

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 20, 2019

Findings Date: December 30, 2019

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: J-11739-19

Facility: Fresenius Kidney Care West Johnston

FID #: 170520

County: Johnston

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Relocate no more than 4 dialysis stations from Southwest Wake County Dialysis (Wake County) pursuant to Policy ESRD-2 for a total of no more than 14 stations upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station)

Project ID #: J-11743-19

Facility: Clayton Dialysis

FID #: 170420

County: Johnston

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating no more than 5 stations from Forest Hills Dialysis (Wilson County) and no more than 5 stations from Wilson Dialysis (Wilson County)

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 – Both Applications

Relocation of ESRD Stations Pursuant to Policy ESRD-2

The 2019 State Medical Facilities Plan (SMFP) includes Policy ESRD-2, which allows for the relocation of dialysis stations within the same county and between contiguous counties. Policy ESRD-2 states that, in proposals to relocate dialysis stations between contiguous counties, the relocation may not result in a deficit or increase an existing deficit in the county losing stations and may not result in a surplus or increase an existing surplus in the county gaining stations. The applicable county surpluses and deficits are reflected in the 2019 July Semiannual Dialysis Report (SDR). According to the July 2019 SDR, there is a deficit of 12 dialysis stations in Johnston County. Two applications were submitted to the Healthcare Planning and Certificate of Need Section, proposing to relocate a total of 14 dialysis stations to Johnston County. However, pursuant to Policy ESRD-2, only 12 dialysis stations may be approved for relocation to Johnston County in this review. See the Conclusion following the Comparative Analysis for the decision.

Need Determination

Neither applicant proposes to add stations via the facility need methodology or the county need methodology published in the 2019 SMFP or the July 2019 SDR. Therefore, there are no need determinations applicable to this review.

Policies

There are two policies applicable to the review of the two applications submitted in response to the county deficit of dialysis stations in the July 2019 SDR for the Johnston County service area.

Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, 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.”

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2019 SMFP, 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 of 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.”

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate four dialysis stations from Southwest Wake County Dialysis (SW Wake) to Fresenius Kidney Care West Johnston (FKC West Johnston), a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

Policy ESRD-2. Johnston County and Wake County are contiguous counties. According to the July 2019 SDR, as of December 31, 2018, SW Wake was serving two in-center patients who were residents of Johnston County. In Table D of the July 2019 SDR, Wake County has a surplus of 15 stations and Johnston County has a deficit of 12 stations. Relocating four stations out of Wake County will not create a deficit in Wake County. Likewise, relocating four stations to Johnston County will not create a surplus in Johnston County.

Policy GEN-4. The project's proposed capital expenditure is less than \$2 million; therefore, Policy GEN-4 is not applicable to this project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

Total Renal Care of North Carolina, LLC (TRC) d/b/a Clayton Dialysis (CD) proposes to develop a new 10-station dialysis facility in Johnston County by relocating 5 existing dialysis stations from Forest Hills Dialysis (FHD) and 5 existing stations from Wilson Dialysis (WD). Both FHD and WD are in Wilson County.

Policy ESRD-2. Johnston County and Wilson County are contiguous counties. According to the July 2019 SDR, as of December 31, 2018, FHD was serving two in-center patients who were residents of Johnston County, and WD was serving one in-center patient and three home patients who were residents of Johnston County. In Table D of the July 2019 SDR, Wilson County has a surplus of 10 stations and Johnston County has a deficit of 12 stations. Relocating 10 stations out of Wilson County will eliminate the surplus and will not create a deficit of stations in Wilson County. Likewise, relocating 10 stations to Johnston County will not create a surplus in Johnston County.

Policy GEN-4. The projected capital cost for the proposed project is greater than \$2 million but less than \$5 million. In Section B, pages 15-16, the applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. The applicant provides examples of energy efficient and water conservation features it will include in the proposed facility and states it is implementing strategies to promote energy conservation, water conservation, paper conservation, and waste reduction. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
 - The applicant adequately demonstrates that 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.

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station). Upon completion of this project, Project I.D. #J-11510-18 (develop FKC Holly Springs by relocating 2 stations from SW Wake and 8 stations from other existing dialysis facilities), Project I.D. #J-11661-19 (add two stations), and Project I.D. #J-11778-19 (add four stations – application conditionally approved on December 17, 2019), SW Wake will have a total of 30 certified dialysis stations.

The applicant did not propose to offer home hemodialysis (HH) or peritoneal dialysis (PD) training and support at FKC West Johnston as part of Project I.D. #J-11435-17, and it does not propose to add those services as part of this application.

Patient Origin

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

In Section C, pages 15-16, the applicant states there is no historical patient origin, as FKC West Johnston is not yet operational, and projects to serve 49 Johnston County patients by the end of the second full operating year following project completion. On pages 16-17, the applicant

provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 17-18, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. As a general rule, patients will receive three treatments per week. The NC SMFP recognizes that this patient population requires frequent and regular treatment. ... Failure to receive dialysis care will ultimately lead to the patient's demise.

The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. ... BMA has identified the population to be served as 45 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”

In Section C, page 16, the applicant states that, in addition to the 32 patients projected to transfer to the new 10-station facility proposed as part of Project I.D. #J-11435-17, it identified 14 patients who did not sign letters of support for the proposed project and who have now signed letters indicating their willingness to consider transferring their care to FKC West Johnston. Exhibit C-3.3 contains 14 letters of support from patients willing to consider transferring their care to FKC West Johnston.

Comments submitted during the public comment period state that four of the patient support letters appear to be from individuals who already signed letters of support stating they would be willing to consider transferring their care to FKC West Johnston as part of Project I.D. #F-11435-17. At the public hearing on September 19, 2019, the applicant acknowledged that three of the patient support letters submitted in Exhibit C.3-3 were from patients who had previously signed letters of support for Project I.D. #F-11435-17 and stated those letters should not be considered. The Project Analyst did not consider any of the four patient support letters that are alleged to be duplicates.

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

- Project I.D. #J-11435-17 projected 32 patients would transfer from other facilities to the proposed FKC West Johnston. Those projections were determined to be reasonable and adequately supported and the applicant proposes no changes in the current application which would affect that determination.
- The applicant adequately documents additional patients are willing to consider transferring care to FKC West Johnston.

Projected Utilization

On Form C in Section Q, the applicant projects to serve 45 Johnston County patients by the end of the first operating year and 49 Johnston County patients by the end of the second operating year following project completion.

In Section C, pages 16-17, the applicant provides the assumptions and methodology it uses to project utilization, which are summarized below.

- The applicant begins its utilization projections with the 32 Johnston County ESRD patients it projected to serve at FKC West Johnston upon offering services as part of Project I.D. #J-11435-17.
- The applicant adds 10 additional Johnston County dialysis patients who did not sign letters of support for Project I.D. #J-11435-17 but who have since signed letters of support and indicated a willingness to consider transferring care to FKC West Johnston.
- The applicant assumes the Johnston County patient population projected to be served at FKC West Johnston will increase annually at a rate of 8.3 percent, which is the Five Year Average Annual Change Rate (AACR) for Johnston County published in the July 2019 SDR.
- The applicant assumes both Project I.D. #J-11435-17 and the current proposed project will be developed concurrently and completed at the same time.
- Both projects are scheduled for completion on December 31, 2020. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 17, the applicant provides the calculations it uses to project the patient census for OY1 and OY2, as summarized in the table below.

FKC West Johnston Utilization Projections	
Starting point of calculations is Johnston County patients who are projected as the starting census for FKC West Johnston in Project I.D. #J-11435-17.	32
10* Johnston County patients who signed letters of support indicating they'd consider transferring care to FKC West Johnston are added to the projected FKC West Johnston starting patient census as of December 31, 2020. This is the starting census for the project	$32 + 10 = 42$
Johnston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (8.3%). This is the projected census on December 31, 2021 (end of OY1).	$42 \times 1.083 = 45.5$
Johnston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (8.3%). This is the projected census on December 31, 2022 (end of OY2).	$45.5 \times 1.083 = 49.3$

*On page 17, the table narrative states 14 patients are added to the previous projected census, but the calculations appear to add only 10 patients. In the remainder of the application, all projections appear to have used 10 patients. The Project Analyst assumes the use of 14 patients in this location of the table is a typo.

The applicant rounds down and projects to serve 45 patients on 14 stations, which is 3.21 patients per station per week ($45 \text{ patients} / 14 \text{ stations} = 3.21$), by the end of OY1 and 49 patients on 14 stations, which is 3.5 patients per station per week ($49 \text{ patients} / 14 \text{ stations} = 3.5$), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Comments submitted during the public comment period suggested that since duplicate patient support letters were included with this application, the Agency should find the application nonconforming. However, the application projects that only 10 of the 14 patients (including alleged duplicates) who signed letters of support will transfer their care as part of the assumptions and methodology. Thus, discounting the four alleged duplicate letters of support does not impact the assumptions and methodology used to project utilization.

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

- The applicant uses projections previously determined to be reasonable and adequately supported in Project I.D. #J-11435-17.
- The applicant provides adequate documentation to support the projection of additional patients who will consider transferring to FKC West Johnston.
- The applicant uses the Five Year AACR for Johnston County as published in the July 2019 SDR to project growth of Johnston County residents.
- The applicant's projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 20, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 55, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

FKC West Johnston Projected Payor Mix CY 2022	
Payment Source	% Patients
Self-Pay	0.57%
Insurance*	5.92%
Medicare*	68.62%
Medicaid*	3.76%
Medicare/Commercial	19.39%
Misc. (including VA)	1.75%
Total	100.00%

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.

- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

TRC does not propose to offer home hemodialysis or home peritoneal dialysis training and support at CD as part of this application.

In Section A, page 9, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with TRC to refer to itself or its facilities. References to DaVita should be interpreted to mean TRC unless otherwise specified.

Patient Origin

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

The following table illustrates projected patient origin.

CD Patients by County		
Operating Year 2 – CY 2022		
County	# of Patients*	% of Patients
Johnston	6	17.6%
Nash	6	17.6%
Wake	1	2.9%
Wilson	21	61.7%
Total	34	100.0%

Source: Section C, pages 19 and 21.

*The number of patients from Johnston County and Wilson County are not consistent on pages 19 and pages 20-21. The Project Analyst assumed the information on pages 20-21 was the correct information and recalculated the percentages in this table accordingly.

In Section C, pages 19-21, the applicant provides the assumptions and methodology it uses to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 21-22, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 21, the applicant states:

“The July 2019 SDR indicates in Table D that there is a projected station deficit of 12 stations in Johnston County. Fresenius Medical Care is the only provider of dialysis services in Johnston County. They currently operate three facilities and are approved to develop two additional facilities.... The development of a sixth dialysis facility by DaVita will eliminate the majority of the station deficit in Johnston County. This will result in providing future dialysis patients a choice of providers....

Total Renal Care of North Carolina has identified 41 in-center patients who live in Johnston County or live in a county contiguous to Johnston County that have signed letters indicating an interest in transferring their care to the proposed Clayton Dialysis. All of the patients indicated that transferring from the facility where they currently receive dialysis will be more convenient for them.”

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

- The applicant provides letters of support from 41 dialysis patients currently residing in Johnston, Nash, Wake, or Wilson counties who state they will consider transferring their care to the proposed facility based on convenience.
- The applicant reasonably projects that the utilization rate of the new facility will be 3.3 patients per station per week at the end of operating year one, which exceeds the required minimum operating standard promulgated in 10A NCAC 14C .2203(b).

Projected Utilization

On Form C in Section Q, the applicant projects to serve 33 patients by the end of both the first and second operating years following project completion.

In Section C, pages 19-21, the applicant provides the assumptions and methodology it uses to project utilization, which are summarized below.

- 41 patients signed letters of support stating they would consider transferring their care to the proposed facility. The 41 patients receive dialysis services at five different facilities: Forest Hills Dialysis and Wilson Dialysis in Wilson County, Wake Forest Dialysis and Oak City Dialysis in Wake County, and Southpoint Dialysis in Durham County. Of those 41 patients, 27 patients reside in Wilson County, 6 patients reside in Nash County, 5 patients reside in Johnston County, and 3 patients reside in Wake County.
- The applicant assumes 33 of those 41 patients will transfer their care to CD once it opens and begins its utilization projections with this number. The applicant assumes all 5

Johnston County patients will transfer care, along with 1 Wake County patient, 6 Nash County patients, and 21 Wilson County patients.

- The applicant assumes the Johnston County patient population will increase annually at a rate of 8.3 percent, which is the Five Year Average Annual Change Rate (AACR) for Johnston County published in the July 2019 SDR.
- The applicant assumes no growth for the patient population residing outside of Johnston County and adds them to the calculations where appropriate.
- The project is scheduled for completion on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 21, the applicant provides the calculations it uses to project the patient census for OY1 and OY2, as summarized in the table below.

CD Utilization Projections	
Starting point of calculations is the 33 patients projected to transfer care to CD. This is the patient census on January 1, 2021 and the starting census for this project.	33
Johnston County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR of 8.3%.	$5 \times 1.083 = 5.42$
The 28 patients from other counties are added to the patient population. This is the projected census on December 31, 2021 (end of OY1).	$5.42 + 28 = 33.42$
Johnston County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR of 8.3%.	$5.42 \times 1.083 = 5.86$
The 28 patients from other counties are added to the patient population. This is the projected census on December 31, 2022 (end of OY2).	$5.86 + 28 = 33.86$

The applicant rounds down and projects to serve 33 patients on 10 stations, which is 3.3 patients per station per week ($33 \text{ patients} / 10 \text{ stations} = 3.3$), by the end of both OY1 and OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on documented patient support.
- The applicant uses the Five Year AACR for Johnston County as published in the July 2019 SDR to project Johnston County patient growth.
- The applicant does not project growth for patients residing outside of Johnston County.

- The applicant’s projected utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 23, 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.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work.

...

Clayton Dialysis will help uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L, page 51, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

CD Projected Payor Mix CY 2022	
Payment Source	% Total Patients
Self-Pay/Charity	0.0%
Insurance*	10.5%
Medicare*	79.9%
Medicaid*	6.3%
Other	3.3%
Total	100.0%

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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 – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

According to the July 2019 SDR, SW Wake had 30 certified dialysis stations as of December 31, 2018. Upon completion of this project and related projects, SW Wake will have 30 certified dialysis stations.

In Section D, page 24, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. The applicant states the proposed station relocation is scheduled to be completed on December 31, 2020, but the facility currently demonstrates a need for five additional stations via the facility need methodology. The applicant states it will submit an application for the October 1, 2019 review period, proposing to add four stations at SW Wake, which will immediately backfill the stations proposed to be relocated (Project I.D. #J-11778-19, proposing to add four stations to SW Wake via the facility need methodology, was submitted to the Agency on September 16, 2019 for the October 1, 2019 review cycle and was conditionally approved on December 17, 2019). The applicant provides the facility need calculations showing the need for five additional stations at SW Wake via the facility need methodology on page 25.

In Section D, page 27, the applicant projects to be serving 112 patients at SW Wake as of the date of the station relocation. In Section D, pages 26-27, the applicant provides the assumptions and methodology it uses to project utilization, which are summarized below.

- The applicant begins its utilization projections with the Wake County patient population dialyzing at SW Wake as of June 30, 2019.
- The applicant states it was serving two patients from Johnston County at SW Wake as of June 30, 2019. The applicant assumes no growth for the Johnston County patient population dialyzing at SW Wake but assumes the patients from Johnston County will continue to utilize SW Wake by choice and adds them to the calculations where appropriate.
- As part of Project I.D. #J-11271-16, eight patients were projected to transfer from SW Wake to FKC Rock Quarry upon project completion. The applicant projects these patients to transfer as of December 31, 2020 and subtracts them from the calculations where appropriate.
- The applicant assumes that the Wake County patient population dialyzing at SW Wake will increase annually at a rate of 3.6 percent, which is the Five Year AACR for Wake County published in the July 2019 SDR.
- The applicant assumes Project I.D. #J-11271-16, Project I.D. #J-11435-17, and the current proposed project will be developed concurrently and completed at the same time.
- The applicant does not include anything about the development of Project I.D. #J-11778-19, as it had not yet been submitted at the time the current application was submitted. However, according to Project I.D. #J-11778-19, it is projected to be completed at the same time as the other projects, and it is reasonable to assume that project will also be developed concurrently.
- All projects are scheduled for completion on December 31, 2020.

In Section D, page 27, the applicant provides the calculations it uses to project the patient census at the time of the station transfer from SW Wake to FKC West Johnston, as shown in the table below.

SW Wake Utilization Projections	
Starting point of calculations is Wake County patients dialyzing at SW Wake as of June 30, 2019.	112
Wake County patient population is projected forward by six months to December 31, 2019, using the one half of Five Year AACR (3.6%).	$112 \times 1.018^* = 114.02$
Wake County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.6%).	$114.02 \times 1.036 = 118.1$
Nine Johnston County patients projected to transfer care to FKC West Johnston are subtracted from calculations as of December 31, 2020.	$118.1 - 8 = 110.1$
The two patients from Johnston County are added to the patient population. This is the projected census on December 31, 2020, when the stations will be relocated.	$110.1 + 2 = 112.1$

*On page 27, the calculations for this part of the table appear to use the full Five Year AACR for Wake County of 3.6 percent, while the narrative states the projections are based on one half of the full growth rate. The mathematical calculations are correct if one half of the full growth rate (1.8 percent) is used. The Project Analyst assumes the use of the 3.6 percent growth rate in this location of the table is a typo.

The applicant projects to be serving 112 patients on 30 stations at SW Wake as of January 1, 2021, which is a utilization rate of 93.3 percent or 3.73 patients per station per week.

In Section D, page 26, the applicant states there will be no impact on access by medically underserved groups to the services to be transferred because the applicant projects that the stations will be immediately backfilled.

Conclusion

The Agency reviewed the:

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

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

- The needs of the population currently using the services to be 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.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

Forest Hills Dialysis

According to the July 2019 SDR, FHD had 31 certified stations as of December 31, 2018. Project I.D. #L-11438-17, to develop Kenly Dialysis in Wilson County, is approved but not yet developed. That project proposed to relocate five stations from FHD and is projected to offer services beginning January 1, 2020. At the completion of Project I.D. #F-11438-17, FHD will have 26 certified stations. In this application, the applicant proposes to relocate five stations to develop Clayton Dialysis, which will leave FHD with 26 stations upon completion of this project and associated projects.

In Section D, pages 27-28, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 28, the applicant states that, due to projected population growth at FHD, it will submit additional applications for dialysis stations as the facility approaches capacity.

In Section D, pages 27-28, the applicant provides the assumptions and methodology used to project utilization, as discussed below.

- The applicant states 113 patients were dialyzing at FHD on December 31, 2018. 103 of those patients were Wilson County residents and 10 patients are from other counties.
- The applicant projects the Wilson County patient population of FHD will grow at a rate of 4.2 percent, which is the Five Year AACR for Wilson County as published in the July 2019 SDR.
- The applicant projects no growth for patients residing outside of Wilson County, but adds those patients to the calculations where appropriate.
- The applicant projects 19 patients from FHD will transfer care to Kenly Dialysis once it opens and subtracts those 19 patients from the calculations at the projected certification date for Kenly Dialysis (January 1, 2020).
- The applicant projects 13 Wilson County patients and 5 patients from other counties dialyzing at FHD will transfer care to CD once it opens and subtracts those patients from the calculations at the projected certification date for CD (January 1, 2021).

In Section D, page 28, the applicant provides the calculations it uses to project the patient census for FHD at the time of the station transfer and during OY1 and OY2 of the proposed project, as shown in the table below.

FHD Utilization Projections	
Starting point of calculations is the 103 Wilson County patients dialyzing at FHD as of December 31, 2018.	103
Wilson County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (4.2%).	$103 \times 1.042 = 107.33$
The 19 patients projected to transfer care to Kenly Dialysis upon project completion are subtracted from the Wilson County patient population dialyzing at FHD as of January 1, 2020.	$107.33 - 19 = 88.33$
Wilson County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.2%).	$88.33 \times 1.042 = 92.04$
The 13 Wilson County patients and 5 patients from other counties projected to transfer care to CD upon project completion are subtracted from the patient population dialyzing at FHD.	$92^* - 13 = 79$ $10 - 5 = 5$
The remaining patients from other counties are added. This is the projected census on December 31, 2020, when the stations will be relocated.	$79 + 5 = 84$
Wilson County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.2%).	$79 \times 1.042 = 82.32$
The patients from other counties are added. This is the projected census on December 31, 2021 (end of OY1).	$82.32 + 5 = 87.32$
Wilson County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.2%).	$82.32 \times 1.042 = 85.78$
The patients from other counties are added. This is the projected census on December 31, 2022 (end of OY2).	$85.78 + 5 = 90.78$

*The applicant appears to have made a typo in this portion of the calculation which affects the result. On page 28, the applicant lists this number as 91, not 92. The Project Analyst completed the remaining calculations with the correct numbers.

The combined calculations of the applicant and the Project Analyst result in a projection to serve 84 patients on 21 stations, which is 4.0 patients per station per week ($84 \text{ patients} / 21 \text{ stations} = 4.0$), for a utilization rate of 100.0 percent on the date of the station transfer. By the end of OY1, the facility is projected to serve 87 patients on 21 stations, which is 4.14 patients per station per week ($87 \text{ patients} / 21 \text{ stations} = 4.14$), for a utilization rate of 103.5 percent, and 90 patients on 21 stations, which is 4.29 patients per station per week ($90 \text{ patients} / 21 \text{ stations} = 4.29$), for a utilization rate of 107.3 percent, by the end of OY2. On page 28, the applicant states it will submit applications for more stations based on facility need as the patient population increases.

Wilson Dialysis

According to the July 2019 SDR, WD had 40 certified stations as of December 31, 2018. WD is the subject of two projects which are approved as of the date of these findings but not yet developed which will impact the number of certified stations at WD:

- Project I.D. #L-11438-17 (relocate five stations to develop Kenly Dialysis)
- Project I.D. #L-11591-18 (add two stations)

At the completion of the two previously approved but not yet developed projects, WD will have 37 certified stations. The applicant proposes to relocate five stations to develop CD, which will leave WD with 32 stations upon completion of this project and associated projects.

In Section D, pages 28-30, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 30, the applicant states that, due to projected population growth at WD, it will submit additional applications for dialysis stations as the facility approaches capacity.

In Section D, pages 28-30, the applicant provides the assumptions and methodology it uses to project utilization, as discussed below.

- The applicant states 126 patients were dialyzing at WD on December 31, 2018. 116 of those patients were Wilson County residents and 10 patients are from other counties.
- The applicant projects the Wilson County patient population of WD will grow at a rate of 4.2 percent, which is the Five Year AACR for Wilson County as published in the July 2019 SDR.
- The applicant projects no growth for patients residing outside of Wilson County, but adds those patients to the calculations where appropriate.
- The applicant projects 13 Wilson County patients and 1 patient from another county dialyzing at WD will transfer care to Kenly Dialysis once it opens and subtracts those patients from the calculations at the projected certification date for Kenly Dialysis (January 1, 2020).
- The applicant projects 14 Wilson County patients and 5 patients from other counties dialyzing at WD will transfer care to CD once it opens and subtracts those patients from the calculations at the projected certification date for CD (January 1, 2021).

On pages 28-30, the applicant lists the number of patients from other counties dialyzing at WD who may transfer care to CD as anywhere from three patients to five patients, depending on where the information is obtained. Based on the table provided by the applicant in Section C, page 20, and based on a review of the patient letters of support in Exhibit C-3, the correct number is four patients.

In Section D, pages 29-30, the applicant provides the calculations it uses to project the patient census for WD at the time of the station transfer and during OY1 and OY2 of the proposed project, as shown in the table below. The Project Analyst uses the correct number of patients

from other counties projected to transfer care to CD when the calculations on pages 29-30 list the erroneous number.

WD Utilization Projections	
Starting point of calculations is the 116 Wilson County patients dialyzing at WD as of December 31, 2018.	116
Wilson County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (4.2%).	$116 \times 1.042 = 120.87$
The 13 Wilson County patients and 1 patient from another county projected to transfer care to Kenly Dialysis upon project completion are subtracted from the patient population dialyzing at WD as of January 1, 2020.	$120.87 - 13 = 107.87$ $10 - 1 = 9$
Wilson County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.2%).	$107 \times 1.042 = 111.49$
The 14 Wilson County patients and 4 patients from other counties projected to transfer care to CD upon project completion are subtracted from the patient population dialyzing at WD.	$111.49 - 14 = 97.49$ $9 - 4 = 5$
The remaining patients from other counties are added. This is the projected census on December 31, 2020, when the stations will be relocated.	$97.49 + 5 = 102.49$
Wilson County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.2%).	$97 \times 1.042 = 101.07$
The patients from other counties are added. This is the projected census on December 31, 2021 (end of OY1).	$101.07 + 5 = 106.07$
Wilson County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.2%).	$101.07 \times 1.042 = 105.32$
The patients from other counties are added. This is the projected census on December 31, 2022 (end of OY2).	$105.32 + 5 = 110.32$

The combined calculations of the applicant and the Project Analyst result in a projection to serve 102 patients on 32 stations, which is 3.19 patients per station per week ($102 \text{ patients} / 32 \text{ stations} = 3.19$), for a utilization rate of 79.8 percent on the date of the station transfer. By the end of OY1, the facility is projected to serve 106 patients on 32 stations, which is 3.31 patients per station per week ($106 \text{ patients} / 32 \text{ stations} = 3.31$), for a utilization rate of 82.8 percent, and 110 patients on 32 stations, which is 3.44 patients per station per week ($110 \text{ patients} / 32 \text{ stations} = 3.44$), for a utilization rate of 86.0 percent, by the end of OY2. On page 30, the applicant states it will submit applications for more stations based on facility need as the patient population increases.

In Section C, page 20, the applicant states 27 patients residing in Wilson County signed letters of support indicating an interest in transferring their care to CD and projects only 21 patients residing in Wilson County to transfer their care to CD. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. However, on pages 28-30, the applicant projects all 27 Wilson County patients to transfer care to CD.

In Section C, page 20, the applicant states:

“We cannot determine which of the patients will transfer, since all patients have a choice of which facility to receive their dialysis services and will make that determination at a time prior to the opening of the facility.”

The assumptions and methodology used to project utilization at the facilities losing stations conflicts with the utilization projections found on pages 20-21 of the application. Adding three Wilson County patients back to each facility’s projections will increase the projected utilization for each facility. However, that change does not impact the determination of conformity with this criterion.

Projected utilization for both FHD and WD is reasonable and adequately supported for the following reasons:

- The applicant uses the Five Year AACR for Wilson County as published in the July 2019 SDR to project patient utilization.
- The applicant does not project growth for patients residing outside of Wilson County.
- The applicant accounts for patients who are proposed to transfer care to a different facility as part of projects under development.
- Any errors and typos in the application do not impact the determination that projected utilization is reasonable and adequately supported.

In Section D, page 30, the applicant states:

“Both Wilson Dialysis and Forest Hills Dialysis, by policy, will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.

Both Wilson Dialysis and Forest Hills Dialysis will continue to assist uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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.

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

In Section E, page 29, 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 maintaining the status quo fails to account for patient growth in the area of FKC West Johnston and will result in more patients than the facility will have capacity for; therefore, this is not an effective alternative.
- **Relocate More Than Four Stations:** the applicant states it must demonstrate the need for the stations it proposes to relocate, and it cannot demonstrate the need to relocate more than four stations; therefore, this is not an effective alternative.
- **Relocate Fewer Than Four Stations:** the applicant states relocating fewer than four stations will not meet the needs of the growing patient population in the area of FKC West Johnston; therefore, this is not an effective alternative.

On pages 29-30, the applicant states its proposal is the most effective alternative because it is the most cost-effective way to meet the need for additional dialysis stations to serve the projected patient population.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 reasons stated above.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

In Section E, page 32, 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 maintaining the status quo leaves a need for dialysis stations unmet and doesn't allow patients in Johnston County a choice of providers; therefore, this is not an effective alternative.
- **Locate the Facility in a Different Area of Johnston County:** The applicant states that, based on the location of the patients who provided letters of support in Exhibit C-3, and based on the proposed facility's location in an area of high population growth, developing the facility in a different part of Johnston County is not an effective alternative.

On pages 32-33, the applicant states its proposal is the most effective alternative because it will address a projected dialysis station deficit in Johnston County and allow patients a choice of providers.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost will be \$15,000 for patient chairs, patient TVs, and water treatment system supplies. On Form F.1b in Section Q, the applicant does not project any other changes to capital expenditure projections made in Project I.D. #J-11435-17. In Section Q, the applicant provides the assumptions it uses to project the capital cost.

In Section F, pages 32-33, the applicant states it is providing updated start-up expenses and initial operating expenses since the information provided by the applicant in Project I.D. #J-11435-17 assumed only 10 stations. In Project I.D. #J-11435-17, the applicant projected \$122,469 in start-up expenses and \$1,016,680 for eight months of initial operating expenses, for a total working capital cost of \$1,139,149. In the current application, on pages 32-33, the applicant projects \$206,930 in start-up expenses and \$899,775 for six months of initial operating expenses, for a total working capital cost of \$1,106,706. On pages 33-35, the applicant provides the assumptions and methodology it uses to project the working capital needs of the project.

Availability of Funds

In Section F, pages 31-32 and 35-36, the applicant states it will fund all capital and working capital costs of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the applicant's parent company, authorizing the use of accumulated reserves for the capital needs of the project, as well as "...any start-up expenses and initial operating expenses as may be needed for this project."

The letter in Exhibit F-2 further states:

"This project is to be funded through Fresenius Medical Care Holdings, Inc., accumulated reserves. Our 2017 Consolidated Balance Sheet reflects more than \$1.8 billion in cash, and total assets exceeding \$20 billion."

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FKC West Johnston	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	6,474	7,011
Total Gross Revenues (Charges)	\$40,727,708	\$44,108,107
Total Net Revenue	\$1,972,220	\$2,135,915
Average Net Revenue per Treatment	\$305	\$305
Total Operating Expenses (Costs)	\$1,799,551	\$1,880,345
Average Operating Expense per Treatment	\$278	\$268
Net Income/Profit	\$172,669	\$255,569

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- 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.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Construction and Site Preparation Costs	\$1,651,263
Architect and Engineering Fees	\$145,700
Medical Equipment	\$217,913
Non-Medical Equipment/Furniture	\$466,355
Interest During Construction	\$37,218
Total	\$2,518,449

In Section Q, the applicant provides the assumptions it uses to project the capital cost.

In Section F, page 35, the applicant projects start-up costs will be \$166,653 and initial operating expenses will be \$654,495 for a total working capital of \$821,148. On page 36, the applicant provides the assumptions and methodology it uses to project the working capital needs of the project.

Availability of Funds

In Section F, pages 34 and 36, the applicant states it will fund both the capital and working capital costs of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., TRC's parent company, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc.,

which showed that as of December 31, 2018, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. On Form F.2 in Section Q, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
CD	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	4,891	4,891
Total Gross Revenues (Charges)	\$1,736,102	\$1,736,102
Total Net Revenue	\$1,811,661	\$1,811,661
Average Net Revenue per Treatment	\$370	\$370
Total Operating Expenses (Costs)	\$1,308,991	\$1,326,266
Average Operating Expense per Treatment	\$268	\$271
Net Income/Profit	\$502,671	\$485,396

On Form F.2, the applicant appears to have erroneously added its bad debt to its gross revenues instead of subtracting the bad debt from the gross revenue. Non-competitive applications from DaVita submitted during the same review cycle subtracted the bad debt from the gross revenues. Additionally, previous and subsequent applications submitted by DaVita subtract the bad debt from the gross revenues. The Project Analyst prepared a revised version of the table above, assuming that the addition of bad debt instead of the subtraction of bad debt was a typographical error. The typographical error does not change the outcome of this decision. The revised table is shown below.

Projected Revenues and Operating Expenses (REVISED BY ANALYST)		
CD	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	4,891	4,891
Total Gross Revenues (Charges)	\$1,736,102	\$1,736,102
Total Net Revenue	\$1,660,542	\$1,660,542
Average Net Revenue per Treatment	\$340	\$340
Total Operating Expenses (Costs)	\$1,308,991	\$1,326,266
Average Operating Expense per Treatment	\$268	\$271
Net Income/Profit	\$351,551	\$334,276

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the 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.

C – Both Applications

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

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Johnston County as of December 31, 2018. All existing and approved facilities and stations in Johnston County are affiliated with BMA.

Johnston County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Location	# of Certified Stations	# In-Center Patients	Utilization
FKC West Johnston*	Garner	0	0	0.00%
FKC Selma*	Selma	0	0	0.00%
FMC Four Oaks	Four Oaks	22	65	73.86%
FMC Stallings Station**	Clayton	24	87	90.63%
FMC Stallings Station*	Clayton	0	0	0.00%
Johnston Dialysis Center	Smithfield	31	107	86.29%

Source: July 2019 SDR, Table B.

* Facility under development or not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. #J-11707-19, this facility is being relocated to a new location.

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

In Section G, pages 40-41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County. The applicant states:

“This is an application to relocate four dialyiss [sic] stations to FKC West Johnston, a CON approved, but not yet developed facility. The July 2019 SDR reports that Johnston County has a defici[t] of 12 dialysis stations. This is an effort to address some portion of that deficit.

To the extent that the SDR identifies a station deficit, approval of this application will not create a station surplus in Johnston County, this application will not duplicate services.

Further, BMA has identified...dialysis patients who have expressed their desire to transfer their care to this facilitiy [sic] upon completion of the project. These patients have expressed that this facility is closer to their residence location (than their current dialysis facility) and would be more convenient for their care.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would reduce part of the existing deficit of dialysis stations as published in the July 2019 SDR for Johnston County.
- The proposal would not create a surplus of dialysis stations in Johnston County.

- The applicant adequately demonstrates that the relocated stations are needed in addition to the existing or approved stations and facilities in Johnston County. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

In Section G, page 39, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Johnston County. The applicant states:

“The July 2019 SDR indicates in Table D that Johnston County has a Projected Station Deficit of 12 stations. Since there is a station deficit in Johnston County, then the development of a new dialysis facility in Johnston County will not unnecessarily duplicate the three existing and two approved facilities in the Johnston County service area.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would reduce much of the existing deficit of dialysis stations as published in the July 2019 SDR for Johnston County.
- The proposal would not create a surplus of dialysis stations in Johnston County.
- The applicant adequately demonstrates the proposed new dialysis facility is needed in addition to the existing or approved dialysis facilities in Johnston County. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

In Section H, page 43, the applicant states the number of projected FTEs has not changed from the projections in Project I.D. #F-11435-17, but it has updated its staffing table on Form H in Section Q to provide updated salary information. On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

FKC West Johnston Projected FTEs – Both OYs 1 & 2 (CYs 2021 & 2022)	
Position	FTEs
Administrator	1.00
Registered Nurses	1.50
Patient Care Technicians	4.00
Dietitian	0.40
Social Worker	0.40
Maintenance	0.60
Administration/Business Office	0.75
FMC Director Operations	0.15
In-Service	0.15
Chief Technician	0.15
Total	9.10

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 42, the applicant describes the methods it uses to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibits H-3.1 and H-3.2. In Section H, page 43, the applicant identifies the proposed medical director.

In Exhibit H-4, the applicant provides a letter from the proposed medical director expressing his support for the proposed project and indicating his intent to serve as medical director for the facility.

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
- 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.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

CD Projected Staffing – Both OYs (CYs 2021 and 2022)	
	# FTE Staff
Administrator	1.0
Registered Nurses	2.0
Patient Care Technicians	4.0
Dietician	0.5
Social Worker	0.5
Administration/Business Office	0.5
Biomedical Technician	0.5
TOTAL	9.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 40-41, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1, H-2, and H-3. In Section H, page 41, the applicant identifies the proposed medical director. In Exhibit H-4, the applicant provides a letter from the proposed medical director expressing his support for the proposed project and indicating his intent to serve as medical director for the facility.

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

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 – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

In Section I, pages 44-45, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service will be made available:

FKC West Johnston – Ancillary and Support Services	
Services	Provider
Self-care training (in-center)	FMC Stallings Station
Home training	
HH	FMC Stallings Station
PD	FMC Stallings Station
Accessible follow-up program	FMC Stallings Station
Psychological counseling	Johnston County Mental Health
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	UNC Johnston Health, WakeMed
Emergency care	Provided on site by staff prior to ambulance transport to hospital
Blood bank services	UNC Johnston Health
Diagnostic and evaluation services	UNC Johnston Health, WakeMed
X-ray services	UNC Johnston Health, WakeMed
Laboratory services	On site
Pediatric nephrology	UNC Healthcare
Vascular surgery	Rex Vascular, Raleigh Access Center
Transplantation services	Duke University Medical Center*
Vocational rehabilitation & counseling	Johnston County Vocational Rehabilitation Services
Transportation	JCATS, Lyft, Uber

*The table on page 45 lists UNC Healthcare; however, Exhibit I-4 is a contract between FKC West Johnston and Duke University Medical Center.

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, page 45, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

In Section I, page 42, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service will be made available:

CD – Ancillary and Support Services	
Services	Provider
Self-care training (in-center)	On site
Home training	
HH	Wilson Dialysis
PD	Wilson Dialysis
Accessible follow-up program	Wilson Dialysis
Psychological counseling	On site by registered nurse
Isolation – hepatitis	On site
Nutritional counseling	On site by registered dietician
Social Work services	On site by MSW
Acute dialysis in an acute care setting	UNC Johnston Health
Emergency care	UNC Johnston Health
Blood bank services	UNC Johnston Health
Diagnostic and evaluation services	UNC Johnston Health
X-ray services	UNC Johnston Health
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	UNC Johnston Health
Vascular surgery	UNC Johnston Health
Transplantation services	Duke Health/Vidant Health
Vocational rehabilitation & counseling	Division of Vocational Rehabilitation
Transportation	Johnston County DSS

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 42, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits H-4 and I-1.

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

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 – Both Applications

Neither applicant projects 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, neither applicant projects 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 – Both Applications

Neither applicant is 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 – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17.

In Section K, page 48, the applicant states it does not propose to construct new space or upfit or renovate existing space as part of the proposed project. Line drawings are provided in Exhibit K-1.

Project I.D. #J-11435-17 was conforming to this criterion, and the applicant does not propose to change the clinical space of the proposed facility or make any other changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

In Section K, page 45, and Exhibit K-1, the applicant states the project involves constructing 10,182 square feet of new space to house the proposed facility, including 8,837 square feet of treatment area. Line drawings are provided in Exhibit K-1.

In Section B, pages 15-16, and Section K, page 45, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section B, page 14, and Section K, page 46, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section B, pages 15-16, and Section K, page 46, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section K, pages 46-47, 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 water, sewer and waste disposal, and power at the site. The applicant provides supporting documentation in Exhibit K-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

FKC West Johnston is not an existing facility. In Section L, page 54, the applicant provides the historical payor mix at SW Wake during CY 2018, as shown in the table below.

SW Wake Historical Payor Mix CY 2018	
Payment Source	% Patients
Self-Pay/Indigent/Charity	3.05%
Insurance*	5.19%
Medicare*	38.80%
Medicaid*	15.64%
Medicare/Commercial	30.25%
Misc. (including VA)	7.07%
Total	100.00%

*Including any managed care plans.

In Section L, pages 52-53, the applicant provides the following comparison.

	% of Total Patients Served by SW Wake during the Last Full OY	% of the Population of Wake County	% of the Population of Johnston County
Female	43.3%	51.3%	51.0%
Male	56.7%	48.7%	49.0%
Unknown	0.0%	0.0%	0.0%
64 and Younger	41.2%	88.4%	87.0%
65 and Older	58.8%	11.6%	13.0%
American Indian	0.0%	0.8%	0.9%
Asian	1.8%	7.5%	0.9%
Black or African-American	58.8%	21.0%	16.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%	0.1%
White or Caucasian	28.9%	68.1%	67.9%
Other Race	10.5%	--	13.7%
Declined / Unavailable	--	2.5%	--

Sources: BMA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

CD is not an existing facility. In Section L, pages 49-50, the applicant provides the historical payor mix at FHD and WD during CY 2018, as shown in the table below.

Historical Payor Mix CY 2018		
Payment Source	FHD	WD
	% Patients	% Patients
Self-Pay/Indigent/Charity	0.0%	0.0%
Insurance*	11.5%	9.5%
Medicare*	80.5%	79.4%
Medicaid*	4.4%	7.9%
Other	3.5%	3.2%
Total	100.0%	100.0%

*Including any managed care plans.

In Section L, pages 48-49, the applicant provides the following comparison.

	% of Total Patients Served by FHD during the Last Full OY	% of Total Patients Served by WD during the Last Full OY	% of the Population of Johnston County
Female	49.5%	39.4%	51.0%
Male	50.5%	60.6%	49.0%
Unknown	0.0%	0.0%	0.0%
64 and Younger	39.6%	38.5%	86.7%
65 and Older	60.4%	61.5%	13.3%
American Indian	0.0%	0.0%	0.9%
Asian	1.0%	0.0%	0.9%
Black or African-American	81.2%	79.8%	16.8%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.1%
White or Caucasian	14.9%	12.5%	79.1%
Other Race	3.0%	7.7%	2.2%
Declined / Unavailable	--	--	--

Sources: TRC Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

FKC West Johnston is not an existing facility. Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 54, that no North Carolina BMA facilities have any obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 55, the applicant states that during the last five years no patient civil rights access complaints have been filed against any BMA facilities located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

CD is not an existing facility. Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 50, that FHD and WD have no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against either FHD or WD.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

In Section L, page 55, 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 illustrated in the following table.

FKC West Johnston Projected Payor Mix CY 2022	
Payment Source	% Patients
Self-Pay/Indigent/Charity	0.57%
Insurance*	5.92%
Medicare*	68.62%
Medicaid*	3.76%
Medicare/Commercial	19.39%
Misc. (including VA)	1.75%
Total	100.00%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects 0.57 percent of total services will be provided to self-pay, indigent, and charity care patients; 88.01 percent to patients who will have some or all their care paid for by Medicare; and 3.76 percent to Medicaid patients.

On page 55, the applicant provides the assumptions and methodology it uses 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 for the following reasons:

- The projected payor mix is based in part on the historical payor mix of FMC Stallings Station, the BMA facility closest in location to the proposed FKC West Johnston facility.
- The projected payor mix has been updated from the projections submitted in Project I.D. #J-11435-17 to reflect the most current information on the historical payor mix of FMC Stallings Stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

In Section L, page 51, 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 illustrated in the following table.

CD Projected Payor Mix CY 2022	
Payment Source	% Total Patients
Self-Pay/Indigent/Charity	0.0%
Insurance*	10.5%
Medicare*	79.9%
Medicaid*	6.3%
Other	3.3%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 79.9 percent of services will be provided to Medicare patients and 6.3 percent of services to Medicaid patients.

On page 51, the applicant provides the assumptions and methodology it uses 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 for the following reasons:

- The projected payor mix is based on the historical payor mix for FHD and WD, the facilities from where the stations will be relocated.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

In Section L, page 56, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

In Section L, page 51, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

In Section M, page 58, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

In Section M, page 53, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

C – Both Applications

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

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Johnston County as of December 31, 2018. All existing and approved facilities and stations in Johnston County are affiliated with BMA.

Johnston County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Location	# of Certified Stations	# In-Center Patients	Utilization
FKC West Johnston*	Garner	0	0	0.00%
FKC Selma*	Selma	0	0	0.00%
FMC Four Oaks	Four Oaks	22	65	73.86%
FMC Stallings Station**	Clayton	24	87	90.63%
FMC Stallings Station*	Clayton	0	0	0.00%
Johnston Dialysis Center	Smithfield	31	107	86.29%

Source: July 2019 SDR, Table B.

* Facility under development or not operational at the time of data collection for the July 2019 SDR.

**Per Project I.D. #J-11707-19, this facility is being relocated to a new location.

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

BMA proposes to relocate four dialysis stations from SW Wake to FKC West Johnston, a new 10-station facility approved but not yet developed, for a total of 14 dialysis stations at FKC West Johnston upon completion of this project and Project I.D. #J-11435-17 (develop FKC West Johnston by relocating 10 existing stations from FMC Stallings Station).

In Section N, pages 59-61, 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 59, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Johnston County. The applicant does not project to serve dialysis patients currently

being served by another provider. The projected patient population for the FKC West Johnston facility begins with patients projected to transfer their care and who supported the original CON application, Project ID # J-11435-17, coupled with...new dialysis patients who have expressed similar desires to transfer their care.

...

Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering a convenient venue for dialysis care and treatment, and promoting access to care."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

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

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

TRC proposes to develop CD, a new 10-station dialysis facility in Johnston County, by relocating five existing dialysis stations from FHD and five existing stations from WD. Both FHD and WD are in Wilson County.

In Section N, pages 54-55, 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 54, the applicant states:

“The development of Clayton Dialysis will have no effect on any dialysis facilities located in Johnston County or in counties contiguous to it. This certificate of need application is being submitted in response to a projected station deficit...in Johnston County as indicated in Table D of the July 2019 SDR. The projected station deficit in Johnston County indicates that there is a need for additional dialysis stations. Since there is only one provider in the county at present, this is a great opportunity for patients, referring hospitals and physicians to have a choice of providers.

The bottom line is Clayton 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 other [sic] involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

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

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

C – Both Applications

Project I.D. J-11739-19/FKC West Johnston/Relocate Four Stations from Wake County for a Total of 14 Stations

On Form A in Section Q, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 127 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 66, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in an immediate jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 127 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County

On Form A in Section Q, the applicant identifies the kidney disease treatment facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 107 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, pages 56-57, 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 Waynesville Dialysis Center. The applicant states that all of the problems in each of these facilities have been corrected. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 107 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C – Both Applications

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to all reviews. All applications are conforming to all applicable criteria, as discussed below.

10 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.*
- C- **BMA/FKC West Johnston.** Project I.D. #J-11435-17 was found to be conforming to this Rule, and the applicant proposes no changes in this application which would affect that determination.
- C- **TRC/Clayton Dialysis.** In Section C, page 21, the applicant projects CD will serve 33 patients on 10 stations, or a rate of 3.3 patients per station per week, as of the end of the first operating year following project completion. 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.*
- C- **BMA/FKC West Johnston.** In Section C, page 17, the applicant projects FKC West Johnston will serve 45 patients on 14 stations, or a rate of 3.21 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- NA- **TRC/Clayton Dialysis.** CD is not an existing facility. Therefore, this Rule is not applicable to this review.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- **BMA/FKC West Johnston.** In Section C, pages 16-17, and Exhibit C-3.3, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **TRC/Clayton Dialysis.** In Section C, pages 19-21, and Exhibit C-3, the applicant provides the assumptions and methodology it uses to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and Policy ESRD-2 in the 2019 State Medical Facilities Plan (SMFP), no more than 12 dialysis stations may be approved for relocation to Johnston County in this review. Because the two applications in this review collectively propose to relocate 14 dialysis stations to Johnston County, both applications as submitted cannot be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposals should be approved.

Below is a brief description of each project included in the Comparative Analysis:

- **J-11739-19/Fresenius Kidney Care West Johnston/Relocate** four stations from Southwest Wake Dialysis in Wake for a total of 14 dialysis stations
- **J-11743-19/Clayton Dialysis/Develop** a new 10-station dialysis facility by relocating five stations from Forest Hills Dialysis in Wilson County and five stations from Wilson Dialysis in Wilson County

Conformity with Review Criteria

Each applicant adequately demonstrates the need for their respective proposal and is conforming to all applicable statutory and regulatory review criteria.

Therefore, each application is an equally effective alternative with respect to this comparative factor.

Geographic Accessibility

The July 2019 Semiannual Dialysis Report (SDR) identifies a 12-station deficit in Johnston County. There are currently three existing dialysis facilities in Johnston County – one each in Clayton, Four Oaks, and Smithfield. Two additional dialysis facilities are approved but not developed – one located in Garner and one located in Selma. Additionally, the existing facility in Clayton has been approved relocate to a different site in Clayton but is not yet developed.

BMA/FKC West Johnston proposes to relocate four stations to FKC West Johnston, its facility in Garner which is approved but not yet developed. **TRC/Clayton Dialysis** proposes to develop a new 10-station dialysis facility by relocating 10 stations to a site in Clayton. The two sites are approximately 4.4 miles, or an 8-minute drive, apart.

Therefore, with regard to geographic accessibility, each application is an equally effective alternative with respect to this comparative factor.

Patient Access to a New Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

BMA or an affiliated entity owns and/or operates all existing and approved but not yet developed dialysis facilities in Johnston County.

TRC does not currently own and/or operate any dialysis facilities in Johnston County.

Therefore, with regard to providing ESRD patients with access to a new provider of dialysis services in Johnston County, **TRC/Clayton Dialysis** is the more effective alternative with respect to this comparative factor.

Access to Home Training and Support Services

Generally, the application proposing to offer the most comprehensive home training and support services is the more effective alternative with regard to this comparative factor.

BMA/FKC West Johnston currently refers patients to FMC Stallings Station for home training. It did not project to offer either home hemodialysis or home peritoneal dialysis training and support services as part of Project I.D. #J-11435-17 (to develop FKC West Johnston), and it does not propose to add any home training and support services as part of the current application.

In Section I, page 42, **TRC/Clayton Dialysis** states it will refer patients in need of home hemodialysis or home peritoneal dialysis training and support services to Wilson Dialysis until it offers such services at Clayton Dialysis; however, it does not project to offer any home training and support services as part of the current application.

Therefore, with regard to access to home training and support services, each application is an equally effective alternative with respect to this comparative factor.

Access by Service Area Residents

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

Generally, the application projecting to serve the highest percentage of Johnston County residents is the more effective alternative with regard to this comparative factor since the service area for these proposals is Johnston County.

Percent of Johnston County Residents Projected to be Served – OY 2 (CY 2022)	
Facility	Percentage
BMA/FKC West Johnston	100.0%
TRC/Clayton Dialysis	17.6%

Source: Section C (both applications)

As shown in the table above, **BMA/FKC West Johnston** projects to serve the highest percentage of Johnston County residents during the second full operating year. Therefore, with regard to projected access by Johnston County residents, **BMA/FKC West Johnston** is the more effective alternative with respect to this comparative factor.

Access by Underserved Groups

The term “underserved groups” is defined in G.S. 131E-183(a)(13) as follows:

“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.”

Projected Charity Care

Charity care is care provided to patients without expectation of receiving payment.¹ Generally, the application proposing to provide more charity care to patients is the more effective alternative with regard to this comparative factor.

Charity Care – OY 2 (CY 2022)	
Facility	Amount
BMA/FKC West Johnston	\$34,856
TRC/Clayton Dialysis	\$0

Source: Form F.2 (both applications)

In the table above, **TRC/Clayton Dialysis** does not project to provide charity care. On Form F.2 in Section Q, **TRC/Clayton Dialysis** states charity care, contractual adjustments, and bad debt are all rolled into one category labeled as bad debt, and thus there is no way to determine the amount of actual charity care projected to be provided to patients at **TRC/Clayton Dialysis**.

In Project I.D. #J-11739-19, in Section Q on the Form F.2 Income Statement Assumptions found on page 85, **BMA** states the following:

“The Charity Care line is actually facility contributions to the American Kidney Fund.”

Additionally, during the public comment period, **BMA** submitted comments stating the following:

“BMA has proposed to provide charitable contributions to the American Kidney Fund.”

Contributions to outside organizations, while commendable, is not care provided to patients without expectation of receiving payment. **BMA** offers no additional information in the application as submitted regarding the amount of actual charity care projected to be provided to patients at **BMA/FKC West Johnston**.

¹ See <https://medical-dictionary.thefreedictionary.com/charity+care>

Therefore, with regard to projected charity care for patients, each application is an equally effective alternative with respect to this comparative factor.

Projected Medicare

The following table shows the percent of services projected to be provided to patients having some or all their care paid for by Medicare in the applicant’s second full operating year. Generally, the application projecting to provide a higher percentage of services to patients having some or all their care paid for by Medicare is the more effective alternative with regard to this comparative factor.

Medicare – OY 2 (CY 2022)		
Facility	Payor Category	Percent of Services
BMA/FKC West Johnston	Medicare*, Medicare/Commercial	88.01%
TRC/Clayton Dialysis	Medicare*	79.90%

*Including any managed care plans
Source: Section L (both applications)

As shown in the table above, during the second full operating year, **BMA/FKC West Johnston** projects to provide 88.01 percent of services to Medicare patients, including patients with Medicare managed care plans and patients who have both Medicare and commercial insurance coverage. **TRC/Clayton Dialysis** projects to provide 79.9 percent of services to Medicare patients, including patients with Medicare managed care plans. **BMA/FKC West Johnston** does not explain in the application as submitted what the difference is between its two payor mix categories which involve Medicare. Due to differences in how each application classifies payor categories with regard to the Medicare payor mix, trying to compare the two applications with regard to this comparative factor would be like trying to compare apples to oranges. There is no meaningful way to compare the two applications with regard to this comparative factor. Therefore, with regard to projected Medicare, the applications cannot be compared.

Projected Medicaid

The following table shows the percent of services projected to be provided to Medicaid patients in the applicant’s second full operating year. Generally, the application projecting to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

Medicaid – OY 2 (CY 2022)	
Facility	Percent of Services
BMA/FKC West Johnston	3.76%
TRC/Clayton Dialysis	6.30%

Source: Section L (both applications)

As shown in the table above, during the second full operating year, **TRC/Clayton Dialysis** projects to provide 6.3 percent of services to Medicaid patients and **BMA/FKC West Johnston** projects to provide 3.76 percent of services to Medicaid patients. Therefore, with regard to the projected percent of services provided to Medicaid patients, **TRC/Clayton Dialysis** is the more effective alternative with respect to this comparative factor.

Projected Average Net Revenue per Treatment

The following table shows the projected average net revenue per dialysis treatment in the second full operating year. Generally, the application proposing a lower average net revenue per dialysis treatment is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Dialysis Treatment – OY 2 (CY 2022)			
Facility	Net Revenue	# of Treatments	Average Net Revenue/Treatment
BMA/FKC West Johnston	\$2,135,915	7,011	\$305
TRC/Clayton Dialysis	\$1,660,542	4,891	\$340

Source: Section Q, Form F.2 (both applications)

As shown in the table above, **BMA/FKC West Johnston** projects the lowest average net revenue per treatment in the second operating year. Therefore, with regard to the lowest average net revenue per treatment, **BMA/FKC West Johnston** is the more effective alternative with respect to this comparative factor.

Projected Average Operating Expense per Treatment

The following table shows the projected average operating expense per dialysis treatment in the second full operating year. Generally, the application proposing a lower average operating expense per dialysis treatment is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per Dialysis Treatment – OY 2 (CY 2022)			
Facility	Operating Expense	# of Treatments	Average Operating Expense/Treatment
BMA/FKC West Johnston	\$1,880,345	7,011	\$268
TRC/Clayton Dialysis	\$1,326,266	4,891	\$271

Source: Section Q, Form F.2 (both applications)

As shown in the table above, **BMA/FKC West Johnston** projects the lowest average operating expense per treatment in the second operating year; however, the difference between the two applicants is three dollars. That amount is too small of a difference to conclude with certainty that the application with the lower average operating expense per treatment is the most effective alternative. Therefore, with regard to the lowest average operating expense per treatment, each application is an equally effective alternative with respect to this comparative factor.

SUMMARY

The following table lists the comparative factors and states which applicant is the more effective or less effective alternative with regard to that particular comparative factor. Note: the comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	BMA/FKC West Johnston	TRC/Clayton Dialysis
Conformity with Review Criteria	Equally Effective	Equally Effective
Geographic Accessibility	Equally Effective	Equally Effective
Patient Access to New Provider	Less Effective	More Effective
Access to Home Training and Support Services	Equally Effective	Equally Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Underserved Groups		
Projected Charity Care	Equally Effective	Equally Effective
Projected Medicare	No Comparison Made	No Comparison Made
Projected Medicaid	Less Effective	More Effective
Projected Average Net Revenue per Treatment	More Effective	Less Effective
Projected Average Operating Expense per Treatment	Equally Effective	Equally Effective

Both applications are conforming to all review criteria, and thus all applications are approvable. However, since collectively they propose to relocate a total of 14 dialysis stations to Johnston County and the deficit for Johnston County in the July 2019 SDR is only 12 stations, pursuant to Policy ESRD-2 in the 2019 SMFP only 12 dialysis stations can be approved to be relocated to Johnston County. As shown in the table above:

- **BMA/FKC West Johnston** is the more effective alternative with regard to:
 - Access by Service Area Residents
 - Projected Average Net Revenue per Treatment
- **TRC/Clayton Dialysis** is the more effective alternative with regard to:
 - Patient Access to New Provider
 - Access by Underserved Groups – Projected Medicaid

CONCLUSION

Each application is individually conforming to Policy ESRD-2 in the 2019 SMFP to relocate additional dialysis stations to Johnston County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that proposed projects must be consistent with applicable policies in the 2019 SMFP, and pursuant to Policy ESRD-2, there is a limit of 12 dialysis stations that can be approved by the Healthcare Planning and Certificate of Need Section to be relocated to Johnston County.

In Chapter 14, the 2019 SMFP requires that new dialysis facilities must have a projected need for at least 10 stations, and thus new facilities with fewer than 10 stations cannot be approved. Approval of **TRC/Clayton Dialysis** as submitted would reduce the Johnston County dialysis station deficit from 12 stations to 2 stations and would also allow approval for **BMA/FKC West Johnston** to relocate two of the four stations it proposes to relocate. Conversely, approval of **BMA/FKC West Johnston** as submitted would reduce the Johnston County dialysis station deficit from 12 stations to 8 stations, but it would preclude the approval of **TRC/Clayton Dialysis** altogether.

Both applications are effective alternatives. It is possible to approve the application for **TRC/Clayton Dialysis** while partially approving the application for **BMA/FKC West Johnston**, but it is not possible to approve the application for **BMA/FKC West Johnston** as submitted as well as partially approve

the application for **TRC/Clayton Dialysis**. Because of that, the application for **TRC/Clayton Dialysis** is approved as submitted and the application for **BMA/FKC West Johnston** is approved to relocate two dialysis stations instead of relocating four dialysis stations as proposed.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

- **Project I.D. J-11743-19/Clayton Dialysis/Develop a New 10-Station Dialysis Facility by Relocating 10 Stations from Wilson County**

And the following application is approved as modified in the description below:

- **Project I.D. J-11739-19/FKC West Johnston/Relocate Two Stations from Wake County for a Total of 14 Stations**

Project I.D. #J-11743-19 is approved subject to the following conditions.

1. Total Renal Care of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.
2. Pursuant to Policy ESRD-2, Total Renal Care of North Carolina, LLC shall develop a new kidney disease treatment center to be known as Clayton Dialysis by relocating no more than 5 dialysis stations from Forest Hills Dialysis (Wilson County) and no more than 5 stations from Wilson Dialysis (Wilson County).
3. Total Renal Care of North Carolina, LLC shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations which shall include any isolation stations.
4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 5 dialysis stations at Forest Hills Dialysis for a total of no more than 21 dialysis stations at Forest Hills Dialysis upon completion of this project and Project I.D. #L-11438-17.
5. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 5 dialysis stations at Wilson Dialysis for a total of no more than 32 dialysis stations at Wilson Dialysis upon completion of this project, Project I.D. #L-11438-17, and Project I.D. #L-11591-18.
6. Total Renal Care of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

Project I.D. #J-11739-19 is approved subject to the following conditions.

1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application.
2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than 2 dialysis stations from Southwest Wake Dialysis (Wake County) to Fresenius Kidney Care West Johnston.
3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than 12 dialysis stations upon completion of this project and Project I.D. #J-11435-17, which shall include any isolation stations.

4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 2 dialysis stations at Southwest Wake County Dialysis for a total of no more than 32 dialysis stations at Southwest Wake County Dialysis.
5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.