

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 6, 2019

Findings Date: June 6, 2019

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: P-11684-19

Facility: Mt. Olive Dialysis

FID #: 000304

County: Wayne

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 3 dialysis stations for a total of no more than 20 stations upon completion of this project and Project ID #P-11598-18 (add 2 stations)

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

DVA Renal Healthcare, Inc. d/b/a Mt Olive Dialysis (the applicant) proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations). While Mt. Olive Dialysis had 1 peritoneal dialysis (PD) patient as of June 30, 2018 the facility does not offer a PD program nor does it offer a home hemodialysis (HH) program. The parent company of DVA Renal Healthcare, Inc. is DaVita, Inc. (DaVita).

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 January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for Wayne County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Mt. Olive Dialysis in the January 2019 SDR is 3.9333 patients per station per week. This utilization rate was calculated based on 59 in-center dialysis patients and 15 certified dialysis stations as of June 30, 2018 (59 patients /15 stations = 3.9333 patients per station per week). Application of the facility need methodology indicates that 5 additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		98.33%
Certified Stations		15
Pending Stations		2
Total Existing and Pending Stations		17
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		59
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		50
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.3600
(ii)	Divide the result of step (i) by 12	0.0300
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.1800
(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	69.6200
(v)	Divide the result of step (iv) by 3.2 patients per station	21.7563
	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 5 stations. Rounding to the nearest whole number is allowed in Step (v) of the facility need methodology, as stated in the January 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 3 new stations and, therefore, is 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, is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a), pages 9-10, Section K.1(g), page 38, Section N, page 48, Section O, page 49, and Exhibits O-2 and O-3. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section C.3, page 15, Section L, pages 42-45, Exhibit L-3 and Section N, page 48. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c) and (d), page 11, Section C, pages 13-15, Section F, pages 22-27, Section K, pages 37-38, Section N.1, page 48 and Section R. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

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.

- (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

The applicant proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations).

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 is Wayne County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate current and projected patient origin for in-center (IC) patients and PD patients.

Mt. Olive Dialysis: Historical Patient Origin as of December 31, 2018

County	IC Patients	PD Patients
Wayne	47	1
Duplin	10	0
Sampson	2	0
Total	59	1

Source: Table on page 18 of the application.

Mt. Olive Dialysis: Projected Patient Origin

County	Operating Year 1 (OY1) [1/1/21 – 12/31/21]		Operating Year 2 (OY2) [1/1/22 – 12/31/22]		County Patients as a % of Total	
	IC Patients	PD Patients	IC Patients	PD Patients	OY1	OY2
Wayne	55	0	59	0	82.1%	83.1%
Duplin	10	0	10	0	14.9%	14.1%
Sampson	2	0	2	0	3.0%	2.8%
Total	67	0	71	0	100.0%	100.0%

Source: Table on page 13 of the application.

However, based on the applicant’s methodology and calculations in Section C, pages 13-14, the number of Wayne County IC patients for OY1 and OY2 is 57 and 60 respectively resulting in the total number of IC patients for OY1 and OY2 being 69 and 72 respectively. The corrections are illustrated in the table below:

Mt. Olive Dialysis: Projected Patient Origin- CORRECTED TABLE

County	Operating Year 1 (OY1) [1/1/21 – 12/31/21]		Operating Year 2 (OY2) [1/1/22 – 12/31/22]		County Patients as a % of Total	
	IC Patients	PD Patients	IC Patients	PD Patients	OY1	OY2
Wayne	57	0	60	0	82.6%	83.3%
Duplin	10	0	10	0	14.5%	13.9%
Sampson	2	0	2	0	2.9%	2.8%
Total	69	0	72	0	100.00%	100.00%

Source: Table on page 13 of the application.

In Section C, pages 13-14, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2019 SMFP utilizing data from the January 2019 SDR.

- The January 2019 SDR shows that Mt. Olive Dialysis operated at a utilization rate of 98.33 percent (3.9333 patients per station per week) as of June 30, 2018, and had 59 in-center patients. The applicant states that 47 of the 59 patients were residents of Wayne County with 12 patients residing in other counties.
- The applicant projects the first full operating year of the project will be January 1, 2021 – December 31, 2021 (CY2021) and the second full operating year will be January 1, 2022 – December 31, 2022 (CY2022).
- The applicant begins the projections for the future patient population of Mt. Olive Dialysis by using the ending in-center patient census of 47 patients from Wayne County, as of June 30, 2018.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Wayne County which is 5.9%, as published in the January 2018 SDR, to project the Wayne County patient population forward.
- The applicant does not project an increase in the 12 patients who utilize the facility and live in other counties.
- The applicant adds the two dialysis stations approved to be added to the Mt. Olive Dialysis facility per Project I.D. #P-11598-18.

Projected Utilization

In Section C, pages 13-14, the applicant provides projected utilization as summarized in the following table

Mt. Olive Dialysis	In-Center Patients
As of June 30, 2018 there were 47 Wayne County IC patients	47
Project the Wayne County IC patients forward six months to December 31, 2018, using the Five Year AACR for Wayne County of 5.9%.	$47 \times 1.0295 = 48.3865$
Project the Wayne County IC patients forward to December 31, 2019, using the Five Year AACR for Wayne County.	$48.3865 \times 1.059 = 51.2413$
Project the Wayne County IC patients forward to December 31, 2020, using the Five Year AACR for Wayne County	$51.2413 \times 1.059 = 54.2645$
Project the Wayne County IC patients forward to December 31, 2021, using the Five Year AACR for Wayne County.	$54.2645 \times 1.059 = 57.4661$
Add the 12 patients from other counties currently dialyzing at Wallace Dialysis. This is the IC patient census at the end of OY1	$57.4661 + 12 = \mathbf{69.4661}$
Project the Wayne County IC patients forward to December 31, 2022, using the Five Year AACR for Wayne County.	$57.4661 \times 1.059 = 60.8565$
Add the 12 patients from other counties currently dialyzing at Wallace Dialysis. This is the IC patient census at the end of OY2.	$60.8565 + 12 = \mathbf{72.8565}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2021) and OY2 (CY2022) the facility is projected to serve 69 and 72 in-center patients, respectively.

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

- OY1: 3.45 patients per station per week, or 86.25% ($69 \text{ patients} / 20 \text{ stations} = 3.45 / 4 = 0.8625$ or 86.25%).
- OY2: 3.6 patients per station per week, or 90.00% ($72 \text{ patients} / 20 \text{ stations} = 3.6 / 4 = 0.9$ or 90.00%).

The projected utilization of 3.45 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 47 existing Wayne County patients.
- The Wayne County patients are projected to increase based on 5.9% per year which is the Five Year AACR for Wayne County as reported in Table D of the January 2019 SDR.

- The applicant projects no growth for patients who utilize the facility and live in other counties.

Access

In Section C, page 15, 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 handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Payment will not be required upon admission. Therefore services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped, elderly, and other under-served.”

In Section L, page 43, 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.

**Mt. Olive Dialysis Payor Mix
FY2**

Payor Category	Percent of Total Patients
Medicaid	14.3%
Medicare	22.2%
Medicare/Commercial	27.0%
Medicare/Medicaid	27.0%
VA	3.2%
Commercial Insurance	4.8%
Private Pay	1.6%
Total	100.0%

Source: Table on page 43 of the application.

Note: Totals might foot due to rounding.

The projected payor mix is reasonable and adequately supported.

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 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 (payer 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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility. 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.

CA

The applicant proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations).

In Section E, page 21, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at the facility.

Relocate Stations from another DaVita Facility in Wayne County- Two of the four operational DaVita dialysis facilities in Wayne County are operating at less than 80.0%: Goldsboro South Dialysis (73.0%) and Coastal Plains Dialysis (27.08%). However, transferring stations from either of these two facilities is not the most effective alternative. Three dialysis stations are approved to be relocated from Goldsboro South to another DaVita facility in Wayne County, Rosewood Dialysis (See Project I.D. #011451-18). The other facility, Coastal Plains Dialysis

(12 stations/ 27.08% utilization) was only certified as of January 2018. Further, Per Chapter 14 of the 2018 SMFP, a dialysis facility cannot have less than 10 dialysis stations, therefore, relocating stations from the twelve station Coastal Plains Dialysis facility is not a feasible option. In addition, the applicant states that relocating stations from Coastal Plains Dialysis or relocating additional stations from Goldsboro South Dialysis would negatively impact patients currently dialyzing at that facility.

On page 21, the applicant states that its proposal is the most effective alternative because:

- The proposed project will proactively address both the issues of growth and access to the facility.
- Developing a third shift is inconvenient for patients and if a facility is at its maximum capacity that eliminates patient choice.

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the January 2019 SDR, DVA Renal Healthcare, Inc. shall develop no more than three additional dialysis stations for a total of no more than 20 certified stations at Mt. Olive Dialysis upon completion of this project and Project I.D. #P-11598-18 (add two stations), which shall include any home hemodialysis training or isolation stations.**
- 3. DVA Renal Healthcare, 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.**

- (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

The applicant proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations).

Capital and Working Capital Costs

In Section F, page 22, the applicant projects the total capital cost of the project as shown in the table below.

Miscellaneous Costs	\$34,956
Total	\$34,956

In Section F, pages 24-25, the applicant states there will be no start-up or initial operating expenses associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F, page 23 the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita Inc.	Total
Accumulated reserves or OE *	\$34,956	\$34,956
Total Financing	\$34,956	\$34,956

* OE = Owner's Equity

Exhibit F-5 contains a letter dated March 13, 2019 from the Chief Accounting Officer for DaVita Inc., parent company to DVA Renal Healthcare, Inc., authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-7 contains a copy of the Consolidated Balance Sheets from DaVita, Inc., for year ending December 31, 2018. DaVita, Inc. had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	10,004	10,448
Total Gross Revenues (Charges)	\$2,667,502	\$2,785,745
Total Net Revenue	\$2,562,901	\$2,676,485
Average Net Revenue per Treatment	\$256	\$256
Total Operating Expenses (Costs)	\$2,441,031	\$2,539,447
Average Operating Expense per Treatment	\$244	\$243
Net Income	\$121,870	\$137,038

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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 costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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

The applicant proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations).

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 is Wayne County. Facilities may also serve residents of counties not included in their service area.

DaVita operates five of the six dialysis facilities (existing or approved) in Wayne County, as shown below.

Facility Name	Provider	Location	# of Stations	Utilization
Goldsboro Dialysis	DaVita	Goldsboro	24	104.17%
Mt Olive Dialysis	DaVita	Mt Olive	15	98.33%
Goldsboro South Dialysis	DaVita	Goldsboro	25	73.00%
Coastal Plains Dialysis	DaVita	Goldsboro	12	27.08%
Rosewood Dialysis	DaVita	Goldsboro	0	0.00%
RAI Care Centers-Goldsboro	RAI/FMC	Goldsboro	16	103.13%

Source: January 2019 SDR, Table B

In Section G, page 28, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wayne County. The applicant states:

“While adding stations at this facility does increase the number of stations in Wayne 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.”

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

- There is a facility need determination for the proposed three additional dialysis stations as calculated using the methodology in the January 2019 SDR.
- The applicant adequately demonstrates that the proposed three dialysis stations are needed in addition to the existing or approved dialysis facilities in Wayne County.

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.

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

C

In Section H.1, page 29, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(CY2018)	2nd Full Fiscal Year (CY2022)
RNs	2.0	3.0
Technician (PCT)	6.0	8.0
Administrator	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Admin Assistant	1.0	1.0
Biomed Tech	0.5	0.5
TOTAL	11.5	14.5

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H.3 and H.4, pages 30 and 31, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 30, the applicant identifies the current medical director. In Exhibit I-3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-2-4, I-1 and I-3, the applicant provides supporting documentation.

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.

In Section I, page 33, the applicant states that the following ancillary and support services are necessary for the proposed services and explains how each ancillary and support service is made available:

MT. OLIVE DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On-Site
Self-care training (in-center)	On-Site
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	Goldsboro Dialysis
Psychological counseling	On-Site
Isolation – hepatitis	On-Site
Nutritional counseling	On-Site
Social Work services	On-Site
Acute dialysis in an acute care setting	Wayne Memorial Hospital
Emergency care	Wayne Memorial Hospital
Blood bank services	Wayne Memorial Hospital
Diagnostic and evaluation services	Wayne Memorial Hospital
X-ray services	Wayne Memorial Hospital
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Wayne Memorial Hospital
Vascular surgery	Wayne Memorial Hospital
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation Services
Transportation	Wayne County DSS

Source: Table on page 33 of the application.

In Section I, pages 33-35, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1 and I-3.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

- (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 make more than minor renovations to 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 46, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

**Mt. Olive Dialysis Payor Mix
 CY2018**

Payor Category	Percent of Total Patients
Medicaid	14.1%
Medicare	23.4%
Medicare/Commercial	26.6%
Medicare/Medicaid	26.6%
VA	3.1%
Commercial Insurance	4.7%
Private Pay	1.6%
Total	100.0%

Source: Table on page 46 of the application.
 Note: Totals might foot due to rounding.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wayne	16%	51%	47%	21%	13%	15%
Duplin	18%	51%	49%	21%	13%	20%
Sampson	17%	51%	49%	20%	14%	19%
Statewide	16%	51%	37%	15%	10%	12%

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

* Excludes "White alone, not Hispanic or Latino"

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

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report

which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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

The Agency reviewed the:

- Application
- 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, in Section L.3(d), page 45, the applicant states

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

In Section L.6, page 45, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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

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 43, 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.

**Mt. Olive Dialysis Payor Mix
FY2**

Payor Category	Percent of Total Patients
Medicaid	14.3%
Medicare	22.2%
Medicare/Commercial	27.0%
Medicare/Medicaid	27.0%
VA	3.2%
Commercial Insurance	4.8%
Private Pay	1.6%
Total	100.0%

Source: Table on page 43 of the application.

Note: Totals might foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 49.2% of total services will be provided to Medicare patients and 14.3% to Medicaid patients and 27.0% to Medicare/Medicaid patients.

On page 43, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient origin is comparable to its historical patient origin.

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.4, page 45, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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 47, 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.

C

The applicant proposes to add three dialysis stations to the existing facility, Mt. Olive Dialysis, for a total of 20 dialysis stations upon completion of this project and Project I.D. #P-11598-18 (add two stations).

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 is Wayne County. Facilities may also serve residents of counties not included in their service area.

DaVita operates five of the six dialysis facilities (existing or approved) in Wayne County, as shown below.

Facility Name	Provider	Location	# of Stations	Utilization
Goldsboro Dialysis	DaVita	Goldsboro	24	104.17%
Mt Olive Dialysis	DaVita	Mt Olive	15	98.33%
Goldsboro South Dialysis	DaVita	Goldsboro	25	73.00%
Coastal Plains Dialysis	DaVita	Goldsboro	12	27.08%
Rosewood Dialysis	DaVita	Goldsboro	0	0.00%
RAI Care Centers-Goldsboro	RAI/FMC	Goldsboro	16	103.13%

Source: January 2019 SDR, Table B

In Section N, page 48, 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 53, the applicant states:

“The expansion of Mt. Olive Dialysis will have no effect on competition in Wayne 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 DVA Renal Healthcare, Inc.”

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 Section 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

In Section A.11, page 5, the applicant states DaVita Inc. owns and operates over 90 dialysis facilities in North Carolina. In Exhibit A-11, the applicant provides a list of those facilities.

In Section O.3, page 49, and Exhibit O-3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant provides documentation regarding the deficiencies and subsequent measures taken by those facilities to ensure compliance with CMS Conditions for Coverage in Exhibit O-3. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- The applicant is not proposing to establish a new ESRD facility.

(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- In Section C, pages 13 - 16, the applicant demonstrates that Mt. Olive Dialysis will serve a total of 69 in-center patients at the end of OY1 (CY 2021) for a utilization rate of 86.25% or 3.45 patients per station per week ($69 \text{ patients} / 20 \text{ stations} = 3.45 / 4 = 0.8625$ or 86.25%). 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 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility.