

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 29, 2018

Findings Date: August 29, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Assistant Chief: Lisa Pittman

Team Leader: Gloria C. Hale

Project ID #: F-11522-18

Facility: Renaissance Park Dialysis

FID #: 180264

County: Mecklenburg

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

Project: Develop a new 10-station dialysis facility by relocating 10 stations from Charlotte Dialysis and offer a peritoneal dialysis training program.

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. (Renal Treatment Centers and/or the applicant) d/b/a Renaissance Park Dialysis proposes to develop a new ten-station dialysis facility in Mecklenburg County, Renaissance Park Dialysis, by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to in-center (IC) dialysis, Renaissance Park Dialysis would offer a peritoneal dialysis (PD) program. Initially, Renaissance Park Dialysis would not offer a home hemodialysis (HH) program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10

stations) and Project ID #F-11155-16 (add 8 stations). The parent company of Renal Treatment Centers is DaVita, Inc. (DaVita).

Need Determination

The county and facility need methodologies in the January 2018 Semiannual Dialysis Report (SDR) and the 2018 State Medical Facilities Plan (SMFP) are not applicable to this review.

Policies

There are two policies in the 2018 SMFP applicable to this review:

- **Policy ESRD-2: Relocation of Dialysis Stations**, on page 27 of the 2018 SMFP, and
- **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities** on page 33 of the 2018 SMFP.

Policy ESRD-2

Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

Renal Treatment Centers is proposing to relocate dialysis stations from Charlotte Dialysis in Mecklenburg County to the proposed Renaissance Dialysis facility which will also be located in Mecklenburg County. Both facilities, Charlotte Dialysis and the proposed Renaissance Dialysis facility are in the same county, Mecklenburg, thus, there will be no change in the dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

In Section B, pages 11-13, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 11, the applicant states

“DaVita’s development department ... is implementing several strategies that help new facilities align with Village Green Environmental Goals (see Exhibit B-5), which include:

- *Energy Conservation- Reduce energy use and carbon emissions by 10% per treatment*
- *Water Conservation- Reduce water use by 30% per treatment”*

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 existing dialysis stations are being relocated within the same county, therefore the proposal is consistent with Policy ESRD-2.
 - The applicant documents strategies to reduce energy use and carbon emissions, and to reduce water use. Therefore, the proposal is consistent with Policy GEN-4.
- (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.

NC

Renal Treatment Centers proposes to develop a new ten-station dialysis facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations as *“a dialysis station’s service area is 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 for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C.1, page 14, the applicant provides the projected patient origin for Renaissance Park Dialysis for IC and PD patients for the first two years of operation following completion of the project as follows:

County	OY1 (CY2020)		OY2 (CY2021)		County Patients as a Percent of Total	
	IC	PD	IC	PD	OY1	OY2
Mecklenburg	30	2*	32	3*	93.8% [94.1%]	94.1% [94.6%]
Gaston	2	0	2	0	6.3% [5.9%]	5.9% [5.4%]
Total	32	2	34	3	100.0%	100.0%

*The table on page 14 of the application did not include PD patients. However, PD patients are referenced and documented in Section C, page 16, and Section R of the application.

Note: The Project Analyst’s corrections are in brackets.

The applicant provides the assumptions and methodology used to project its patient origin on pages 14-16. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, pages 16, and Exhibit C-1, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 14-16, the applicant describes its assumptions and methodology for projecting utilization of the proposed facility as follows:

- A total of 25 Mecklenburg County residents who are currently in-center patients at a DaVita dialysis facility in Mecklenburg County (21 patients from Charlotte Dialysis and 4 patients from South Charlotte Dialysis) have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and, in many cases, will be closer to their home and that they would consider transferring their care to Renaissance Park Dialysis.
- Two patients who are residents of Gaston County and currently receiving their dialysis care from a DaVita facility in South Carolina have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and, in many cases, will be closer to their home and that they would consider transferring their care to Renaissance Park Dialysis.
- Two PD patients who reside in Mecklenburg County, both of whom currently receive their dialysis support at Charlotte East Dialysis, have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and they would consider transferring to the proposed Renaissance Park Dialysis facility.
- Per the January 2018 SDR, Table B, there are a total of eight DaVita dialysis facilities (six existing and two approved) in Mecklenburg County. Based on the signed letters from patients currently dialyzing at Charlotte Dialysis, South Charlotte Dialysis and a DaVita dialysis facility in South Carolina (Fort Mills Dialysis), the applicant concludes

that the proposed new facility will be more convenient for them and, in many cases, will be closer to their home.

The information is reasonable and adequately supported for the following reasons:

- See Exhibit C-1 which contains 29 patient letters of support, 27 from IC patients and two from PD patients. The letters state:

In-Center:

“I fully support this new dialysis facility ... to be built in Charlotte. ... Having my dialysis treatments at Renaissance Park Dialysis would be more convenient for me. I could travel between home and that location more easily and quickly, which would save me time and money.”

Peritoneal Dialysis:

“... Having support for my home training at Renaissance Park Dialysis would be closer to my home and much more convenient for me. ...”

Projected Utilization – In-center

On pages 14-16, the applicant illustrates how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- A total of 25 Mecklenburg County residents who are currently in-center patients at a DaVita dialysis facility in Mecklenburg County (21 patients from Charlotte Dialysis and 4 patients from South Charlotte Dialysis) have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and, in many cases, will be closer to their home and that they would consider transferring their care to Renaissance Park Dialysis.
- Two patients who are residents of Gaston County and currently receiving their dialysis care from a DaVita facility in South Carolina have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and, in many cases, will be closer to their home and that they would consider transferring their care to Renaissance Park Dialysis.
- Two PD patients who reside in Mecklenburg County both of whom currently receive their dialysis support at Charlotte East Dialysis have signed letters indicating that the proposed Renaissance Park Dialysis facility will be more convenient for them and they would consider transferring to the proposed Renaissance Park Dialysis facility.

- The applicant assumes at least 31 patients will transfer their dialysis care to the proposed Renaissance Park Dialysis upon certification of that facility based on the overall growth at all DaVita dialysis facilities in Mecklenburg County.
- The applicant projects no growth for the two IC patients who live outside of Mecklenburg County (Gaston County).
- The in-center patient population of Mecklenburg County residents is projected to grow at 5.1% (the Five-Year Average Annual Change Rate (AACR) for Mecklenburg County) pursuant to Table D, page 58, of the January 2018 Semi-Annual Dialysis Report (SDR).

The following table illustrates application of these assumptions and the methodology used.

Renaissance Park Dialysis	In-Center Patients
Begin with Renaissance Park Dialysis in-center ESRD patient population of Mecklenburg County residents as of January 1, 2020. This is the beginning patient census for OY1.	29
Project the in-center ESRD population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County.	$29 \times 1.051 = 30.479$
Add the 2 Gaston County in-center patients. This is the patient census at the end of OY1.	$30.479 + 2 = \mathbf{32.479}$
Project the in-center ESRD population forward one year to December 31, 2021, using the Five Year AACR for Mecklenburg County	$30.479 \times 1.051 = 32.034$
Add the 2 Gaston County in-center patients. This is the patient census at the end of OY2.	$32.034 + 2 = \mathbf{34.034}$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of both OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 32 and 34 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.2 patients per station per week, or 80.0% ($32 \text{ patients}/10 \text{ stations} = 3.2/4 = 0.80$ or 80.0%).
- OY2: 3.4 patients per station per week, or 85.0% ($34 \text{ patients}/10 \text{ stations} = 3.4/4 = 0.85$ or 85.0%).

The projected utilization of 3.2 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

However, projected utilization is not reasonable and adequately supported for the following reasons:

- The applicant projects 29 IC patients who are Mecklenburg County residents as the beginning patient census (as of January 1, 2020) for Renaissance Park Dialysis.

However, while the applicant does provide support for 25 of the 29 IC patients projected as the beginning patient census, the applicant does not provide its assumptions and methodology for the remaining 4 projected IC patients. The applicant does make the following statement, “Given the significant growth at DaVita-operated facilities in Mecklenburg County, it is assumed that at least 31 patients will transfer to Renaissance Park Dialysis upon its certification.” (see page 14 of the application) However, the applicant does not provide documentation to support “significant growth at DaVita-operated facilities in Mecklenburg County” and does not provide an explanation of why four additional IC patients would transfer their dialysis care to Renaissance Park Dialysis.

As shown below, if the beginning patient census for Renaissance Park Dialysis is only 25 IC patients who are Mecklenburg County residents, the required projected minimum utilization of 80.0% or 3.2 patients per station per week at the end of OY1 is not met.

Renaissance Park Dialysis	In-Center Patients
Begin with Renaissance Park Dialysis in-center ESRD patient population of Mecklenburg County residents as of January 1, 2020. This is the beginning patient census for OY1.	25
Project the in-center ESRD population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County.	$25 \times 1.051 = 26.275$
Add the 2 Gaston County in-center patients. This is the patient census at the end of OY1.	$26.275 + 2 = \mathbf{28.275}$

- The projected utilization rates for the first operating year would then be as follows:
- OY1: 2.8 patients per station per week, or 70.0% (28 patients/10 stations = $2.8/4 = 0.70$ or 70.0%).
- The projected utilization of 2.8 patients per station per week at the end of OY1 does not meet the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected Utilization-PD Patients

The applicant provides projected utilization for its PD patients in Section C.1, page 16, as follows:

Operating Year	Start Date	Beginning Census of PD Patients	Ending Census of PD Patients
Operating Year 1	1/1/20	1	2
Operating Year 2	1/1/21	2	3

On pages 15-16, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains two letters of support for the proposed facility from PD patients who currently receive their support at a DaVita facility indicating that they would consider transferring their care to Renaissance Park Dialysis, if approved, based on the fact that they either live closer to the proposed new facility or it would be more convenient for them.
- Renal Treatment Centers assumes that “*at least one of the patients*” who signed letters of support for the proposed facility will transfer their care to Renaissance Park Dialysis upon certification.
- Renal Treatment Centers assumes that the PD patients will increase one patient each year.

Projected utilization for the PD dialysis program is reasonable and adequately supported for the following reasons:

- The applicant identifies the patient origin.
- The applicant projects the starting PD patient census for the proposed facility based on two existing patients who currently receive their home training support services from a DaVita facility in Mecklenburg County who have signed letters expressing their intention to transfer their care to the proposed Renaissance Park Dialysis facility. The applicant further assumed that at least one of the PD patients who signed the letters of support would transfer their care to Renaissance Park Dialysis and that the PD program would grow by one patient per year.

Access

In Section C.3, page 16, the applicant states, “*By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*”

In Section L.1, page 50, the applicant projects the following payor mix during the second full fiscal year of operation (CY2021) following completion of the project, as illustrated in the following table.

Payor Category	Percent of Total Patients
Medicaid	3.8%
Medicare	26.9%
Medicare/Medicaid	24.4%
Medicare/Commercial	29.5%
VA	3.2%
Commercial Insurance	12.2%
Total	100.0%

Source: Table, page 50 of the application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- Projected utilization for IC patients is not reasonable and is not adequately supported.

(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

Renal Treatment Centers proposes to develop a new ten-station dialysis facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

The following table shows the projected relocation of stations from Charlotte Dialysis to the proposed Renaissance Park Dialysis facility and identifies the number of patients projected to transfer from the existing facility to the proposed new facility.

Proposed Renaissance Park Dialysis Project		
Facility	Number of Stations to be Relocated	Number of Patients Transferring*
Charlotte Dialysis	10	21
South Charlotte Dialysis	0	4
Fort Mill Dialysis (South Carolina)	0	2
Total Relocated and Transferred	10	27

*See patient letters in Exhibit C-1.

In Section D.1, pages 24-26, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Charlotte Dialysis

According to the January 2018 SDR, there were 120 patients dialyzing at Charlotte Dialysis and 36 certified dialysis stations for a utilization rate of 83.33%, or 3.333 patients per station per week ($120/36 = 3.333/4 = 0.83325$ or 83.33%) as of June 30, 2017. In Section D.1, page 24, the applicant states that on June 30, 2017, 114 of the 120 in-center patients reside in Mecklenburg County, and 6 reside outside of Mecklenburg County.

The applicant assumes that the number of in-center patients at Charlotte Dialysis who reside in Mecklenburg County will increase at a rate of 5.1% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Mecklenburg County, as reported in Table D of the January 2018 SDR. The applicant assumes that there will be no increase in the number of patients from the other counties. The applicant projects that 18 Charlotte Dialysis patients, who reside in Mecklenburg County, will transfer their care to Brookshire Dialysis (Project ID# F-11109-15) upon certification of that facility on January 1, 2019. Furthermore, in this application the applicant projects that 21 Charlotte Dialysis patients, who reside in Mecklenburg County, will transfer their care to the proposed Renaissance Park Dialysis facility upon certification of that facility on January 1, 2020.

As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. As of January 1, 2020, Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project (relocate 10 stations), Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

In Section D.1, pages 24-25, the applicant calculates the in-center patient census for Charlotte Dialysis starting July 1, 2017 through the first two operating years of the proposed project (CY2020 and CY2021), summarized as follows:

Charlotte Dialysis	In-Center Patients
Begin with Charlotte Dialysis's in-center ESRD patient population from Mecklenburg County, as of June 30, 2017.	114
Project the Mecklenburg County population forward six months to December 31, 2017, using one half of the Five Year AACR for Mecklenburg County, 2.55%.	$114 \times 1.0255 = 116.907$
Project the Mecklenburg County population forward one year to December 31, 2018, using the Five Year AACR for Mecklenburg County, 5.1%.	$116.907 \times 1.051 = 122.869$
Subtract out the 18 in-center patients projected to transfer their dialysis care from Charlotte Dialysis to Brookshire Dialysis (Project ID# F-11109-15).	$122.869 - 18 = 104.869$
Project the Mecklenburg County population forward one year to December 31, 2019, using the Five Year AACR for Mecklenburg County, 5.1%.	$104.869 \times 1.051 = 110.217$
Subtract out the 21 in-center patients projected to transfer their dialysis care from Charlotte Dialysis to the proposed Renaissance Park Dialysis facility.	$110.217 - 21 = 89.217$
Project the Mecklenburg County population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County, 5.1%.	$89.217 \times 1.051 = 93.767$
Add the 6 non-Mecklenburg County patients. This is the in-center patient census at the end of OY1.	$93.767 + 6 = \mathbf{99.767}$
Project the Mecklenburg County population forward one year to December 31, 2021, using the Five Year AACR for Mecklenburg County, 5.1%.	$93.767 \times 1.051 = 98.549$
Add the 6 non-Mecklenburg County patients. This is the in-center patient census at the end of OY2.	$98.549 + 6 = \mathbf{104.549}$

*Note: In the table and calculations on page 25 of the application the applicant states that at the patient census for Charlotte Dialysis at the end of OY1 will be 128 in-center patients and that at the end of OY2 there will be 135 in-center patients. The projected numbers of in-center patients for OY1 and OY2 are incorrect. In row b of the table on page 25 that applicant grew the starting Mecklenburg County 114 in-center patients by 25.5% instead of 2.55%. This error was corrected in the table above and the analysis below.

Thus, on December 31, 2020, Charlotte Dialysis is projected to have 24 certified dialysis stations with an in-center patient population of 99, which is equivalent to a utilization rate of 5.33 patients per station per week ($99 / 24 = 4.125 / 4 = 1.031$ or 103.1%). In Section D.1, page 25, the applicant states that given this projected in-center growth, as the facility approaches full capacity additional Certificate of Need applications based on facility need will be submitted to ensure that the needs of the facility's patients continue to be met.

Projected utilization for Charlotte Dialysis is reasonable and adequately supported for the following reasons:

- The applicant projects the patient census for Charlotte Dialysis is based on existing Charlotte Dialysis patients.
- The applicant adjusts for the projected transfer of in-center patients to Brookshire Dialysis and Renaissance Park Dialysis (the proposed facility in this application).
- The applicant factors in the relocation of stations, both to and from, Charlotte Dialysis, as relates to this application, Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).
- The applicant's growth projections are based on an assumption that the Mecklenburg County patient census will increase at an annual rate of 5.1%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Mecklenburg County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, pages 25-26, the applicant states that the proposed relocation of stations will not will not adversely affect 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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.

NC

Renal Treatment Centers proposes to develop a new ten-station dialysis facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this

project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

In Section E, page 27, 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 is not the most effective alternative because maintaining the status quo would not meet the needs of the growing Mecklenburg County in-center patient population.

Locate a Facility in a Different Location in Mecklenburg County- The primary and secondary sites proposed for Renaissance Park Dialysis are geographic locations that will provide improved access to the patient population identified in the patient letters submitted in support of this application in Exhibit C-1. A facility located in a different area of Mecklenburg County would not address the access needs of the identified patients.

On page 27, the applicant states that its proposal is the most effective alternative because the proposed project offers convenience and reduced travel time to existing dialysis patients who utilize DaVita dialysis facilities.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Projected utilization of IC patients is not reasonable or adequately supported. Thus, the applicant does not adequately demonstrate that this proposal is the most effective alternative.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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.

NC

Renal Treatment Centers proposes to develop a new ten-station facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

Capital and Working Capital Costs

In Section F, page 29, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$27,136
Construction Costs	\$1,412,030
Miscellaneous Costs	\$914,316
Total	\$2,353,482

In Section F.1, page 29, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 31-32, the applicant projects that start-up costs will be \$198,078 and initial operating expenses will be \$798,403 for a total working capital of \$996,480. On page 32, 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 30, the applicant states that the capital cost will be funded as shown in the table below.

Type	DaVita, Inc.	Total
Accumulated reserves or OE *	\$2,353,482	\$2,353,482
Total Financing	\$2,353,482	\$2,353,482

* OE = Owner's Equity

In Section F.13, pages 32-33, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Source of Financing for Working Capital	Amount
Cash Reserves	\$996,480
Total *	\$996,480

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments*	4,890	5,262
Total Gross Revenues (Charges)	\$1,665,297	\$1,801,287
Total Net Revenue	\$1,604,382	\$1,735,764
Average Net Revenue per treatment	\$328.09	\$329.87
Total Operating Expenses (Costs)	\$1,596,805	\$1,683,987
Average Operating Expense per treatment	\$326.55	\$320.03
Net Income	\$7,576	\$51,777

*Includes IC and PD treatments from Form C of Section R.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported for the following reason:

- Projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reason:

- The applicant does not adequately demonstrate 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.

Renal Treatment Centers proposes to develop a new ten-station facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is 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 for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	98.44%
BMA Nations Ford	BMA	Charlotte	28	98.21%
BMA of East Charlotte	BMA	Charlotte	25	87.00%
BMA of North Charlotte	BMA	Charlotte	36	108.33%
BMA West Charlotte	BMA	Charlotte	29	81.03%
FMC Charlotte	BMA	Charlotte	43	89.53%
FMC Matthews	BMA	Matthews	21	119.05%
Fresenius Medical Care Southwest Charlotte	BMA	Charlotte	10	75.00%
FMC Regal Oaks	BMA	Charlotte	12	16.67%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	83.33%
Charlotte East Dialysis	DaVita	Charlotte	34	83.82%
Huntersville Dialysis	DaVita	Huntersville	10	95.00%
Mint Hill Dialysis	DaVita	Mint Hill	16	82.81%
North Charlotte Dialysis Center	DaVita	Charlotte	41	70.12%
South Charlotte Dialysis**	DaVita	Charlotte	22	82.95%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	19.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%

Source: January 2018 SDR, Table B.

* Facility under development.

**Under Project ID #F-11323-17 this facility is being relocated to a new location.

In Section G, pages 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. On page 35 the applicant states:

“This certificate of need application does not propose to increase the number of stations in Mecklenburg County. Transferring ten stations from Charlotte Dialysis will create a new facility at a different location to better serve patients living in the area of the new facility, but will not result in duplication of existing services.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reason:

- Projected utilization is not reasonable or adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by

reference. Therefore, since the applicant failed to demonstrate the need for the project based on reasonable or adequately supported utilization projections, the applicant failed to show that its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not 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

In Section H.1, pages 36, the applicant provides projected staffing for the proposed services as illustrated in the following table.

Projected Staffing: Renaissance Park Dialysis OY2 (CY2021)

Position	Projected Total FTE Positions
Medical Director	NA*
RN	2.0
Technician (PCT)	4.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Home Training RN	0.5
Admin Assistant	1.0
Biomed Tech	0.5
TOTAL	10.0

*Medical Director is an independent contractor, not an employee.

The assumptions and methodology used to project staffing are provided in Section H.1, page 36 and Sections H.6 and H.7, page 39. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3, H-4 and I-3, the applicant provides supporting documentation. In Section I.3, page 41, the applicant identifies the proposed medical director. In Exhibit I-3, the applicant

provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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

In Section I.1, page 40, the applicant identifies the ancillary and support services necessary for the proposed services.

RENAISSANCE PARK DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Renaissance Park Dialysis
Self-care training (in-center)	Renaissance Park Dialysis
Home training HH PD	Charlotte East Dialysis Renaissance Park Dialysis Renaissance Park Dialysis
Accessible follow-up program	Renaissance Park Dialysis
Psychological counseling	Renaissance Park Dialysis
Isolation – hepatitis	Renaissance Park Dialysis
Nutritional counseling	Renaissance Park Dialysis
Social Work services	Renaissance Park Dialysis
Acute dialysis in an acute care setting	Atrium Health
Emergency care	Atrium Health
Blood bank services	Atrium Health
Diagnostic and evaluation services	Atrium Health
X-ray services	Atrium Health
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Atrium Health
Vascular surgery	Atrium Health
Transplantation services	Atrium Health
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	Mecklenburg Transportation System

On page 40, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1 and I-2.

In Section I, pages 41-42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1, I-2(a), I-2(b) and I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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.

- (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

In Section K, pages 45 and 47, the applicant states that the project involves construction and up-fitting of 6,467 square feet in leased space in a building to be constructed by a developer at Tax Parcel 14315103 (Parkway Plaza Blvd) in Charlotte. A line drawing of the proposed facility is provided in Exhibit K-1(a).

In Section K, page 44, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On page 46, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of public water and sewer at the site. See also Exhibit K-4(h).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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

Renaissance Park Dialysis is not an existing facility. The applicant projects a total of 32 IC patients and 2 PD patients in OY1 upon project completion. There are 29 in-center patients projected to be transferring their care to Renaissance Park Dialysis, 25 of those 29 in-center patients currently receive their dialysis care from Charlotte Dialysis. The ten stations proposed for Renaissance Park Dialysis will be relocated from Charlotte Dialysis

In Section L.7, page 53, the applicant reports that 86.8% of the patients who received treatments at Charlotte Dialysis had some or all of their services paid for by Medicare or Medicaid, in CY2017. The table below shows the historical (CY2017) payment source for Charlotte Dialysis:

Payment Sources CY2017	Charlotte Dialysis Patients as Percent of Total
Medicaid	4.9%
Medicare	27.0%
Medicare/Medicaid	29.5%
Medicare/Commercial	25.4%
VA	2.5%
Commercial Insurance	10.7%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Mecklenburg	11%	52%	53%	12%	6%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

- Application

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 52, the applicant states

“Renaissance Park Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 52, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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

In Section L.1, page 50, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	3.8%
Medicare	26.9%
Medicare/Medicaid	24.4%
Medicare/Commercial	29.5%
VA	3.2%
Commercial Insurance	12.2%
Total	100.0%

Source: Table, page 50 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 84.6% of total services will be provided to Medicaid/Medicare patients.

On page 50, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on historical payor mix during the last full operating year from DaVita facilities in Mecklenburg County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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

In Section L.4, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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

In Section M, page 54, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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.

NC

Renal Treatment Centers proposes to develop a new ten-station facility, Renaissance Park Dialysis, in Mecklenburg County by relocating ten dialysis stations from Charlotte Dialysis in Mecklenburg County. In addition to IC dialysis, Renaissance Park Dialysis would offer a PD program. As of June 30, 2017, Charlotte Dialysis was certified for 36 dialysis stations. Charlotte Dialysis will be certified for 24 dialysis stations upon completion of this project and Project ID# F-11109-15 (relocate 10 stations) and Project ID #F-11155-16 (add 8 stations).

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“a dialysis station’s service area is 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 for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the January 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
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FMC Matthews	BMA	Matthews	21	119.05%
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FMC Regal Oaks	BMA	Charlotte	12	16.67%
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FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
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Charlotte Dialysis	DaVita	Charlotte	36	83.33%
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Carolinas Medical Center	CMC	Charlotte	9	19.44%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.19%

Source: January 2018 SDR, Table B.

* Facility under development.

**Under Project ID #F-11323-17 this facility is being relocated to a new location.

In Section N, page 55, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 55, the applicant states:

“DaVita operates six [8] of the 24 [23] existing/proposed facilities in the county.

The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore there can be no effect on the competition. [Note- this sentence is incorrect. There are other dialysis facilities in Mecklenburg County operated by other providers.]

The bottom line is Renaissance Park Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

The applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate that any enhanced competition would have a positive impact on the cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

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

C

In Section A, page 5, the applicant states DaVita operates more than 85 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 56, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

- (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.

NC

The application is not conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- NC- In Section C.1, page 14, the applicant projects to serve 32 in-center patients by the end of OY1 (CY2020) for a utilization rate of 80.0% or 3.2 patients per station per week (32 patients / 10 stations = $3.2 / 4 = 0.8$ or 80.0%). However, projected utilization is not based on reasonable and adequate assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

- NA- The applicant is not proposing to increase the number of dialysis stations in an existing facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-NC- In Section C, pages 14-16, the applicant provides the assumptions and methodology used to project utilization of the facility. However, the applicant fails to provide and document its assumptions regarding the growth from 25 to 29 for Mecklenburg County IC patients.