

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: Tanya M. Saporito

Team Leader: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #: G-11737-19

Facility: BMA of South Greensboro

FID #: 980838

County: Guilford

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

Project: Relocate no more than 12 dialysis stations from BMA Burlington (Alamance County) pursuant to Policy ESRD-2 for a total of no more than 56 stations upon project completion

Project ID #: G-11744-19

Facility: Central Greensboro Dialysis

FID #: 190319

County: Guilford

Applicant(s): Total Renal Care of North Carolina, LLC

Project: Develop a new 10-station dialysis facility by relocating no more than 7 stations from Reidsville Dialysis (Rockingham County) and no more than 3 stations from Burlington Dialysis (Alamance County), and develop a home training and support program

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C – Both Applicants

Relocation of ESRD Stations Pursuant to Policy ESRD-2

Chapter 2 of 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 20 dialysis stations in Guilford County.

However, pursuant to Policy ESRD-2, only 20 dialysis stations maybe approved for relocation to Guilford County in this review. See the conclusion following the Comparative Analysis for the decision.

Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency) on July 15, 2019, for the review cycle beginning August 1, 2019, based on the 20-station deficit projected in the July 2019 SDR for Guilford County. The two applications submitted were for a total of 22 dialysis stations. Both applications propose to relocate existing dialysis stations from counties that are contiguous to Guilford County, pursuant to Policy ESRD-2. However, pursuant to Policy ESRD-2, only 20 dialysis stations may be approved for relocation in this review.

Need Determination

Neither applicant proposes to add stations pursuant to either 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 Guilford 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 ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

Bio-Medical Applications of North Carolina, Inc. (BMA) proposes to relocate 12 dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro upon project completion.

Policy ESRD-2. Guilford County and Alamance County are contiguous counties. According to Table A in the July 2019 SDR, BMA of Burlington was serving 20 in-center patients who were residents of Guilford County as of December 31, 2018. Table D of the July 2019 SDR shows that Alamance County has a surplus of 36 dialysis stations and Guilford County has a deficit of 20 dialysis stations. Relocating 12 stations from Alamance County will not create a

deficit of dialysis stations in Alamance County. Similarly, relocating 12 stations to Guilford County will not create a surplus of dialysis stations in Guilford 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station dialysis facility by relocating 10 stations from Alamance and Rockingham counties

Total Renal Care of North Carolina, LLC (TRC) proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home training and support program for peritoneal dialysis (PD) patients.

The Project Analyst notes that there is a discrepancy between the table the applicant submitted as part of its response to Section A.4, pages 6 – 8 of the application, and the accompanying narrative on those same pages. Comments submitted during the public comment period also note the discrepancy. The tables on pages 7-8 illustrate that the applicant intends to relocate seven dialysis stations from Burlington Dialysis in Alamance County and three dialysis stations from Reidsville Dialysis in Rockingham County; while the narrative on page 6 states the opposite. The remainder of the application confirms that the narrative in Section A.4, page 6 is what the applicant proposes in this application: *“Develop a new 10-station dialysis facility by relocating seven stations from Reidsville Dialysis (Rockingham County) and three stations from Burlington Dialysis (Alamance County), and develop a home training and support program.”* The Project Analyst therefore analyzed the application as described by the applicant in the narrative on page 6 of its application.

Policy ESRD-2. Guilford and Alamance counties are contiguous counties. Likewise, Guilford and Rockingham counties are contiguous counties. According to Table A in the July 2019 SDR, Reidsville Dialysis was serving one in-center patient who was a resident of Guilford County, and Burlington Dialysis was serving seven in-center patients who were residents of Guilford County as of December 31, 2018. Table D of the July 2019 SDR shows that Rockingham County has a surplus of 12 dialysis stations, Alamance County has a surplus of 36 dialysis stations and Guilford County has a deficit of 20 dialysis stations. Relocating seven

stations from Rockingham County will not result in a deficit of dialysis stations in Rockingham County. Relocating three dialysis stations from Alamance County will not result in a deficit of dialysis stations in Alamance County. Similarly, relocating ten stations to Guilford County will not create a surplus of dialysis stations in Guilford County.

Policy GEN-4. The project's proposed capital expenditure 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 because the applicant adequately demonstrates that the proposal is consistent with Policy ESRD-2 and 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro and 33 certified stations at BMA Burlington upon project completion.

In Project ID #G-11303-17, BMA was approved to develop a new 28-station dialysis facility (FKC Garber-Olin) by relocating 14 stations from BMA of Greensboro and 14 stations from BMA of South Greensboro. In Section C, page 17 the applicant states that the 14 stations approved for relocation from BMA of South Greensboro pursuant to Project ID# G-11303-17

were de-certified as of July 7, 2019. The last progress report submitted to the Agency on July 5, 2019 states the project is complete, and all 28 dialysis stations are certified.

The applicant does not currently offer or propose to offer home hemodialysis (HHD) or peritoneal dialysis (PD) training and support at BMA of South Greensboro as a part of this application.

In Section A, page 5, the applicant states that its parent company is Fresenius Medical Care Holdings (FMCH).

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 for this facility consists of Guilford County. Facilities may serve residents of counties not included in their service area.

In Section C, page 15, the applicant provides the historical patient origin for BMA of South Greensboro for the last full operating year prior to submitting the application, calendar year (CY) 2018, as illustrated in the following table:

**Historical Patient Origin for BMA of South Greensboro
 CY 2018**

COUNTY	# IN-CENTER PATIENTS
Guilford	187
Beaufort	2
Lee	1
Mecklenburg	1
Randolph	1
South Carolina	1
Other States	2
Total	195

On page 16, the applicant projects patient origin for BMA of South Greensboro for the second full operating year (CY 2022) upon project completion, as illustrated in the following table:

**BMA of South Greensboro
 Projected Patient Origin, CY 2022**

COUNTY	# IN-CENTER PTS	% OF TOTAL
Guilford	210.8	99.5%
Randolph	1	0.5%
Total	211.8	100.0%

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 18 - 19, 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 July 2019 SDR indicates that Guilford County has a deficit of 20 dialysis stations. Approval of this application will reduce that deficit to eight stations.

BMA notes that the BMA Greensboro facility qualifies to apply for seven stations pursuant to the Facility Need Methodology in the July 2019 SDR, and FMC High Point qualifies to apply for four stations pursuant to the Facility Need Methodology in the July 2019 SDR...”

The Project Analyst notes that there were two additional facilities in Guilford County owned/operated by the applicant that also qualified to add stations to its facility pursuant to the Facility Need Methodology in the July 2019 SDR that the applicant did not mention. Both FMC of East Greensboro and BMA of South Greensboro qualified to apply for additional stations. Applications were due to the Agency on September 15, 2019 for the October 1 Review cycle. No applications were submitted by the applicant to add stations pursuant to the Facility Need Methodology for either FMC of East Greensboro or BMA of South Greensboro.

In Section C, pages 18 – 19, the applicant states that this application will reduce the deficit of dialysis stations in Guilford County to eight stations. Likewise, this application will also reduce the surplus of dialysis stations in Alamance County from 36 to 24.

On page 19, the applicant states that *“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.”*

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

- In Project ID #G-11303-17, the applicant was approved to develop FKC Garber-Olin a new 28 station dialysis facility by relocating 14 dialysis stations from BMA Greensboro and 14 stations from BMA of South Greensboro. All 28 stations were certified at the FKC Garber-Olin facility effective July 8, 2019.
- BMA of South Greensboro facility utilization has remained in excess of 90% since relocation of 14 stations to FKC Garber-Olin.
- The applicant adequately documents additional patients are willing to consider transferring to the BMA of South Greensboro facility.

- The applicant reasonably projects that the utilization rate of the facility will be in excess of 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 201 Guilford County patients by the end of the first operating year and 211 Guilford County patients by the end of the second operating year following project completion.

In Section C, pages 16 – 18 and in Section Q, pages 77 – 79, the applicant provides the assumptions and methodology it used to project utilization, summarized as follows:

- The applicant begins its projections with the facility census at BMA of South Greensboro as of June 30, 2019, as reported on the ESRD Data Collection Forms submitted to the Agency.
- The applicant states that BMA of South Greensboro was dialyzing 169 in-center patients, 167 of whom were residents of Guilford County. The applicant provides a table to illustrate the patient census, but indicates that 16 patients were from Guilford County, one from Randolph County and one from “*other states*.” The Project Analyst determined that the number 16 is a typographical error and should have read 167, since the total patients indicated in the table is 169 and the remainder of the applicant’s analysis uses 169. A total of 167 Guilford County patients is also indicated on the June 30, 2019 ESRD Data Collection Form submitted to the Agency.
- The applicant states the one Randolph County patient will be added after projecting utilization for the Guilford County patients and the patient from “*other states*” will not be carried forward. The applicant concludes that the patient from “*other states*” is a transient patient and will not likely dialyze three days per week on a regular basis.
- The applicant projects growth of only the Guilford County patient population, using the 5.4% Guilford County Five Year Average Annual Change Rate (AACR) from the July 2019 SDR.
- The applicant states all of the 14 stations approved to be relocated from BMA of South Greensboro pursuant to Project ID G-11303-17 have been decertified effective July 7, 2019.
- The applicant states the facility census at BMA of South Greensboro remains high even after patients transferred their care to the new FKC Garber-Olin facility (Project ID #G-11303-17). After the patients transferred and the stations relocated, the applicant states the facility census was 171 patients dialyzing on 44 stations, which is 3.8 patients per station, or 97% utilization [$171 / 44 = 3.88$; $3.88 / 4 = 0.9715$].

- The applicant states 19 patients who currently dialyze at other BMA facilities have signed letters of support indicating a desire to transfer their care to BMA of South Greensboro.
- The applicant states Operating Year (OY) one is Calendar Year (CY) 2021, and OY two is CY 2022.

The following table from page 18 illustrates the applicant’s calculations using its assumptions and methodology¹:

BMA of South Greensboro Methodology

Begin with 167 Guilford County patients dialyzing at the facility as of June 30, 2019.	167
Project population forward six months to 12/31/19 using one-half of the Guilford County Five Year AACR. ¹	$167 \times 1.027 = 171.50$
Project population forward one year to 12/31/20.	$171.5 \times 1.054 = 180.77$
Add nine patients ² projected to transfer their care. This is the projected certification date for this project (12/31/2020).	$180.77 + 9 = 189.77$
Add one Randolph County patient	$189.77 + 1 = 190.77$
Project Guilford County population forward one year to 12/31/21.	$189.77 \times 1.054 = 200.018$
Add one Randolph County patient. This is the ending census for OY 1 (CY 2021).	$200.018 + 1 = 201.018$
Project Guilford County population forward one year to 12/31/22.	$200.018 \times 1.054 = 210.819$
Add one Randolph County patient. This is the ending census for OY 2 (CY 2022).	$210.819 + 1 = 211.819$

- (1) The applicant uses 1.0275 in its calculations. One-half of 5.4 is 2.7, which is reflected in the table above. The Project Analyst recalculated the projections using 1.027 instead of 1.0275. The difference is minimal and has no impact on the outcome of this decision.
- (2) See footnote below.

The applicant thus projects to serve 201 in-center patients on 56 dialysis stations at the end of OY 1 (CY 2021), which is 89.7% utilization [$201 / 56 = 3.589$; $3.589 / 4 = 0.8970$ and 211 in-center patients on 56 dialysis stations at the end of OY2 (CY 2022), which is 94.2% utilization [$211 / 56 = 3.768$; $3.768 / 4 = 0.942$].

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

¹ The applicant states on page 17 that it will assume half of the 19 patients who signed letters of support will actually transfer their care. One half of 19 is 9.5. The applicant calculates its projections using nine patients, but states eight patients will transfer. The Project Analyst concludes the verbiage is a typographical error and the applicant adds nine patients as indicated in the table on page 18. The Project Analyst recalculated the applicant’s projections using eight patients instead of nine. The difference in the number of patients projected is minimal and has no impact on the outcome of this decision.

- The applicant provides adequate documentation to support the projection of additional patients who will consider transferring to BMA of South Greensboro following the relocation of stations.
- The applicant reasonably uses the Five Year AACR for Guilford County as published in the July 2019 SDR to project growth of Guilford County residents.
- The applicant does not project growth for patients from counties other than Guilford at the end of each year's growth projections.
- 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, pages 24 – 25, the applicant states:

“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.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”

In Section L, page 57, the applicant projects the following payor mix for BMA of South Greensboro during the second full operating year following project completion:

**BMA of South Greensboro
Projected Payor Mix, CY 2022**

PAYOR SOURCE	# OF PATIENTS
Self Pay	1.19%
Insurance*	58.55%
Medicare*	5.73%
Medicaid*	5.35%
Medicare/Commercial	25.13%
Misc. (includes VA)	4.04%
Total	100.0%

*Includes 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station dialysis facility by relocating 10 stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

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 TRC or DaVita in these findings are also used interchangeably 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 for this facility consists of Guilford County. Facilities may serve residents of counties not included in their service area.

In Section C, page 18, the applicant states there is no historical patient origin, as Central Greensboro Dialysis will be a new facility with no historical patient data. The following table illustrates projected patient origin, from Section C, page 19 of the application.

Central Greensboro Dialysis Projected Patient Origin, OY 2 (CY 2022)

COUNTY	# IN-CENTER PTS	% OF TOTAL	# PD PTS	% OF TOTAL
Guilford	11	33.3%	4	100.0%
Alamance	16	48.5%	0	0.0%
Chatham	1	3.0%	0	0.0%
Randolph	2	6.1%	0	0.0%
Rockingham	3	9.1%	0	0.0%
Total	33	100.0%	4	100.0%

Source: Section C, pages 19 and 22

In Section C, pages 19 - 22, 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 22 - 23, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The July 2019 Semiannual Dialysis Report indicated in Table D that there is a projected station deficit of 20 stations in Guilford County.

...

Total Renal Care of North Carolina, LLC has identified 40 in-center patients [sic] who live in Guilford County or live in a county contiguous to Guilford County that have signed letters indicating an interest in transferring their care to the proposed Central Greensboro Dialysis. All of the patients indicated that transferring from the facility where they currently receive dialysis will be more convenient. The development of Central Greensboro Dialysis will give these patients the opportunity to receive dialysis services in their home county or in a location in Greensboro that is more convenient for them than where they are currently receiving their dialysis services as indicated in the patient letters.”

As part of its assumptions, the applicant relies on letters of support included in Exhibit C-3 signed by patients who currently dialyze in a DaVita facility. The applicant states on page 20 that there are 40 patient letters. However, there are a total of 48 patient letters, 43 of which are signed by in-center patients and five of which are signed by HHD patients. The applicant states on page 19 that 11 in-center patients in Guilford County signed letters, 23 in-center patients in Alamance County signed letters, one in-center patient in Chatham County signed a letter, two in-center patients in Randolph County signed letters and three in-center patients in Rockingham County signed letters. The Project Analyst examined the letters in Exhibit C-3

and determined that the number of patients who signed support letters for the proposed project is not the same as what the applicant states, as illustrated in the following table, prepared by the Project Analyst from information in Section C, pages 19 -20 and Exhibit C-3:

APPLICANT'S ANALYSIS		PROJECT ANALYST'S ANALYSIS	
COUNTY	# PATIENT LETTERS	COUNTY	# PATIENT LETTERS
Alamance	23	Alamance	27
Guilford	11	Guilford	14
Chatham	1	Chatham	2
Rockingham	3	Rockingham	3
Randolph	2	Randolph	2
Total	40		48

The fact that there are more patient support letters in the Exhibit than stated by the applicant in Section C demonstrates that existing patients will consider transferring their care to the proposed facility.

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

- The applicant provides letters of support from 43 in-center dialysis patients currently residing in Guilford, Alamance, Chatham, Rockingham or Randolph 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 In-Center Utilization

On Form C in Section Q, the applicant projects to serve 33 in-center patients by the end of the first operating year and 34 in-center patients by the end of the second operating year following project completion.

In Section C, pages 19 - 22, the applicant provides the assumptions and methodology it uses to project utilization, which are summarized below.

- DaVita is the parent company of three dialysis facilities in Alamance County and one dialysis facility in Rockingham County, each of which is contiguous to Guilford County.
- 48 patients signed letters of support for the proposed project, each letter stating that the patient who signed the letter would consider transferring their care to Central Greensboro Dialysis because it would be more convenient for the patient to receive dialysis care at that facility. Each of the patients who signed a letter is currently dialyzing at a facility owned or operated by DaVita in Alamance, Rockingham, Chatham, Randolph or Guilford County.

- Of those 48 total patients, 14 live in Guilford County, 27 live in Alamance County (five of those are home training patients and 22 are in-center patients), two live in Chatham County, two live in Randolph County and three live in Rockingham County.
- The applicant assumes 33 of the 48 patients who signed letters will actually transfer their care to the proposed facility. The applicant assumes 11 Guilford County residents will transfer their care, 16 Alamance County residents will transfer their care, one Chatham County resident will transfer, two Randolph County patients and three Rockingham County patients will transfer their care to the proposed facility.
- The applicant assumes the Guilford County patients will increase annually at a 5.4% rate consistent with the Five Year AACR from the July 2019 SDR.
- The applicant assumes no growth for the patients who live in a county other than Guilford.
- The applicant begins the period of growth on January 1, 2021 and calculates it forward to December 31, 2022. The applicant states OY1 is CY 2021 and OY2 is CY 2022.

The following table from page 21 illustrates the applicant’s calculations using its assumptions and methodology:

Begin with 33 patients who have signed letters of support for the project, which is projected to be certified as of January 1, 2021.	33
The facility’s Guilford County patient census is projected forward one year to 12/31/2021 by the Guilford County AACR of 5.4%.	$11 \times 1.054 = 11.594$
The 22 patients from outside Guilford County are added to the facility’s census. This is the ending census for the first OY (CY 2021).	$11.59 + 22 = 33.59$
Project the Guilford County patient census one year to 12/31/2022 by the Guilford County AACR of 5.4%.	$11.59 \times 1.054 = 12.220$
The 22 patients from outside Guilford County are added to the facility’s census. This is the ending census for the second OY (CY 2022).	$12.22 + 22 = 34.22$

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 OY1 and 34 patients per station per week ($34 / 10 = 3.4$) 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).

Projected PD Utilization

On pages 21 - 22, the applicant projects the number of PD patients it projects to serve. The assumptions are summarized as follows:

- The applicant states five PD patients who currently receive PD support at Alamance County Dialysis will consider transferring their care to Central Greensboro Dialysis. Five letters signed by those patients are included in Exhibit C-3.
- The applicant assumes that at least two PD patients will actually transfer their care and training upon certification of the new facility.
- The applicant begins its calculations of PD patients on January 1, 2021 (the beginning of OY 1) and ends on December 31, 2022 (the end of OY 2).
- The applicant assumes the PD patient population will increase by one patient per year.

The following table from page 22 illustrates the applicant's calculations used to project PD patient census for Central Greensboro Dialysis for the first two OYs following project completion:

PD PATIENT PROJECTIONS	START DATE	# PTS. BEGIN	# PTS. END	AVERAGE # PTS. IN YEAR
Operating Year 1	1/1/21	2	3	2.5
Operating Year 2	1/1/22	3	4	3.5

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 5.4% Five Year AACR for Guilford County as published in the July 2019 SDR to project Guilford County patient growth.
- The applicant does not project growth for patients residing outside of Guilford County, but adds them to the patient census at appropriate times.
- 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 24, 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. ...

Central Greensboro 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.

Projected Payor Mix by Percent, Second Operating Year (CY 2022)

PAYOR SOURCE	IN-CENTER PATIENTS	PD PATIENTS
Self Pay	0.0%	0.0%
Insurance*	9.9%	16.7%
Medicare*	75.6%	66.7%
Medicaid*	6.1%	16.7%
Other	8.4%	0.0%
Total	100.0%	100.0%

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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro upon project completion.

According to the July 2019 SDR, BMA Burlington had 45 certified dialysis stations as of December 31, 2018. Upon completion of this project, BMA Burlington will have 33 certified dialysis stations [45 – 12 = 33]. The applicant states on page 28 that the number of stations remaining at BMA Burlington would be 30; however, on the same page and in its utilization projections, the applicant states that BMA Burlington would have 33 stations. The Project Analyst determined that, based on the number of existing stations at BMA Burlington and the number of stations to be relocated as a result of this application, the use of 30 is a typographical error which does not affect the analysis in these Findings.

In Section D, page 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 this project. The applicant states the proposed relocation is scheduled to be complete as of December 31, 2020. The applicant states the facility has stations which are not currently effectively utilized, with 86 in-center patients dialyzing on 45 stations [86 / 45 = 1.911; 1.911 / 4 = 0.477 or 47.7% utilization].

In Section D, page 28, the applicant states BMA Burlington would have capacity to serve a maximum of 132 dialysis patients on 33 stations, using traditional shifts (three times per week, 52 weeks per year) once the 12 stations are relocated to BMA of South Greensboro [132 / 33 = 4.0]. The applicant states the facility census has been declining for several years, and illustrates the decline with a table prepared from SDRs from July 2015 to July 2019, which reports facility census from December 31, 2014 to December 31, 2018. See the following table prepared by the Project Analyst using information provided by the applicant on page 29 to illustrate the decline in patient census at BMA Burlington:

BMA Burlington Historical Utilization, 12/31/2014 – 12/31/2018

SDR	# STATIONS	CENSUS DATE	IN-CENTER PTS	# PTS./STATION	% UTILIZATION
July 2019	45	12/31/2018	97	2.16	53.9%
July 2018	45	12/31/2017	98	2.18	54.4%
July 2017	45	12/31/2016	94	2.09	52.2%
July 2016	45	12/31/2015	102	2.27	56.7%
July 2015	45	12/31/2014	114	2.53	63.3%

The applicant states on page 29 that the facility census as of June 30, 2019 (the date data is collected for the ESRD Data Collection Forms) was 86 in-center patients. The applicant states that *“If calculated in the same manner as a county five year average annual change rate, the BMA Burlington in-center census is averaging -3.78%.”*

In Section D, pages 29 - 30, the applicant provides the assumptions and methodology it uses to project utilization at BMA Burlington following the station relocation, summarized as follows:

- The applicant notes on page 29 that the BMA Burlington patient census included 22 patients who are residents of Guilford County as of June 30, 2019.
- The applicant begins projections of future patients to be served with 86 total patients, the BMA Burlington patient census as of June 30, 2019.
- The applicant projects growth of the Alamance County patient population using the 3.0% Alamance County Five Year AACR as published in the July 2019 SDR.
- The applicant projects growth of the Guilford County patient population using the 5.4% Guilford County Five Year AACR as published in the July 2019 SDR.
- The applicant states that as of June 30, 2019 BMA Burlington was serving one patient from each of the following counties/areas: Columbus County, Orange County, and Other States. The applicant states it will add the Columbus and Orange County patients to the projections of future patients to be served, but will not add the one patient from Other States. The applicant assumes that one patient will not continue to dialyze at the facility.
- The applicant projects the completion date for this project will be December 31, 2020.

Following is the table prepared by the applicant, on page 30:

BMA Burlington In-Center Patient Projections

	ALAMANCE COUNTY	GUILFORD COUNTY
Begin with 68 Alamance County ESRD patients, who were dialyzing at the facility as of June 30, 2019.	68	22
Begin with 22 Guilford County ESRD patients, who were dialyzing at the facility as of June 30, 2019.		
BMA projects this population forward six months to December 31, 2019, using one half of the Five Year Average Annual Change Rate.	$(68 \times 1.015) + 68 = 68.1$	$(22 \times 1.0275) + 22 = 22.6$
BMA projects this population forward one year to December 31, 2020.	$(68.1 \times 1.03) + 68.1 = 70.1$	$(22.6 \times 1.054) + 22.6 = 23.8$
Add the Alamance and Guilford county projected patient population	$70.1 + 23.8 = 93.9$	
Add the two patients from Columbus and Orange Counties.	$93.9 + 2 = 95.9$, rounded to 96	

However, the applicant's calculations are inaccurate due to an apparent mathematical error. The applicant states in its assumptions that 22 of the 86 total patients are residents of Guilford County; one patient is from Columbus County, one patient is from Orange County and one patient is from Other States. That leaves a total of 61 Alamance County patients [$86 - 22 = 64$. $64 - 3$ (1 Columbus County, 1 Orange County and 1 Other States) = 61]. The ESRD Data Collection Form for BMA Burlington as of June 30, 2019 likewise reflects 61 Alamance County patients and 22 Guilford County patients as of June 30, 2019. Therefore, the Project Analyst utilized the applicant's assumptions but calculated projected utilization for BMA Burlington based on 61 Alamance County patients and 22 Guilford County patients.

Following is a table prepared by the Project Analyst:

BMA Burlington In-Center Patient Projections

	ALAMANCE COUNTY	GUILFORD COUNTY
Begin with 61 Alamance County ESRD patients who were dialyzing at the facility as of June 30, 2019.	61	22
Begin with 22 Guilford County ESRD patients who were dialyzing at the facility as of June 30, 2019.		
Project this population forward six months to December 31, 2019, using one half of the Five Year Average Annual Change Rate (3.0% Alamance County and 5.4% Guilford County).	$61 \times 1.015 = 61.915$	$22 \times 1.027 = 22.594$
Project this population forward one year to December 31, 2020.	$61.915 \times 1.03 = 63.772$	$22.594 \times 1.054 = 23.814$
Add the Alamance and Guilford county projected patient population	$63.772 + 23.814 = 87.586$	
Add the two patients from Columbus and Orange Counties.	$87.586 + 2 = 89.586$, rounded to 90	

Therefore, utilizing the data reflected in the ESRD Data Collection Form as of June 30, 2019 and the Project Analyst's mathematical calculations shown above, BMA Burlington would

serve 90 in-center patients on 33 dialysis stations as of December 31, 2020, for a utilization rate of 68% [$90 / 33 = 2.72$; $2.72 / 4 = 0.680$].

On pages 30 – 31, the applicant states that BMA Burlington provides training for home hemodialysis (HHD) patients, and one station is dedicated to HHD training. Additionally, one station is reserved for isolation patients and thus cannot be utilized for the general ESRD patient population. The applicant states the projected utilization should therefore involve analysis of 28 dialysis stations at BMA Burlington following the relocation of 12 stations as proposed in this application. However, the mathematical calculation of this analysis is likewise inaccurate, because $33 - 2 = 31$, not 28. Thus, future utilization of BMA Burlington begins with 90 in-center patients on 33 stations. Assuming one station is subtracted from the inventory for HHD training and one station is subtracted for isolation patients, that leaves 31 in-center stations and 90 patients as of December 31, 2020, for a utilization rate of 73% [$90 / 31 = 2.9$; $2.9 / 4 = 0.73$].

Relocation of the 12 stations from BMA Burlington will not have an adverse impact on the patient population at that facility. In addition, the applicant states on page 31 that this proposal will not have any adverse effect on access by medically underserved groups, because the remaining stations at BMA Burlington will continue to be well utilized.

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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station dialysis facility by relocating 10 stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

Reidsville Dialysis

According to the July 2019 SDR, Reidsville Dialysis had 27 certified stations as of December 31, 2018, and 75 in-center patients. Upon completion of this project, the facility would have 20 dialysis stations.

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 29, the applicant states that, due to projected population growth at Reidsville Dialysis, it will submit additional applications for dialysis stations as the facility approaches capacity.

In Section D, pages 28 - 29, the applicant provides the assumptions and methodology used to project utilization at Reidsville Dialysis, as summarized below.

- The applicant states 75 patients were dialyzing at Reidsville Dialysis on December 31, 2018, 62 of whom were residents of Rockingham County and 13 of whom lived outside of Rockingham County.
- The applicant projects the Rockingham County patient population will grow at a rate of 1.8%, which is the Five Year AACR for Rockingham County as published in the July 2019 SDR.
- The applicant projects no growth for patients residing outside of Rockingham County, but adds those patients to the calculations where appropriate.
- The applicant projects seven stations and seven patients from outside of Rockingham County will transfer to Central Greensboro Dialysis once it opens. The applicant subtracts those seven stations and patients from the calculations at the projected certification date for Central Greensboro Dialysis (January 1, 2021).
- The applicant states the period of growth begins January 1, 2019 and ends December 31, 2022, the end of the second OY for Central Greensboro Dialysis.

In Section D, page 29, the applicant provides the calculations it uses to project the patient census for the facility at the time of the station transfer and during OY 1 and OY 2 of the proposed project, as shown in the table below:

REIDSVILLE DIALYSIS ASSUMPTIONS	CALCULATIONS
Begin with 75 patients on 27 stations as of 1/1/19.	75 patients, 27 stations
Project Rockingham County population forward one year to 12/31/19 using the 1.8% Rockingham County AACR in the July 2019 SDR.	$62 \times 1.018 = 63.12$
Add 13 patients who reside outside of Rockingham County. This is the ending census as of 12/31/19.	$63.12 + 13 = 76.12$
Project Rockingham County population forward one year to 12/31/20 using the 1.8% Rockingham County AACR in the July 2019 SDR.	$63.12 \times 1.018 = 64.25$
Add 13 patients who reside outside of Rockingham County. This is the ending census as of 12/31/20.	$64.25 + 13 = 77.25$
Central Greensboro Dialysis is projected to be certified as of 1/1/21. Thus, subtract seven patients and seven stations projected to transfer and relocate.	a. 13 patients – 7 = 6 patients remain b. 27 stations – 7 = 20 stations remain
As of 1/1/21, Reidsville Dialysis census on 20 stations	$64.25 + 6 = 70.25$
Project Rockingham County population forward one year to 12/31/21 using the 1.8% Rockingham County AACR in the July 2019 SDR.	$64.25 \times 1.018 = 65.41$
Add 6 patients who reside outside of Rockingham County. This is the ending census as of 12/31/21, OY 1.	$65.41 + 6 = 71.41$
Project Rockingham County population forward one year to 12/31/22 using the 1.8% Rockingham County AACR in the July 2019 SDR.	$65.41 \times 1.018 = 66.59$
Add 6 patients who reside outside of Rockingham County. This is the ending census as of 12/31/22, OY 2.	$66.59 + 6 = 72.59$

The applicant projects to serve 71 patients on 20 stations, which is 3.5 patients per station per week ($71 \text{ patients} / 20 \text{ stations} = 3.5$), for a utilization rate of 87.5% on the date of the patient and station transfer. By the end of OY 1, the facility is projected to serve 71 patients on 20 stations, which is 3.6 patients per station per week ($71 \text{ patients} / 20 \text{ stations} = 3.55$), for a utilization rate of 88.7%, and 72 patients on 20 stations, which is 3.6 patients per station per week ($72 \text{ patients} / 20 \text{ stations} = 3.6$), for a utilization rate of 90.0%, by the end of OY 2. On page 29, the applicant states it will submit applications for more stations based on facility need as the patient population increases.

The Project Analyst notes that the patient letters provided in Exhibit C-3 reflect that patients from Alamance, Guilford, Rockingham, Chatham and Randolph counties signed letters indicating an intent to consider transferring care to the proposed facility. In Section D, the applicant states that there are 13 patients who reside outside of Rockingham County who signed letters indicating an intent to consider transferring care to the proposed facility. According to the most recent ESRD Data Collection Forms submitted to the Agency in June 2019, the patient census at Reidsville Dialysis consisted of 62 patients from Rockingham County, 11 patients from Caswell County, one patient from Virginia and one patient from Guilford County, for a total of 13 patients. None of the patients who signed letters were residents of Caswell County, where the majority of the current non-Rockingham County Reidsville Dialysis patients reside; however, this does not change the fact that Reidsville

Dialysis will continue to be well-utilized following the transfer of stations to the proposed Central Greensboro Dialysis facility.

Burlington Dialysis

According to the July 2019 SDR, Burlington Dialysis had 16 certified stations as of December 31, 2018, and 65 in-center patients. Upon completion of this project, the facility would have 13 dialysis stations.

In Section D, pages 29 - 30, the applicant provides the assumptions and methodology used to project utilization at Burlington Dialysis, as summarized below.

- The applicant states 65 patients were dialyzing at Burlington Dialysis on December 31, 2018, 58 of whom were residents of Alamance County and seven of whom lived outside of Alamance County.
- The applicant projects the Alamance County patient population of Burlington Dialysis will grow at a rate of 3.0%, which is the Five Year AACR for Alamance County as published in the July 2019 SDR.
- The applicant projects no growth for patients residing outside of Alamance County, but adds those patients to the calculations where appropriate.
- The applicant projects 19 patients and three stations will transfer to Central Greensboro Dialysis once it opens and subtracts those 19 patients and stations from the calculations at the projected certification date for Central Greensboro Dialysis (January 1, 2021).
- The applicant states the period of growth begins January 1, 2019 and ends December 31, 2022, the end of the second OY for Central Greensboro Dialysis.

In Section D, page 30, the applicant provides the calculations it uses to project the patient census for the facility at the time of the station transfer and during OY 1 and OY 2 of the proposed project, as shown in the table below:

BURLINGTON DIALYSIS ASSUMPTIONS	CALCULATIONS
Begin with 65 patients on 16 stations as of 1/1/19.	65 patients, 16 stations
Project Alamance County population forward one year to 12/31/19 using the 3.0% Alamance County AACR in the July 2019 SDR.	$58 \times 1.03 = 59.740$
Add seven patients who reside outside of Alamance County. This is the ending census as of 12/31/19.	$59.74 + 7 = 66.74$
Project Alamance County population forward one year to 12/31/20 using the 1.8% Rockingham County AACR in the July 2019 SDR.	$59.74 \times 1.03 = 61.53$
Add seven patients who reside outside of Rockingham County. This is the ending census as of 12/31/20.	$61.53 + 7 = 68.53$
Central Greensboro Dialysis is projected to be certified as of 1/1/21. Subtract 13 Alamance County patients, 6 patients from outside Alamance County, and three stations projected to transfer and relocate.	a. 16 stations – 3 = 13 stations remain b. 61.53 Alamance County Patients – 13 = 48.53 c. Seven patients from outside Alamance County – 6 = 1
As of 1/1/21, Burlington Dialysis census on 13 stations	$48.53 + 1 = 49.53^*$
Project Alamance County population forward one year to 12/31/21 using the 3.0% Alamance County AACR in the July 2019 SDR.	$48.53 \times 1.03 = 49.99$
Add 1 patient who resides outside of Alamance County. This is the ending census as of 12/31/21, OY 1.	$49.99 + 1 = 50.99$
Project Alamance County population forward one year to 12/31/22 using the 3.0% Alamance County AACR in the July 2019 SDR.	$49.99 \times 1.03 = 51.48$
Add 1 patient who resides outside of Alamance County. This is the ending census as of 12/31/22, OY 2.	$51.48 + 1 = 52.48$

*the applicant includes the following: “ $48.53 + 1 = 48.53$ ”. Clearly this is an error and the remaining calculations in the table reflect the Project Analyst’s corrections.

The applicant also performs calculations using 49.44 rather than 49.99. The table above reflects the correct numbers.

The applicant projects to serve 49 patients on 13 stations, which is 3.7 patients per station per week ($49 \text{ patients} / 13 \text{ stations} = 3.7$), for a utilization rate of 94.2% on the date of the patient and station transfer. By the end of OY 1, the facility is projected to serve 50 patients on 13 stations, which is 3.8 patients per station per week ($50 \text{ patients} / 13 \text{ stations} = 3.8$), for a utilization rate of 96.2%, and 52 patients on 13 stations, which is 4.0 patients per station per week ($52 \text{ patients} / 13 \text{ stations} = 4.0$), for a utilization rate of 100.0%, by the end of OY 2. 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 Project Analyst notes the applicant states that, based on patient letters, 16 Alamance County patients would consider transferring their care to the proposed new facility, not 19. In Exhibit C-3, there are 27 letters signed by patients who live in Alamance County. Thus, that discrepancy does not have any effect on the outcome of this decision.

Relocation of the stations and patients from Reidsville Dialysis and Burlington Dialysis will not have an adverse impact on the patient population at either facility.

Public Comments submitted during the public comment period indicate that the applicant failed to answer question number three in Section D, which asks the applicant to describe the effect of the relocation, reduction or elimination of the stations on each of the following groups: low income persons, racial and ethnic minorities, women and handicapped persons, for each facility that would lose stations as a result of this proposal. In Section L, the application asks the applicant to document the extent to which “*medically underserved populations*” currently use the applicant’s existing services and the extent to which those groups are projected to use the applicant’s services. Specifically, the question states:

“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...[emphasis added].”

In Section L, pages 49 - 50, the applicant provides a total of four tables, two of which illustrate the percentage of total patients served in each of the categories listed in the application question for both Burlington Dialysis and Reidsville Dialysis. The other two tables illustrate the payor mix for each of Burlington Dialysis and Reidsville Dialysis for CY 2018, which includes Medicare and Medicaid recipients. Additionally, in Exhibit L the applicant provides the DaVita Patient Financial Evaluation Policy, which explains how each DaVita facility will meet the needs of the medically underserved patients who may be served by a DaVita facility, including the proposed facility. The applicant does not propose to eliminate a service, and adequately demonstrates that there will be sufficient capacity at the existing facilities to continue to meet the needs of the underserved populations that it currently serves. The applicant adequately demonstrates the applicant’s intent to continue to provide access to dialysis services to those groups considered underserved.

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.

- (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 ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

In Section E, pages 34 - 35, 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 this alternative does not recognize the growth in the patient population residing in the service area for BMA South Greensboro. The applicant states that the facility would likely reach in excess of 100% of capacity without relocating the stations.
- Relocate more than 12 stations – the applicant states this is not an effective alternative because relocating more than 12 stations could adversely impact patients remaining at BMA Burlington.
- Relocate fewer than 12 stations – the applicant states this is not an effective alternative because it would not meet the needs of the current and future patients at BMA South Greensboro, given the growth rate and utilization.
- Relocate stations from another BMA facility in Guilford County – the applicant states this is not an effective alternative because all of its facilities in Guilford County are well utilized.

On page 35, the applicant states the proposal to relocate 12 stations is the cost effective approach to provide necessary dialysis services for the patient population projected to be served by the facility.

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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

In Section E, pages 32 - 33, 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 this alternative is not a satisfactory alternative because it would ignore the applicant's proposal to offer dialysis patients a choice of providers in the greater Greensboro area of Guilford County. It would also not address the patients who currently dialyze with DaVita who desire to do so in the greater Greensboro area.
- Locate the facility in a different area of Guilford County – the applicant states the proposed site for the new facility would allow the applicant to provide better access to the patient population as identified in the patient letters of support. The applicant states the proposed site is located near a high population growth area of Greensboro. Therefore, locating the proposed facility in a different area of Guilford County is not an effective alternative.

On page 32, the applicant states the proposal will give future dialysis patients living in the greater Greensboro area and in contiguous counties a choice of dialysis providers. The applicant states it has nephrologists in the area and patient letters to support the proposed location.

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.

- (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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

Capital and Working Capital Costs

On Form F.1(a) in Section Q, page 83 the applicant states this project will incur no capital cost, because the proposal is to relocate existing dialysis stations, which consist of dialysis machines and patient chairs, to an existing facility that already has available space for those stations. In Section F, page 38, the applicant states there will be no start up costs or initial operating expenses, since BMA of South Greensboro is an operational facility.

Financial Feasibility

In Section Q, 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 following table:

BMA South Greensboro Projected Revenues and Operating Expenses

	OPERATING YEAR 1 CY 2021	OPERATING YEAR 2 CY 2022
Total Treatments	28,992	30,549
Total Gross Revenues (Charges)	\$182,390,904	\$192,189,735
Total Net Revenue	\$8,310,771	\$8,757,261
Average Net Revenue per Treatment	\$286.65	\$286.65
Total Operating Expenses (Costs)	\$6,561,223	\$6,807,765
Average Operating Expense per Treatment	\$226.31	\$222.84
Net Income/Profit	\$1,749,547	\$1,949,496

In Criterion (3) the Project Analyst noted several mathematical errors with regard to projected utilization made by the applicant. The Project Analyst notes here that those errors do not change the fact that the proposed project is financially feasible. The BMA of South Greensboro facility projects a profit in both OYs one and two, and the applicant has demonstrated the financial feasibility of the project. 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 because 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

Capital and Working Capital Costs

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

Site Preparation Costs	\$141,152
Construction Costs	\$1,510,400
Architect and Engineering Fees	\$146,500
Medical Equipment	\$151,580
Non-Medical Equipment	\$300,030
Furniture	\$158,325
Interest During Construction	\$36,120
Total	\$2,444,107

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

In Section F.3, page 35, the applicant projects start-up costs will be \$180,019 and initial operating expenses will be \$679,552 for a total working capital of \$859,571. 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 the accumulated reserves of DaVita, Inc., TRC's parent company. In Exhibit F-2 the applicant provides a July 15, 2019 letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the capital and working 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 following table:

Projected Revenue and Operating Expenses

	OY 1 CY 2021	OY 2 CY 2022
Total Number Treatments	5,305	5,544
Total Gross Revenues (Charges)	\$1,860,849	\$1,952,685
Total Net Revenue	\$1,945,731	\$2,041,385
Average Net Revenue per Treatment	\$367	\$368
Total Operating Expenses (Costs)	\$1,359,104	\$1,402,880
Average Operating Expense per Treatment	\$256	\$253
Net Income/Profit	\$586,627	\$638,505

On its Form F.2 in Section Q, 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:

Project Analyst's Revision of Projected Revenue and Operating Expenses

	OY 1 CY 2021	OY 2 CY 2022
Total Number Treatments	5,305	5,544
Total Gross Revenues (Charges)	\$1,860,849	\$1,952,685
Total Net Revenue	\$1,775,967	\$1,863,985
Average Net Revenue per Treatment	\$335	\$336
Total Operating Expenses (Costs)	\$1,359,104	\$1,402,880
Average Operating Expense per Treatment	\$256	\$253
Net Income/Profit	\$416,863	\$461,105

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 Applicants

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 in this review consists of Guilford 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 Guilford County as of December 31, 2018:

FACILITY	LOCATION	PROVIDER	# CERTIFIED STATIONS	# IN-CENTER PATIENTS	UTILIZATION
BMA of Greensboro	Greensboro	BMA	56	191	85.3%
BMA of South Greensboro	Greensboro	BMA	49	195	99.5%
BMA of Southwest Greensboro	Greensboro	BMA	33	101	76.5%
FMC of East Greensboro	Greensboro	BMA	39	141	90.4%
Fresenius Kidney Care Garber-Olin*	Greensboro	BMA	0	0	0.0%
Fresenius Medical Care High Point	High Point	BMA	10	36	90.0%
High Point Kidney Center of Wake Forest University	High Point	Wake Forest University Health Sciences	41	150	91.5%
Northwest Greensboro Kidney Center	Greensboro	BMA	37	117	79.1%
Triad Dialysis Center of Wake Forest University	High Point	Wake Forest University Health Sciences	27	94	87.0%

Source: July 2019 SDR, Table B, pages 44 – 45.

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

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

In Section G, page 43, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County. The applicant states:

“This is an application to relocate 12 dialyiss [sic] stations to BMA of South Greensboro. The July 2019 SDR reports that Guilford County has a defic[i]t of 20 dialysis stations. This is an effort to address some portion of that deficit. To the extent that the SDR identifies a station deficit, and approval of this application will not create a station surplus in Guilford 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 Guilford County.
- The proposal would not create a surplus of dialysis stations in Guilford County.
- The applicant adequately demonstrates that the relocated stations are needed in addition to the existing or approved stations and facilities in Guilford 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

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 Guilford County has a Projected Station Deficit of 12 stations. Since there is a station deficit in Guilford County, then the development of a new dialysis facility in Guilford County will not unnecessarily duplicate the existing and approved facilities in the Guilford County service area. ... The development of Central Greensboro Dialysis will provide future ESRD patients a choice of providers in the greater Greensboro area of Guilford County.”

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 a portion of the existing deficit of dialysis stations as published in the July 2019 SDR for Guilford County.
- The proposal would not create a surplus of dialysis stations in Guilford County.
- The applicant adequately demonstrates the proposed new dialysis facility is needed in addition to the existing or approved dialysis facilities in Guilford 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for both OYs (CYs 2021 and 2022), as illustrated in the following table:

BMA of South Greensboro Projected FTEs OYs 1 and 2

POSITION	FTEs
Administrator	1.0
Registered Nurse	7.3
Licensed Practical Nurse	0.1
Patient Care Technician	21.2
Dietician	1.5
Social Worker	1.5
Maintenance	1.0
Administration/Business Office	3.0
FMC Director Operations	0.2
In-Service	0.3
Chief Technician	0.3
Total	37.40

The assumptions and methodology used to project staffing are provided in Section Q on page 95. 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 44, 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 45, 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

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.

**Central Greensboro Dialysis Projected Staffing
OYs 1 and 2 (CYs 2021 and 2022)**

POSITION	# FTEs
Administrator	1.0
Registered Nurse	2.0
Home Training Nurse	0.5
Patient Care Technician	4.0
Dietician	0.5
Social Worker	0.5
Administration Business Office	0.5
Biomedical Technician	0.5
Total	9.5

The assumptions and methodology used to project staffing are provided in application 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 41 - 42, 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 42, 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

In Section I, pages 46 - 47, the applicant provides a table to illustrate that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service will be made available:

BMA OF SOUTH GREENSBORO DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training (in-center)	BMA of Greensboro
Home training	BMA of Greensboro
Home Hemodialysis	BMA of Greensboro
Peritoneal Dialysis	BMA of Greensboro
Accessible follow-up program	BMA of Greensboro
Isolation – hepatitis	Provided on site by applicant
Nutritional counseling	Provided on site by applicant
Social Work services	Provided on site by applicant
Laboratory services	Provided on site by applicant
Acute dialysis in an acute care setting	Cone Health Moses Cone Memorial Hospital
Emergency care	Provided by facility staff until ambulance arrives
Blood bank services	Cone Health Moses Cone Memorial Hospital
Diagnostic and evaluation services	Greensboro Diagnostic Center or Cone Health
X-ray services	Greensboro Diagnostic Center or Cone Health
Pediatric nephrology	UNC Healthcare
Vascular surgery	Vein and Vascular Specialists of Greensboro; Carolina Kidney Associates Vascular Center
Transplantation services	UNC Healthcare
Vocational rehabilitation & counseling	Guilford County Vocational Rehabilitation Services
Transportation	Specialty Community Area Transportation; Greensboro Transit Authority; Guilford County Transportation

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

In Section I, page 47, 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

In Section I, page 43, the applicant provides a table to illustrate that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service will be made available:

CENTRAL GREENSBORO DIALYSIS ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
Self-care training (in-center)	Central Greensboro Dialysis
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On site
Psychological Counseling	Provided on site by Registered Nurse
Isolation – hepatitis	Provided on site by applicant
Nutritional counseling	Provided on site by Registered Dietician
Social Work services	Provided on site by MSW
Laboratory services	DaVita Laboratory Services, Inc.
Acute dialysis in an acute care setting	Cone Health
Emergency care	Cone Health
Blood bank services	Cone Health
Diagnostic and evaluation services	Cone Health
X-ray services	Cone Health
Pediatric nephrology	Cone Health
Vascular surgery	Cone Health
Transplantation services	Duke Health / Vidant Health
Vocational rehabilitation & counseling	Division of Vocational Rehabilitation
Transportation	Guilford County DSS / CJ Medical

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 43, the applicant describes its existing and proposed relationships with other local health care and social service providers.

In Section A, page 6, the applicant states the project description is:

“Develop a new 10-station dialysis facility by relocating seven stations from Reidsville Dialysis (Rockingham County) and three stations from Burlington Dialysis (Alamance County) and develop a home training and support program.”

Public comments submitted during the public comment period indicate that the application submitted by TRC is internally inconsistent in part because the application fails to indicate

where HHD patients will be trained, since the table provided by the applicant on page 43 groups all home trained patients in one “block” which indicates training will be provided “*on site*”. TRC does not indicate in its application that it proposes to provide training to HHD patients, and thus does not identify where HHD patients will be served, but adequately addresses provision of training to its proposed PD patient population. In Section C, page 21, the applicant provides projections for PD patients based on the historical service to PD patients currently served by DaVita.

While the applicant does not specifically identify the facility to which it will refer patients for HHD training and support, it does identify a host of other ancillary and support services and provides supporting documentation as referenced above. In Exhibit F-2, page 4, the applicant states that many of the DaVita dialysis centers offer services for dialysis patients who prefer either HHD or PD training and support and for whom such training and support is appropriate.

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 Applicants

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 Applicants

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.

NA – Bio-Medical Applications of North Carolina, Inc.
C – Total Renal Care of North Carolina, LLC

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

In Section K, page 50, the applicant states:

“BMA South Greensboro is an existing dialysis facility. It has recently had as many as 59 dialysis stations. However some stations were relocated to develop other facilities.”

The applicant provides a table to illustrate the history of dialysis station additions and relocations to and from BMA of South Greensboro. The applicant does not propose to:

- Construct any new space
- Renovate any existing space

Therefore, Criterion (12) is not applicable to this application.

Project ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

Both Rockingham and Alamance counties are contiguous to Guilford County.

In Section K, page 46, and Exhibit K-1, the applicant states the project involves constructing 9,300 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 47, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section B, page 13, and Section K, page 47, 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 47, the applicant identifies the 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

In Section L, page 55, the applicant provides the historical payor mix during CY 2018 as shown in the table below.

**BMA of South Greensboro Historical Payor Mix
CY 2018**

PAYOR CATEGORY	PERCENT OF TOTAL PATIENTS
Self Pay	1.19%
Insurance*	5.35%
Medicare*	58.55%
Medicaid*	5.73%
Medicare/Commercial	25.13%
Miscellaneous (Includes VA)	4.04%
Total	100.00%

*Includes managed care plans
Source: application page 55

In Section L, page 55, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	47.7%	51.3%
Male	52.3%	48.7%
Unknown	0.0%	0.0%
64 and Younger	59.3%	83.1%
65 and Older	40.7%	16.9%
American Indian	0.0%	1.4%
Asian	2.3%	1.8%
Black or African-American	50.0%	20.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	32.6%	73.9%
Other Race	0.0%	2.2%
Declined / Unavailable	22.1%	0.0%

Sources: BMA Internal Data, US Census Bureau

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 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

Central Greensboro Dialysis is not an existing facility. In Section L, page 50, the applicant provides the historical payor mix at each facility from which stations will relocate (Reidsville Dialysis and Burlington Dialysis) during CY 2018, as shown in the following tables:

**Reidsville Dialysis Historical Payor Mix
 CY 2018**

PAYOR CATEGORY	% OF IN-CENTER PATIENTS	% OF PERITONEAL PATIENTS
Self Pay	0.0%	0.0%
Insurance*	7.6%	16.7%
Medicare*	84.8%	66.7%
Medicaid*	4.5%	16.7%
Other	3.0%	0.0%
Total	100.0%	100.00%

*Includes managed care plans

Source: application page 50

**Burlington Dialysis Historical Payor Mix
 CY 2018**

PAYOR CATEGORY	% OF IN-CENTER PATIENTS	% OF PERITONEAL PATIENTS ¹
Self Pay	0.0%	0.0%
Insurance*	12.3%	8.0%
Medicare*	66.2%	43.0%
Medicaid*	7.7%	5.0%
Other	13.8%	9.0%
Total	100.0%	100.0%

(1) the applicant put whole numbers in this column in the application, but totaled the numbers as "100%". Therefore, the Project Analyst concludes the numbers in the column above the total are intended to represent percentages.

*Includes managed care plans

Source: application page 50

In Section L, pages 49 and 50, the applicant provides the following comparisons:

Reidsville Dialysis

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	40.5%	52.7%
Male	59.5%	47.3%
Unknown	0.0%	0.0%
64 and Younger	49.4%	84.8%
65 and Older	50.6%	15.2%
American Indian	0.0%	0.8%
Asian	0.0%	5.4%
Black or African-American	58.2%	35.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	40.5%	56.2%
Other Race	1.3%	2.4%
Declined / Unavailable	0.0%	0.0%

Sources: TRC internal data, US Census Bureau

Burlington Dialysis

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	56.3%	52.7%
Male	43.8%	47.3%
Unknown	0.0%	0.0%
64 and Younger	54.7%	84.8%
65 and Older	45.3%	15.2%
American Indian	0.0%	0.8%
Asian	1.6%	5.4%
Black or African-American	48.4%	35.1%
Native Hawaiian or Pacific Islander	1.6%	0.1%
White or Caucasian	39.1%	56.2%
Other Race	9.4%	2.4%
Declined / Unavailable	0.0%	0.0%

Sources: TRC internal data, US Census Bureau

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 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 56, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities or handicapped persons.

In Section L.2, page 56, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against the facility.

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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

Central Greensboro Dialysis is not an existing facility. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 51, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities or handicapped persons.

In Section L.2, page 51, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against the facility.

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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

In Section L.3, page 57, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below:

**BMA of South Greensboro Projected Payor Mix
CY 2022**

PAYOR CATEGORY	PERCENT OF TOTAL PATIENTS
Self Pay	1.19%
Insurance*	58.55%
Medicare*	5.35%
Medicaid*	5.73%
Medicare/Commercial	25.13%
Miscellaneous (Includes VA)	4.04%
Total	100.00%

*Includes managed care plans

Source: application page 57

When the Project Analyst compares the tables provided by the applicant in Section L, pages 55 and 57 (historical and projected payor mix), it appears as though the applicant transposed the values in the “insurance”, “Medicare” and “Medicaid” categories. Comments submitted during the public comment period likewise acknowledged that the applicant appears to have transposed the values for Medicare and Insurance. The Project Analyst examined Form F.2 Income Statement submitted in Section Q, and it confirms that the numbers in the Insurance and Medicare categories listed in Section L were incorrectly transposed. The values in Form F.2 reflect projected payor mix of 58.55% for Medicare recipients and 5.35% for Insurance recipients. In addition, other applications submitted by this applicant in the past and since this application was submitted contain values similar to those represented in the table on page 55. Therefore,

the Project Analyst prepared a table to illustrate the values similarly to those in the table on page 55 and in subsequent applications:

**BMA of South Greensboro Payor Mix
CY 2022**

PAYOR CATEGORY	PERCENT OF TOTAL PATIENTS
Self Pay	1.19%
Insurance*	5.35%
Medicare*	58.55%
Medicaid*	5.73%
Medicare/Commercial	25.13%
Miscellaneous (Includes VA)	4.04%
Total	100.00%

*Includes managed care plans

Source: application page 57, Form F.3

As shown in the table above, during the second full fiscal year of operation, the applicant projects 1.19% of total services will be provided to self-pay patients; 83.68% to patients who will have some or all their care paid for by Medicare; and 5.73% to Medicaid patients.

On page 57, 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 because it is based on the historical payor mix of the BMA of South Greensboro facility.

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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

In Section L.3, 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 shown in the table below:

**Central Greensboro Dialysis Projected Payor Mix
CY 2022**

PAYOR CATEGORY	% OF IN-CENTER PATIENTS	% OF PERITONEAL PATIENTS
Self Pay	0.0%	0.0%
Insurance*	9.9%	16.7%
Medicare*	75.6%	66.7%
Medicaid*	6.1%	16.7%
Other	8.4%	0.0%
Total	100.0%	100.00%

*Includes managed care plans
Source: application page 51

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 75.6% of in-center and 66.7% of PD services will be provided to Medicare patients and 6.1% of in-center and 16.7% of PD 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 the two existing facilities from which stations will relocate.
- 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

In Section L, pages 57 - 58, 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

In Section L, page 52, 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

In Section M, page 59, 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

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 Applicants

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 in this review consists of Guilford 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 Guilford County as of December 31, 2018:

FACILITY	LOCATION	PROVIDER	# CERTIFIED STATIONS	# IN-CENTER PATIENTS	UTILIZATION
BMA of Greensboro	Greensboro	BMA	56	191	85.3%
BMA of South Greensboro	Greensboro	BMA	49	195	99.5%
BMA of Southwest Greensboro	Greensboro	BMA	33	101	76.5%
FMC of East Greensboro	Greensboro	BMA	39	141	90.4%
Fresenius Kidney Care Garber-Olin*	Greensboro	BMA	0	0	0.0%
Fresenius Medical Care High Point	High Point	BMA	10	36	90.0%
High Point Kidney Center of Wake Forest University	High Point	Wake Forest University Health Sciences	41	150	91.5%
Northwest Greensboro Kidney Center	Greensboro	BMA	37	117	79.1%
Triad Dialysis Center of Wake Forest University	High Point	Wake Forest University Health Sciences	27	94	87.0%

Source: July 2019 SDR, Table B, pages 44 – 45.

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

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 stations

BMA proposes to relocate 12 certified dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro in Guilford County, for a total of 56 dialysis stations at BMA of South Greensboro in Guilford County upon project completion.

In Section N, pages 60 - 62, 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 60, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Guilford County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the

BMA of South Greensboro facility begins with patients the current patient population and eight new dialysis patients who have expressed similar desires to transfer their care [sic].”

There are currently nine dialysis facilities within Guilford County. With this application, BMA seeks the opportunity to continue providing dialysis care and treatment to the patients of the area who have expressed their desire to receive dialysis care and treatment at BMA of South Greensboro.

...

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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

TRC proposes to develop Central Greensboro Dialysis, a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County, and develop a home PD training and support program.

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 Central Greensboro Dialysis will have no effect on any dialysis facilities located in Guilford County or in counties contiguous to it. This certificate of need application is being submitted in response to a projected station deficit of 20 stations in Guilford County as indicated in Table D of the July 2019 SDR. The projected station deficit in Guilford County indicates that there is a need for additional dialysis stations. Since there is only one provider in the greater Greensboro area at present, this is a great opportunity for patients, referring hospitals and physicians to have a choice of providers.

The bottom line is Central Greensboro 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. Patient selection is the determining factor as the patient will select the provider that gives them the highest quality service and best meets their needs.”

The applicant 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 Applicants

Project ID #G-11737-19 / BMA of South Greensboro/ Relocate 12 stations from Alamance County for a total of 56 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 67, 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 ID #G-11744-19 / Central Greensboro Dialysis / Develop a new 10-station facility by relocating existing stations from Alamance and Rockingham counties

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 Applicants

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.*
- NA- **BMA/BMA of South Greensboro.** BMA does not propose to establish a new End Stage Renal Disease facility.
- C- **TRC/Central Greensboro Dialysis.** In Section C, page 19, the applicant projects Central Greensboro Dialysis 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/BMA of South Greensboro.** In Section C, page 16, the applicant projects BMA South Greensboro will serve 211 patients on 56 stations, or a rate of 3.7 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/Central Greensboro Dialysis.** CGD 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/BMA of South Greensboro.** In Section C, pages 16 - 18, and Section Q, pages 77 - 79, 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/Central Greensboro Dialysis.** In Section C, pages 19 - 22, 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 20 dialysis stations may be approved for relocation to Guilford County in this review. Because the two applications in this review collectively propose to relocate 22 dialysis stations to Guilford County, both applications 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:

- **Project ID #G-11737-19 BMA/BMA of South Greensboro** – relocate no more than 12 existing dialysis stations from BMA Burlington in Alamance County for a total of 56 stations at BMA of South Greensboro upon project completion
- **Project ID #G-11744-19 TRC/Central Greensboro Dialysis** – relocate no more than seven stations from Reidsville Dialysis in Rockingham County and no more than three stations from Burlington Dialysis in Alamance County to develop a new 10-station dialysis facility in Greensboro

Following is a brief discussion of the comparative factors considered in this review:

Conformity to Statutory and Regulatory Review Criteria

Each applicant adequately demonstrates the need for its 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 20-station deficit of dialysis stations in Guilford County. There are currently nine existing dialysis facilities in Guilford County, mostly around Greensboro. **BMA/BMA of South Greensboro** proposes to relocate 12 existing dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro. BMA of South Greensboro is an existing facility, located just south of I-85, south of central Greensboro. **Wake Forest Baptist Health** operates two facilities, each of which is located in High Point, a bit further south and west of both Jamestown and central Greensboro.

TRC/Central Greensboro Dialysis proposes to develop a new 10-station dialysis facility by relocating seven existing stations from Reidsville Dialysis in Rockingham County and three existing stations from Burlington Dialysis in Alamance County. The proposed facility would be located within the I-85 loop in the greater Greensboro area. All of the existing dialysis facilities and the proposed TRC facility would thus be within the greater Greensboro area, some within the I-85 loop and some on the outside of the I-85 loop; the High Point facilities notwithstanding.

Therefore, each application is equally effective with regard to the issue of geographic accessibility in the greater Greensboro area.

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 seven of the nine existing dialysis facilities in Guilford County.

Wake Forest Baptist Health owns or operates two of the nine existing dialysis facilities in Guilford County.

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

Therefore, with regard to providing ESRD patients with access to a new dialysis provider of dialysis in Guilford County, **TRC/Central Greensboro 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/BMA of South Greensboro does not propose to offer either home hemodialysis or home peritoneal dialysis training and support services at the BMA of South Greensboro facility.

TRC/Central Greensboro Dialysis states it will develop a home peritoneal dialysis training and support program as part of its application and projects to serve PD patients at the facility.

Therefore, with regard to access to home training and support services, **TRC/Central Greensboro Dialysis** is the more 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 Guilford County. Facilities may also serve residents of counties not included in their service area.

Generally, the application projecting to serve the highest percentage of Guilford County residents is the more effective alternative with regard to this comparative factor since the service area for these proposals is Guilford County. The following table, prepared by the Project Analyst from information

provided in each of the applications, illustrates each applicant’s projection of Guilford County residents to be served:

PERCENT OF GUILFORD COUNTY RESIDENTS PROJECTED TO BE SERVED – OY 2 (CY 2022)		
FACILITY	% IN-CENTER PATIENTS	% PD PATIENTS
BMA/BMA of South Greensboro	99.5%	0.0%
TRC/Central Greensboro Dialysis	33.3%	100.0%

Source: Section C (both applications)

As shown in the table above, **BMA/BMA of South Greensboro** projects to serve the highest percentage of in-center Guilford County residents during the second full operating year. **TRC/Central Greensboro Dialysis** projects to serve the highest percentage of PD Guilford County residents during the second full operating year; however, since **BMA/BMA of South Greensboro** does not propose to provide home training at the facility, the analysis for this particular comparative factor will focus on in-center patients only. Therefore, with regard to projected access by Guilford County residents, **BMA/BMA of South Greensboro** 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 defined as care provided to patients without expectation of receiving payment.² Generally, the application proposing to provide more charity care to patients is the more effective alternative with regard to this comparative factor. The following table illustrates each applicant’s information regarding charity care, taken from form F.2 in Section Q of each application:

CHARITY CARE – OY 2 (CY 2022)	
FACILITY	AMOUNT
BMA of South Greensboro	\$75,524
Central Greensboro Dialysis	\$0

Source: Form F.2, both applications

In the Assumptions following Form F.2 in Section Q, page 87 **BMA/BMA of South Greensboro** states: “Charity Care line is actually facility contributions to the American Kidney Fund.” Contributions to outside organizations, while commendable, is not care provided to patients without expectation of receiving payment.

² See <https://medical-dictionary.thefreedictionary.com/charity+care>

At the bottom of Form F.2 in Section Q, page 86, **BMA/BMA of South Greensboro** states it does not collect data on patients receiving charity care, stating, “... *in some cases, patients do not have sufficient financial resources to attend to all medical bills; this results in unpaid or uncollectible accounts. The applicant allocates these un-collectibles to a ‘Bad Debt’ account.*” Therefore, there is no way to determine the amount of actual charity care projected to be provided to patients at **BMA/BMA of South Greensboro**.

On Form F.2 in Section Q, note (3), **TRC/Central Greensboro Dialysis** states that “*charity care and Contractual Adjustments are rolled into the Bad Debt line item by the Finance Department. This cannot be drilled down to provide a count of patients per category.*” Therefore, there is no way to determine the amount of actual charity care projected to be provided to patients at **TRC/Central Greensboro Dialysis**.

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 each of 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	% OF IN-CENTER SERVICES	% OF PD SERVICES
BMA South Greensboro	Medicare* ¹ , Medicare/Commercial	83.68%	0.00%
Central Greensboro Dialysis	Medicare*	75.6%	66.7%

*Including any managed care plans

(1) in the table provided by the applicant on page 57, it appears as though the applicant transposed the values for Medicare and Insurance, as noted above in the Agency Findings.

Source: Section L (both applications)

As shown in the table above, during the second full operating year, **BMA/BMA of South Greensboro** projects to provide 83.68% of services to Medicare in-center patients, including patients with Medicare managed care plans and patients who have both Medicare and commercial insurance coverage. **TRC/Central Greensboro Dialysis** projects to provide 75.6% of services to Medicare in-center patients, including patients with Medicare managed care plans. **TRC/Central Greensboro Dialysis** projects to provide 66.7% of services to Medicare PD patients. **BMA/BMA of South Greensboro** 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, there is no meaningful way to compare the two applications with regard to this comparative factor. Therefore, with regard to projected service to Medicare recipients, 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	% OF IN-CENTER SERVICES	% OF PD SERVICES
BMA South Greensboro	5.35%	0.00%
Central Greensboro Dialysis	6.10%	16.70%

Source: Section L (both applications)

As shown in the table above, during the second full operating year, **TRC/Central Greensboro Dialysis** projects to provide 6.1% of services to in-center Medicaid patients and **BMA/BMA of South Greensboro** projects to provide 5.35% of services to in-center Medicaid patients. Therefore, with regard to the projected percent of services provided to Medicaid patients, **TRC/Central Greensboro Dialysis** is the more effective alternative with respect to this comparative factor. Since, **BMA/BMA of South Greensboro** does not propose to offer home training at the facility, provision of service to home patients is not comparable in this particular 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 South Greensboro	\$8,757,261	30,549	\$286
Central Greensboro Dialysis	\$1,863,985*	5,544	\$336

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

*See Project Analyst’s discussion in Criterion (5) regarding net revenue calculations for Central Greensboro Dialysis

As shown in the table above, **BMA/BMA of South Greensboro** 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/BMA of South Greensboro** 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 COSTS	# OF TREATMENTS	AVERAGE OPERATING COST/TREATMENT
BMA South Greensboro	\$6,807,765	30,549	\$222
Central Greensboro Dialysis	\$1,482,880	5,544	\$267

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

As shown in the table above, **BMA/BMA of South Greensboro** projects the lowest average operating expense per treatment in the second operating year. Therefore, with regard to the lowest average operating cost per treatment, **BMA/BMA of South Greensboro** is the more effective alternative with respect to this comparative factor.

SUMMARY

The following table lists the comparative factors and states which applicant is the most effective or more effective alternative with regard to that particular comparative factor. The comparative factors are listed in the same order in which they were discussed in the Comparative Analysis; that does not indicate an order of importance.

COMPARATIVE FACTOR	BMA SOUTH GREENSBORO	CENTRAL GREENSBORO 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	Less Effective	More 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	More Effective	Less Effective

Both applications are conforming to all statutory and regulatory review criteria, and thus each application standing alone is approvable. However, collectively the applications propose to relocate a total of 22 dialysis stations to Guilford County, and the deficit for Guilford County in the July 2019 SDR is 20 stations, then pursuant to Policy ESRD-2 in the 2019 SMFP only 20 dialysis stations can be approved to be relocated to Guilford County.

As shown in the table above:

- **BMA/BMA of South Greensboro** is the more effective alternative with regard to:
 - Access by Service Area Residents
 - Projected Average Net Revenue per Treatment
 - Average Operating Cost per Treatment

- **TRC/Central Greensboro Dialysis** is the more effective alternative with regard to:
 - Patient Access to a New Provider
 - Access to Home Training and Support Services
 - 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 Guilford County, as well as individually conforming to all statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that proposed projects must be consistent with applicable policies in the 2019 SMFP. Pursuant to Policy ESRD-2 in the 2019 SMFP, there is a limit of 20 dialysis stations that can be approved by the Healthcare Planning and Certificate of Need Section to be relocated to Guilford 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 that propose to develop fewer than 10 stations cannot be approved. Approval of **BMA/BMA of South Greensboro** as submitted would reduce the Guilford County dialysis station deficit from 20 stations to eight stations, but would completely preclude approval of **TRC/Central Greensboro Dialysis**, since **TRC** proposes to relocate 10 stations. Conversely, approval of **TRC/Central Greensboro Dialysis** as submitted would reduce the Guilford County dialysis station deficit from 20 stations to 10 stations, but it would preclude the approval of **BMA/BMA of South Greensboro** as submitted.

While each application represents an effective alternative, approval of the **BMA** application as submitted precludes the approval of the **TRC** application. Furthermore, approval of the **BMA** application as submitted would leave Guilford County with an unaddressed dialysis station deficit of eight stations. Approval of the **TRC** application as submitted would leave Guilford County with a dialysis station deficit of 10 stations, which could be addressed by modified approval of the **BMA** application, and would bring the Guilford County dialysis station deficit to zero.

Because of that, and because it is possible to approve the application for **TRC/Central Greensboro Dialysis** while partially approving the application for **BMA/BMA of South Greensboro**, but it is not possible to approve the application for **BMA/BMA of South Greensboro** as submitted while partially approving the application for **TRC/Central Greensboro Dialysis**, the application for **TRC/Central Greensboro Dialysis** is approved as submitted and the application for **BMA/BMA of South Greensboro** is approved to relocate 10 dialysis stations instead of relocating 12 dialysis stations as proposed.

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

- **Project ID #G-11744-19 /Develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County pursuant to Policy ESRD-2, and develop a home peritoneal training and support program**

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

- **Project ID #G-11737-19 Relocate no more than 10 dialysis stations from BMA Burlington (Alamance County) pursuant to Policy ESRD-2 for a total of no more than 54 stations at BMA of South Greensboro upon project completion**

Project ID #G-11744-19 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 Central Greensboro Dialysis by relocating no more than 7 dialysis stations from Reidsville Dialysis (Rockingham County) and no more than 3 stations from Burlington Dialysis (Alamance 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 7 dialysis stations at Reidsville Dialysis for a total of no more than 24 dialysis stations at Reidsville Dialysis upon completion of this project.**
- 5. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 3 dialysis stations at Burlington Dialysis for a total of no more than 13 dialysis stations at Burlington Dialysis upon completion of this project.**
- 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 ID #G-11737-19 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 10 dialysis stations from BMA of Burlington (Alamance County) to BMA of South Greensboro, for a total of no more than 54 dialysis stations at BMA of South Greensboro upon project completion.**

- 3. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify 10 dialysis stations at BMA of Burlington for a total of no more than 35 dialysis stations at BMA of Burlington.**
- 4. 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.**