NA

In the previously approved application, Project I.D. #R-10264-14, the applicant demonstrated that the needs of the populations presently served at Elizabeth City Dialysis Center and Edenton Dialysis Center will continue to be adequately met following the proposed relocation of six dialysis stations from Elizabeth City Dialysis Center and four dialysis stations from Edenton Dialysis Center to Perquimans County Dialysis, and that access for medically underserved groups will not be negatively impacted. The applicant proposes no change in this application that would affect that determination. Consequently, the application is conforming to this criterion.

(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

In Section E.1, page 20, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo the applicant states that this alternative was dismissed because the project does require a change in location which contributed to higher capital costs.
- Submit the Cost Overrun and Change of Location Application the applicant states that this alternative was chosen to be able to complete the project.

On page 20, the applicant states that its proposal is the most effective alternative because, "the selection of a new site and the additional capital funds are necessary to complete the project."

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because otherwise the applicant would have to abandon the project.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Supplemental information requested by the Agency
- 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. Therefore, the application is approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall materially comply with the representations in this application and the representations in Project I.D. #R-10264-14. Where representations conflict, DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall materially comply with the last made representation.
- 2. The total approved capital expenditure for Project I.D. #R-10264-14 and Project I.D. #R-11454-18 combined is \$1,821,999, an increase of \$435,233 over the previously approved capital expenditure of \$1,386,766.
- **3.** DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.
- 4. DVA Healthcare Renal Care, Inc. d/b/a Perquimans County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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.

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The proposed project is a change of site and cost overrun for Project I.D. #R-10264-14 (develop a new 10-station dialysis facility in Hertford by relocating six stations from Elizabeth City Dialysis Center and four stations from Edenton Dialysis Center and provide peritoneal dialysis training and support).

## **Capital and Working Capital Costs**

The total capital cost is now expected to be \$1,821,999, an increase of \$435,233 over the previously approved Project I.D. #R-10264-14 capital cost of \$1,386,766, which is above the allowed 115 percent overage for capital expenditures.

The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported on Section F.1, page 21.

| PERQUIMANS COUNTY DIALYSIS<br>Previously Approved vs. Proposed Capital Expenditures |  |                                     |                    |  |  |  |
|---|--|-------------------------------------|--------------------|--|--|--|
| Item/Category   | Previously Approved Cost<br>R-10264-14 | Total Additional Cost<br>R-11454-18 | Total Overrun Cost |  |  |  |
| Construction Contract   | \$780,500                              | \$408,313                           | \$1,188,813        |  |  |  |
| Dialysis Machines   | \$131,700                              | \$33,660                            | \$165,360          |  |  |  |
| (RO) Water Treatment<br>Equipment   | \$90,000                               | \$40,360                            | \$130,360          |  |  |  |
| Equipment/Furniture   | \$294,566                              | \$(67,026)                          | \$227,540          |  |  |  |
| Architect/Engineering Fees  | \$90,000                               | \$(7,000)                           | \$83,000           |  |  |  |
| Interest During Construction  | \$0                                    | \$26,926                            | \$26,926           |  |  |  |
| Total   | \$1,386,766                            | \$435,233                           | \$1,821,999        |  |  |  |

In Section R, the applicant provides the assumptions used to project capital cost.

In Section F, pages 23-24, the applicant projects that start-up costs will be \$145,610 and initial operating expenses will be \$727,814 for a total working capital of \$873,424. On page 24, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

## Availability of Funds

In Section F.2, page 22, the applicant states the total capital cost of the project (original and additional capital) will be funded with accumulated reserves. In Exhibit F-5, the applicant provides a February 13, 2018 letter from the Chief Accounting Officer of DaVita, Inc., the parent company of DVA HealthCare Renal Care, Inc., which states:

"DaVita, Inc. and DVA HealthCare Renal Care, Inc. have committed cash reserves for this project. We will ensure that these funds are made available for the development and operation of this project."

Exhibit F-7 contains DaVita, Inc. United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2016. As of December 31, 2016, DaVita had \$913,187,000 in cash and cash equivalents, \$18,741,257,000 in total assets, and \$5,822,999,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

### **Financial Feasibility**

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In Form X.4, page 56, the applicant projects that revenues will exceed operating expenses in the second operating year of the project. The financial projections in Section R of this application are identical to those provided in the previously approved application, Project I.D. # R-10264-14. In response to a request for additional information by the Agency, the applicant states the adjustment in the development timetable will have no effect on the financial projections made in the application.

In the previously approved application, the assumptions used by the applicant in preparation of the pro forma financial statements were determined to be reasonable, including projected utilization, costs and charges. The applicant proposes no change in this application that would affect that determination.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Additional information provided by the applicant in response to a request from the Agency
- 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.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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The applicant, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Perquimans County Dialysis proposes a cost overrun for Project I.D. #R-10264-14 (develop a new 10-station dialysis facility in Hertford by relocating six stations from Elizabeth City Dialysis Center and four stations from Edenton Dialysis Center and provide peritoneal dialysis training and support).

On page 365, the 2018 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." Perquimans County Dialysis is located in Perquimans County; thus, the service area for this facility consists of Perquimans County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #R-10264-14, the applicant was approved to develop a new 10-station dialysis facility in Hertford by relocating six dialysis stations from Elizabeth City Dialysis Center and four dialysis stations from Edenton Dialysis Center. The current application is a change in site

and cost overrun for that project. In Project I.D.# R-10264-14, the application was found to adequately demonstrate that the project would not result in unnecessary duplication of existing or approved dialysis services and no changes are proposed in this application that would affect that determination. Consequently, the application is conforming to this criterion.

(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.

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In Section H.8, page 31, the applicant states that there are no changes in the staffing levels or positions from the original project. In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.

(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.

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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

In Project I.D. #R-10264-14, the criterion was found to be not applicable, and the applicant proposes no changes in the current application that would affect that determination. Consequently, this criterion is not applicable to this cost overrun application.

(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

In Project I.D. #R-10264-14, the criterion was found to be not applicable, and the applicant proposes no changes in the current application that would affect that determination. Consequently, this criterion is not applicable to this cost overrun application.

- (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.

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The proposed project is for a cost overrun for Project I.D. #R-10264-14. The following table compares the previously approved capital cost for Project I.D. #R-10264-14 and the proposed capital cost in this application, as reported in Section F.1, page 21.

| PERQUIMANS COUNTY DIALYSIS<br>Previously Approved vs. Proposed Capital Expenditures |  |                                     |               |  |  |  |
|---|--|-------------------------------------|---------------|--|--|--|
| Item/Category   | Previously Approved Cost<br>R-10264-14 | Total Additional Cost<br>R-11454-18 | Total Overrun |  |  |  |
| Construction Contract   | \$780,500                              | \$408,313                           | \$1,188,813   |  |  |  |
| Dialysis Machines   | \$131,700                              | \$33,660                            | \$165,360     |  |  |  |
| (RO) Water Treatment<br>Equipment   | \$90,000                               | \$40,360                            | \$130,360     |  |  |  |
| Equipment/Furniture   | \$294,566                              | \$(67,026)                          | \$227,540     |  |  |  |
| Architect/Engineering Fees  | \$90,000                               | \$(7,000)                           | \$83,000      |  |  |  |
| Interest During Construction  | \$0                                    | \$26,926                            | \$26,926      |  |  |  |
| Total   | \$1,386,766                            | \$435,233                           | \$1,821,999   |  |  |  |

In Section C.14(b), page 17, the applicant describes the reasons for the cost overrun application, as summarized below:

• The original primary and secondary sites were no longer available when project development began, so it was necessary to select a new site.

- In the original application, the applicant proposed ground up construction for the building, however, in this cost overrun application, the applicant proposes a build out for the new facility, which increases the construction costs.
- The \$435,233 cost overrun includes \$408,313 for construction costs, \$33,660 for dialysis machines, \$40,360 for water treatment equipment and \$26,926 for interest during construction.
- The applicant was able to reduce cost for equipment/furniture (\$67,026) and architect/engineering fees (\$7,000) in this application.

The discussion regarding the need for the cost overrun 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. Therefore, 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;

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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;

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

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In Project I.D. #R-10264-14, the application was found conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

The applicant, DVA Healthcare Renal Care, Inc. (DVA) d/b/a Perquimans County Dialysis proposes a cost overrun for Project I.D. #R-10264-14 (develop a new 10-station dialysis

facility in Hertford by relocating six stations from Elizabeth City Dialysis Center and four stations from Edenton Dialysis Center and provide peritoneal dialysis training and support).

On page 365, the 2018 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." Perquimans County Dialysis is located in Perquimans County; thus, the service area for this facility consists of Perquimans County. Facilities may also serve residents of counties not included in their service area.

Project I.D. #R-10264-14, the applicant was approved to develop a new 10-station dialysis facility in Hertford by relocating six stations from Elizabeth City Dialysis Center and four stations from Edenton Dialysis Center, and develop a PD dialysis training and support program. In Project I.D. #R-10264-14, the application was found conforming to this criterion and no changes are proposed in this application that affect that determination. Consequently, the change in site/cost overrun application is conforming to this criterion.

- (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.

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In Section B.4, pages 8-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O, the applicant lists one dialysis facility in the state owned by DaVita, Goldsboro South Dialysis, that was cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibit O. In Section O.3, page 49, the applicant states the facility is currently in compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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.

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In Project I.D. #R-10264-14, the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 were found conforming to that review, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to the performance standards in this rule.