

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 12, 2019

Findings Date: December 12, 2019

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: G-11787-19

Facility: Dialysis Care of Rockingham County

FID #: 955844

County: Rockingham

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than 1 station for a total of no more than 26 stations upon project completion

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.

NC

Total Renal Care of North Carolina, LLC (TRC or “the applicant”) proposes to add one dialysis station to Dialysis Care of Rockingham County (DC-RC) for a total of 26 dialysis stations at DC-RC upon project completion.

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 12 dialysis stations in Rockingham County. Therefore, the July 2019 SDR does not indicate a need for additional stations in Rockingham County based on the county need methodology. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most

recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for DC-RC in the July 2019 SDR is 3.24 patients per station per week, or 81 percent, based on 81 in-center dialysis patients and 25 certified dialysis stations [$81 / 25 = 3.24$; $3.24 / 4 = 0.81$ or 81%].

Application of the facility need methodology indicates that up to a potential maximum of five additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW – JULY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		81.00%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		25
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		81
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		74
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1892
(ii)	Divide the result of Step (i) by 12	0.0158
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1892
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	96.3243
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.1014
	and subtract the number of certified and pending stations to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the July 2019 SDR. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add one new station and is therefore consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 31 of the 2019 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall

document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project will promote safety and quality in Section B, pages 12-13; Section N, page 49; Section O, pages 51-52; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 13; Section C, pages 22-23; Section L, pages 44-47; Section N, page 49; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 13-14; Section C, pages 19-21; Section F, pages 29-32; Section K, pages 41-42; Section N, page 49; and referenced exhibits. However, the information provided by the applicant is not reasonable and does not adequately support the determination that the applicant’s proposal would maximize healthcare value because projected utilization is not based on reasonable and adequately supported assumptions. 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 not conforming to this criterion because the applicant does not adequately demonstrate how the projected volumes incorporate maximum healthcare value for the resources expended.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which

all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The applicant proposes to add one dialysis station to DC-RC for a total of 26 dialysis stations upon project completion.

DC-RC currently offers home peritoneal dialysis training and support (PD) but not home hemodialysis training and support (HH). In Section C, page 21, the applicant states it projects no changes to the types of dialysis services offered at DC-RC – it will continue to offer both in-center dialysis and PD training and support.

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

Patient Origin

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

The following table illustrates current and projected patient origin.

DC-RC – Current and Projected Patient Origin						
	Current (12/31/2018)			Projected (Operating Year 2 – CY 2022)		
Location	# of IC* Patients	# of PD Patients	% of Total	# of IC* Patients	# of PD Patients	% of Total
Rockingham	69	5	83.1%	76	9	85.0%
Virginia	10	0	11.2%	10	0	10.0%
Stokes	1	0	1.1%	1	0	1.0%
Caswell	1	1	2.2%	1	1	2.0%
Other States	0	2	2.2%	0	2	2.0%
Total	81	8	100.0%	88	12	100.0%

Table may not foot due to rounding.

Source: Section C, pages 18-19

*IC = In-Center

In Section C, pages 19-21, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions start with the number of Rockingham County in-center patients dialyzing at DC-RC as of January 1, 2019; growing the Rockingham County patient population by a specific growth rate; and adding one dialysis station.

On pages 19-20, the applicant states it projects the Rockingham County in-center patient population to grow at an Average Annual Change Rate (AACR) of 2.5 percent, which the applicant describes as the Rockingham County Five Year AACR published in the July 2019 SDR. However, in Table D of the July 2019 SDR, the Rockingham County Five Year AACR is listed as 1.8 percent, not 2.5 percent, and the applicant provides no support to justify its use of a 2.5 percent AACR. In Section G, page 34, the applicant states ESRD Data Collection Forms for dialysis facilities were submitted to the Agency in August 2019, at least one and a half months before this application was submitted. According to the ESRD Data Collection Form for DC-RC, not only did the overall facility census decline from 81 in-center patients on December 31, 2018 to 79 in-center patients on June 30, 2019, the Rockingham County in-center patient census declined from 69 in-center patients on December 31, 2018 to 64 in-center patients on June 30, 2019. The patient origin projections are based on an unsupported growth rate higher than the Rockingham County Five Year AACR and on a historical Rockingham County in-center patient population higher than the current Rockingham County in-center patient population.

The applicant's assumptions relative to in-center patient origin are not reasonable or adequately supported; therefore, the applicant does not adequately identify the population to be served.

Analysis of Need

In Section C, page 21, the applicant states that the facility need methodology table in Section B, page 10, outlines the need the in-center patient population to be served has for the proposed one-station expansion.

The applicant uses the following assumptions to support its stated need for one additional station and projected utilization, as discussed in Section C, pages 19-21:

- The applicant projects OY1 of the project will be January 1, 2021 – December 31, 2021 (CY2021) and OY2 will be January 1, 2022 – December 31, 2022 (CY2022).
- Per the July 2019 SDR, as of December 31, 2018, DC-RC was providing dialysis treatment for 81 in-center patients on 25 stations at a utilization rate of 81 percent. Of the 81 total patients, 69 patients lived in Rockingham County.
- The applicant projects growth of the Rockingham County in-center patient population utilizing the facility by using an AACR of 2.5 percent and projects the growth of the Rockingham County in-center patient population beginning on January 1, 2019.

However, the information provided is not reasonable or adequately supported for the following reasons:

- The Rockingham County Five Year AACR as published in the July 2019 SDR is 1.8 percent, not 2.5 percent.

- Based on the ESRD Data Collection Form submitted to the Agency in August 2019, Rockingham County in-center patient census shows a decline of five Rockingham County in-center patients between December 31, 2018 and June 30, 2019, which results in utilization projections that are not reasonable and adequately supported.
- Despite the facility need methodology showing a need for up to five additional stations at DC-RC, the facility’s historical growth rates are consistently negative, with little positive growth.

According to the applicant’s historical ESRD Data Collection Forms that have been submitted to the Agency, DC-RC’s total in-center patient population as well as its Rockingham County in-center patient population have experienced a net decrease during the time period between December 31, 2015 and June 30, 2019. The table below shows the historical total in-center patient census as well as the Rockingham County in-center patient census as reported by the applicant to the Agency.

DC-RC Historical Census as Reported on ESRD Data Collection Forms								
In-Center Census	12/31/15	6/30/16	12/31/16	6/30/17	12/31/17	6/30/18	12/31/18	6/30/19
Total	80	80	77	80	77	74	81	79
Rockingham County	69	69	62	65	63	59	69	64

The table below shows selected growth rates based on in-center patient census.

Selected Growth Rates of DC-RC In-Center Patients*		
	Total	Rockingham County
Total CAGR** (42 months)	-0.11%	-0.63%
Total AGR*** (42 months)	-2.37%	-1.44%
3-yr CAGR (12/2015 to 12/2018)	0.41%	0.00%
3-yr AGR (12/2015 to 12/2018)	0.48%	0.33%
3-yr CAGR (6/2016 to 6/2019)	-0.42%	-2.48%
3-yr AGR (6/2016 to 6/2019)	-0.25%	-2.19%
2-yr CAGR (12/2015 to 12/2017)	-1.89%	-4.45%
2-yr AGR (12/2015 to 12/2017)	-1.88%	-4.27%
2-yr CAGR (6/2016 to 6/2018)	-3.82%	-7.53%
2-yr AGR (6/2016 to 6/2018)	-3.75%	-7.52%
2-yr CAGR (12/2016 to 12/2018)	2.56%	5.49%
2-yr AGR (12/2016 to 12/2018)	2.60%	5.57%
2-yr CAGR (6/2017 to 6/2019)	-0.63%	-0.77%
2-yr AGR (6/2017 to 6/2019)	-0.37%	-0.38%

*See the Working Papers for explanations of how each growth rate was calculated.

**CAGR = Compound Annual Growth Rate

***AGR = Average Growth Rate

The in-center facility census – both for total patients and for Rockingham County patients – reported for DC-RC on December 31, 2018 appears to be an outlier year with regard to growth. In the table above, the only calculations that show a positive growth rate involve a period of time ending on the December 31, 2018 outlier. All other growth rates are

negative. The applicant provides no information to support its stated need for an additional dialysis station at a facility which has experienced a net decline in utilization even with an outlier data set over the last three and a half years.

Projected Utilization

In Section C, pages 18-19, the applicant provides historical and projected utilization as illustrated in the following table.

DC-RC – Historical and Projected Utilization						
	Current (12/31/2018)			Projected (Operating Year 2 – CY 2022)		
Location	# of IC* Patients	# of PD Patients	% of Total	# of IC* Patients	# of PD Patients	% of Total
Rockingham	69	5	83.1%	76	9	85.0%
Virginia	10	0	11.2%	10	0	10.0%
Stokes	1	0	1.1%	1	0	1.0%
Caswell	1	1	2.2%	1	1	2.0%
Other States	0	2	2.2%	0	2	2.0%
Total	81	8	100.0%	88	12	100.0%

Table may not foot due to rounding.

Source: Section C, pages 18-19

*IC = In-Center

In Section C, pages 19-21, the applicant provides the assumptions and methodology used to project in-center and PD patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections with the in-center patient facility census as of January 1, 2019. On page 19, the applicant states that, as of December 31, 2018, it was serving 69 Rockingham County patients and 12 patients residing outside of Rockingham County.
- The applicant states the Rockingham County Five Year AACR as published in the July 2019 SDR is 2.5 percent and applies that growth rate to the Rockingham County in-center patient census.
- The applicant assumes no growth for DC-RC patients living outside of Rockingham County but assumes the patients will continue to dialyze at DC-RC and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 20, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

DC-RC IC Projected Utilization	
Starting point of calculations is Rockingham County patients dialyzing in-center at DC-RC on January 1, 2019.	69
Rockingham County patient population is projected forward by one year to December 31, 2019, using the applicant's growth rate (2.5%).	$69 \times 1.025 = 70.725$
Rockingham County patient population is projected forward by one year to December 31, 2020, using the applicant's growth rate (2.5%).	$70.725 \times 1.025 = 72.4931$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$72.4931 + 12 = 84.4931$
Rockingham County patient population is projected forward by one year to December 31, 2021, using the applicant's growth rate (2.5%).	$72.4931 \times 1.025 = 74.3055$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2021 (OY1).	$74.3055 + 12 = 86.3055$
Rockingham County patient population is projected forward by one year to December 31, 2022, using the applicant's growth rate (2.5%).	$74.3055 \times 1.025 = 76.1631$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2022 (OY2).	$76.1631 + 12 = 88.1631$

The applicant's calculations result in a projection to serve 86 in-center patients on 26 stations, which is 3.31 patients per station per week ($86 \text{ patients} / 26 \text{ stations} = 3.31$), by the end of OY1 and 88 in-center patients on 26 stations, which is 3.38 patients per station per week ($88 \text{ patients} / 26 \text{ stations} = 3.38$), by the end of OY2.

However, the projections as provided by the applicant on pages 19-20 do not use the correct Five Year AACR for Rockingham County and do not account for the recent decline in the Rockingham County in-center patient census. The applicant begins its patient census calculation at 69 Rockingham County patients instead of 64 Rockingham County patients as the applicant reported on the ESRD Data Collection Form it submitted to the Agency in August 2019.

The table below shows the same assumptions and methodology used by the applicant but substitutes the correct Rockingham County Five Year AACR of 1.8 percent and the in-center patient census as of June 30, 2019 (64 Rockingham County residents and 15 patients living outside of Rockingham County).

DC-RC IC Projected Utilization – Adjusted Calculations	
Starting point of calculations is Rockingham County patients dialyzing in-center at DC-RC on June 30, 2019.	64
Rockingham County patient population is projected forward by six months to December 31, 2019, using one half of the Rockingham County Five Year AACR (1.8%).	$64 \times 1.009 = 64.576$
Rockingham County patient population is projected forward by one year to December 31, 2020, using the Rockingham County Five Year AACR (1.8%).	$64.576 \times 1.018 = 65.7384$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2020 and the starting census for this project.	$65.7384 + 15 = 80.7384$
Rockingham County patient population is projected forward by one year to December 31, 2021, using the Rockingham County Five Year AACR (1.8%).	$65.7384 \times 1.018 = 66.9217$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2021 (OY1).	$66.9217 + 15 = 81.9217$
Rockingham County patient population is projected forward by one year to December 31, 2022, using the Rockingham County Five Year AACR (2.5%).	$66.9217 \times 1.018 = 68.1263$
The patients from outside Rockingham County are added. This is the projected census on December 31, 2022 (OY2).	$68.1263 + 15 = 83.1263$

The revised calculations result in a projection to serve 82 in-center patients on 26 stations, which is 3.15 patients per station per week ($82 \text{ patients} / 26 \text{ stations} = 3.15$), by the end of OY1 and 83 in-center patients on 26 stations, which is 3.19 patients per station per week ($83 \text{ patients} / 26 \text{ stations} = 3.19$), by the end of OY2. These projections do not meet 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).

Additionally, as discussed above in the Analysis of Need section, the facility has a net decline in historical utilization, with any positive growth rates based on an outlier data set in the facility census.

The applicant’s in-center projected utilization is not reasonable or adequately supported for the following reasons:

- The applicant does not use the current Five Year AACR for Rockingham County as published in the July 2019 SDR and does not provide any support for its use of a higher AACR.
- The applicant does not account for the reduction in Rockingham County patients at its facility between December 31, 2018 and June 30, 2019.

Home Peritoneal Dialysis Patients

- The applicant begins its utilization projections with the PD patient facility census as of January 1, 2019. On page 21, the applicant states that, as of January 1, 2019, it was providing training and support to 8 PD patients from Rockingham and other counties and states.
- The applicant assumes the DC-RC PD patient population will increase by one patient every calendar year, and that patient will be a Rockingham County patient.
- The project is scheduled to begin offering services on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

The applicant's utilization projections for the PD patient census at DC-RC through OY1 and OY2 are summarized in the table below.

DC-RC PD Projected Utilization	
Starting point of calculations is DC-RC PD patients on January 1, 2019.	8
DC-RC PD patient population is projected forward by one year to December 31, 2019.	$8 + 1 = 9$
DC-RC PD patient population is projected forward by one year to December 31, 2020. This is the starting census for the project.	$9 + 1 = 10$
DC-RC PD patient population is projected forward by one year to December 31, 2021. This is the projected census at the end of OY1.	$10 + 1 = 11$
DC-RC PD patient population is projected forward by one year to December 31, 2022. This is the projected census at the end of OY2.	$11 + 1 = 12$

The applicant's PD patient projected utilization is reasonable and adequately supported for the following reasons:

- According to the applicant's ESRD Data Collection Forms submitted to the Agency, between June 30, 2017 and June 30, 2019, the total PD patient population at DC-RC increased from 5 PD patients to 8 PD patients, which is a higher growth rate than the applicant's projected growth rate.
- According to the applicant's ESRD Data Collection Forms submitted to the Agency, between June 30, 2017 and June 30, 2019, the Rockingham County PD patient population at DC-RC increased from 2 PD patients to 7 PD patients, which is a higher growth rate than the applicant's projected growth rate.

Access

In Section C, pages 22-23, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

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

Dialysis Care of Rockingham County 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 46, 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.

DC-RC Projected Payor Mix CY 2022				
Type of Dialysis	In-Center		Home Peritoneal Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0	0.0%
Insurance*	6.5	7.4%	0	0.0%
Medicare*	69.5	79.0%	12	100.0%
Medicaid*	6.5	7.4%	0	0.0%
Other	5.5	6.2%	0	0.0%
Total	88.0	100.0%	12	100.0%

*Including any managed care plans

Note: The Project Analyst manually calculated the number of patients in each payor category by multiplying the total number of projected patients by the percentage in each payor category.

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 not conforming to this criterion for the following reasons:

- The applicant does not adequately identify the population to be served.

- The applicant does not adequately explain why the population to be served needs the services proposed in this application.
 - Projected utilization is not reasonable and is not adequately supported.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

The applicant proposes to add one station to DC-RC for a total of 26 stations upon project completion.

In Section E, page 28, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo could result in restricted admissions or a third shift; therefore, this is not an effective alternative.
- Relocate Stations from Another DaVita Facility: the applicant states its other facility in Rockingham County, Reidsville Dialysis, has a patient census which has increased by three patients in the last six months. The applicant assumes the facility census will grow by another three patients by the end of the year, which would result in a utilization rate of 75 percent, and states there is no facility need determination for the facility in 2020; therefore, this is not an effective alternative.

On page 28, the applicant states its proposal is the most effective alternative because it meets the growing demand for services at DC-RC.

The applicant states it is reasonable to expect the facility census of Reidsville Dialysis to grow from 75 patients to 81 patients in a 12 month period – a growth rate of eight percent, which is more than four times higher than the Five Year AACR for Rockingham County as published in the July 2019 SDR. Further, the applicant's ESRD Data Collection Form for Reidsville

Dialysis submitted to the Agency for the June 30, 2019 patient census shows the additional three patients are not from Rockingham County. The applicant provides no support for its assumption of growth at Reidsville Dialysis.

The applicant also submitted an application on July 15, 2019, proposing to relocate seven stations from Reidsville Dialysis to Guilford County (Project I.D. #G-11744-19). The applicant does not mention the proposal to relocate seven stations from Rockingham County to Guilford County in the current application. If the application to relocate stations from Reidsville Dialysis to Guilford County is approved, that would support the applicant's determination that relocating stations from Reidsville Dialysis is not the most effective alternative.

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

- The applicant does not adequately demonstrate the need to add an additional station to DC-RC and the assumptions and methodology used to project utilization at DC-RC are not reasonable and adequately supported.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

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

NC

The applicant proposes to add one station to DC-RC for a total of 26 stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$12,918, to be used entirely for medical equipment. In Section Q, the applicant provides the assumptions used to

project the capital cost. In Section F, pages 30-31, the applicant states there are no projected start-up expenses or initial operating expenses because DC-RC is an existing and operational facility. The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.

Availability of Funds

In Section F, page 29, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., DC-RC's parent company, authorizing the use of accumulated reserves for the capital needs and any other 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 needs of the proposed project. The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
DC-RC	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	14,153	14,620
Total Gross Revenues (Charges)	\$4,442,623	\$4,583,205
Total Net Revenue	\$4,442,623	\$4,583,205
Average Net Revenue per Treatment	\$314	\$313
Total Operating Expenses (Costs)	\$3,203,463	\$3,286,944
Average Operating Expense per Treatment	\$226	\$225
Net Income/Profit	\$1,239,159	\$1,296,261

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate 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.

NC

The applicant proposes to add one station to DC-RC for a total of 26 stations upon project completion.

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 Rockingham County. Facilities may serve residents of counties not included in their service area.

There are three facilities which provide dialysis and/or dialysis home training and support in Rockingham County. Information on these facilities is provided below.

Rockingham County Dialysis Facilities						
Certified Stations and Utilization as of December 31, 2018						
Dialysis Facility	Owner	Location	# of Certified Stations	# Patients	Patients/Station	Utilization
DC-RC	DaVita	Eden	25	81	3.2400	81.00%
Reidsville Dialysis	DaVita	Reidsville	27	75	2.7778	69.44%
Rockingham Kidney Center	BMA	Reidsville	19	56	2.9474	73.68%

Sources: Section G, page 34; Table B, July 2019 SDR

In Section G, page 34, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Rockingham County. The applicant states:

“Of the three [existing and approved dialysis facilities in Rockingham County] listed, two are operated by subsidiaries of the applicant’s parent company, DaVita. ...

.... The census at Reidsville Dialysis did increase during the first six months of 2019, as reported in the ESRD Data Collection Forms which were submitted to DHSR Healthcare Planning in August, 2019, and is currently above 70%. ..., we demonstrate the need that Dialysis Care of Rockingham County has for adding stations. While adding stations at this facility does increase the number of stations in Rockingham County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

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

- The applicant does not adequately identify the population to be served or demonstrate the need the proposed population has for the stations.
- Projected utilization is not based on reasonable and adequately supported assumptions.

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 not conforming to this criterion for the reasons stated above.

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

C

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services. The applicant proposes no changes in staffing as a result of the proposed project.

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 36-37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-1 through H-3. In Section H, page 37, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating his interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 38, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

DC-RC – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	Durham West Dialysis On site On site
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	UNC Rockingham Health Care
Emergency care	UNC Rockingham Health Care
Blood bank services	UNC Rockingham Health Care
Diagnostic and evaluation services	UNC Rockingham Health Care
X-ray services	UNC Rockingham Health Care
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	UNC Rockingham Health Care
Vascular surgery	UNC Rockingham Health Care
Transplantation services	Wake Forest Baptist Medical Center
Vocational rehabilitation & counseling	Vocational & Rehabilitation Services of Rockingham County
Transportation	RCATS

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 39, the applicant describes its existing 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.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing

the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(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

In Section L, page 45, the applicant provides the historical payor mix during CY 2018 for its existing services, as illustrated in the following table.

DC-RC Historical Payor Mix CY 2018				
Type of Dialysis	In-Center		Home Peritoneal Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients
Self-Pay	0	0.0%	0	0.0%
Insurance*	6	7.4%	0	0.0%
Medicare*	64	79.0%	8	100.0%
Medicaid*	6	7.4%	0	0.0%
Other	5	6.2%	0	0.0%
Total	81	100.0%	8	100.0%

*Including any managed care plans

Note: The Project Analyst manually calculated the number of patients in each payor category by multiplying the total number of historical patients by the percentage in each payor category.

In Section L, page 44, the applicant provides the following comparison.

	Percentage of Total Patients Served by DC-RC during the Last Full OY	Percentage of the Population of Rockingham County
Female	41.4%	51.8%
Male	58.6%	48.2%
Unknown	0.0%	0.0%
64 and Younger	54.0%	79.5%
65 and Older	46.0%	20.5%
American Indian	0.0%	0.6%
Asian	0.0%	0.7%
Black or African-American	48.3%	19.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	49.4%	77.6%
Other Race	2.3%	2.0%
Declined / Unavailable	0.0%	0.0%

Sources: TRC Internal Data, US Census Bureau

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 45, that DC-RC has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 45, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 46, 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.

DC-RC Projected Payor Mix CY 2022				
Type of Dialysis	In-Center		Home Peritoneal Dialysis	
Payment Source	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	0	0.0%
Insurance*	6.5	7.4%	0	0.0%
Medicare*	69.5	79.0%	12	100.0%
Medicaid*	6.5	7.4%	0	0.0%
Other	5.5	6.2%	0	0.0%
Total	88.0	100.0%	12	100.0%

*Including any managed care plans

Note: The Project Analyst manually calculated the number of patients in each payor category by multiplying the total number of projected patients by the percentage in each payor category.

As shown in the table above, during the applicant's second full fiscal year following project completion, all PD services will be provided to Medicare patients; 79 percent of in-center services will be provided to Medicare patients; and 7.4 percent of in-center services will be provided to Medicaid patients.

On page 46, 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 facility's historical payor mix.

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

In Section L, pages 46-47, 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

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area 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.

NC

The applicant proposes to add one station to DC-RC for a total of 26 stations upon project completion.

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 Rockingham County. Facilities may serve residents of counties not included in their service area.

There are three facilities which provide dialysis and/or dialysis home training and support in Rockingham County. Information on these facilities is provided below.

Rockingham County Dialysis Facilities						
Certified Stations and Utilization as of December 31, 2018						
Dialysis Facility	Owner	Location	# of Certified Stations	# Patients	Patients/Station	Utilization
DC-RC	DaVita	Eden	25	81	3.2400	81.00%
Reidsville Dialysis	DaVita	Reidsville	27	75	2.7778	69.44%
Rockingham Kidney Center	BMA	Reidsville	19	56	2.9474	73.68%

Sources: Section G, page 34; Table B, July 2019 SDR

In Section N, page 49, 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. The applicant states:

“The expansion of Dialysis Care of Rockingham County will have no effect on competition in Rockingham County. ..., this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.

The expansion of Dialysis Care of Rockingham County will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our

patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

The applicant adequately demonstrates:

- Quality services will be provided (see Sections B and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C and L of the application and any exhibits).

However, the applicant does not adequately demonstrate the cost-effectiveness of the proposal and thus does not adequately describe the expected effects of the proposed services on competition in the service area. The discussions regarding projected utilization found in Criterion (3) and financial feasibility found in Criterion (5) 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 not conforming to this criterion for the reasons stated above.

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

C

On Form A in Section Q, the applicant identifies the kidney disease treatment centers 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 51-52, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy violation occurred in one of these facilities. The applicant states that the problem has 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.

NC

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is not 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- DC-RC is an existing facility. Therefore, this Rule is not applicable to this review.

(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.*

-NC- In Section C, page 20, the applicant projects that DC-RC will serve 86 patients on 26 stations, or a rate of 3.31 patients per station per week, as of the end of the first operating year following project completion. However, the applicant's projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

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