

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 29, 2018

Findings Date: June 29, 2018

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: F-11490-18

Facility: Marshville Dialysis

FID #: 060374

County: Union

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 stations at Marshville Dialysis

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 Healthcare Renal Care, Inc. (DVA and/or the applicant), d/b/a Marshville Dialysis proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. The parent company of DVA is DaVita, Inc. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Need Determination

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

Policies

There are one policy in the 2018 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2

Policy ESRD-2 states:

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

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

Marshville Dialysis and Union County Dialysis are both located in Union County. Therefore, the proposed project is in compliance with Policy ESRD-2.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the proposal is consistent with Policy ESRD 2 because the four dialysis stations are being relocated from Union County Dialysis to Marshville Dialysis. Both facilities are in the same county, Union County.

(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

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Marshville Dialysis: Historical and Projected Utilization

County	Current (12/31/17)	OY2 (CY2020)
	IC	IC
Union	24	43
Anson	11	14
Stanly	2	2
Total	27	59

Source: Tables on pages 12 and 17 of the application.

The applicant provides the assumptions and methodology used to project its patient origin on pages 12-14. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section B.3, page 7, Section C.1, pages 12-13 and Exhibit C-1, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In Section C.1, pages 12-14, the applicant describes its need methodology assumptions for projecting utilization of the proposed facility as follows:

- 13 Union County residents who currently receive in-center patients dialysis treatments at Union County Dialysis have signed letters indicating that they would consider

transferring their care to Marshville Dialysis based on the fact that Marshville Dialysis is either closer to their home and/or a more convenient location. See Exhibit C-1.

- Assumes that the 13 dialysis patients who signed letters of support will transfer their care to Marshville Dialysis center upon certification of the transferred stations.

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

- See Exhibit C-1 which contains 13 patient letters of support. The letters state:

In-Center:

“I fully support the transfer of four stations to the Marshville facility. Having my dialysis treatments at Marshville would be more convenient for me. I could travel between that my home [sic] home and that location more easily and quickly, which would save me time and money.”

Projected Utilization

The applicant provides historical and projected utilization as illustrated in the following table.

County	Current (12/31/17)	OY2 (CY2020)
	IC	IC
Union	24	43
Anson	11	14
Stanly	2	2
Total	27	59

Source: Tables on pages 12 and 17 of the application.

On pages 12-14, the applicant illustrates how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2019 – December 31, 2019.
- Operating Year Two (OY2) is January 1, 2020 – December 31, 2020.
- As of June 30, 2017, Marshville Dialysis had 37 in-center patients, 24 residents of Union County and 13 non-Union County residents.
- Assumes that the 13 dialysis patients who signed letters of support will transfer their care to Marshville Dialysis center upon certification of the transferred stations.
- Of the 13 dialysis patients who signed letters of support 10 are Union county residents and 3 are Anson county residents.

- The applicant projects no growth of the 16 non-Union county patients (13 already dialyzing at Marshville Dialysis plus the 3 Anson county patients who signed letters of support and are projected to transfer Marshville Dialysis upon project completion).
- In-center patient population of Union County residents is projected to grow at 8.9% (the Five-Year Average Annual Growth Rate (AAGR) for Union County) pursuant to Table D in the January 2018 Semi-Annual Dialysis Report (SDR).

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

Marshville Dialysis	In-Center Patients
Begin with Marshville’s in-center ESRD patient population from Union County, as of June 30, 2017.	24
Project the Union County population forward six months to December 31, 2017, using the Five Year AACR for Union County.	$24 \times 1.0445 = 25.068$
Project the Union County population forward one year to December 31, 2018, using the Five Year AACR for Union County.	$25.068 \times 1.089 = 27.299$
Add the 10 Union County patients projected to transfer from Union City Dialysis to the overall Union County patient population. This is the projected number of Union County patients as of the beginning of the completed project on January 1, 2018.	$27.299 + 10 = 37.299$
Project the Union County population forward one year to December 31, 2019, using the Five Year AACR for Union County.	$37 \times 1.089 = 40.293$
Add the 16 non-Union County patients: 3 Anson County patients projected to transfer from Union County Dialysis and the 13 non-Union County patients already dialyzing at Marshville Dialysis. $[3 + 13 = 16]$. This is the patient census at the end of OY1.	$40.293 + 16 = \mathbf{56.293}$
Project the Union County population forward one year to December 31, 2021, using the Five Year AACR for Union County.	$40.293 \times 1.089 = 43.879$
Add the 16 non-Union County patients: 3 Anson County patients projected to transfer from Union County Dialysis and the 13 non-Union County patients already dialyzing at Marshville Dialysis. $[3 + 13 = 16]$. This is the patient census at the end of OY2.	$43.879 + 16 = \mathbf{59.879}$

The applicant states on page 16 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of both OY1 (CY 2020) and OY2 (CY2021) the facility is projected to serve 56 and 59 in-center patients, respectively.

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

- OY1: 3.5 patients per station per week, or 87.5% ($56 \text{ patients} / 16 \text{ stations} = 3.5 / 4 = 0.875$ or 87.5%).
- OY2: 3.69 patients per station per week, or 92.25% ($59 \text{ patients} / 16 \text{ stations} = 3.69 / 4 = 0.9225$ or 92.25%).

The projected utilization of 3.5 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 in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth for the following reasons:

- The applicant’s starting Union County patient census is based on historic existing patient data.
- The applicant’s Union County patient growth projections are based on an assumption that Union County patient census will increase at an annual rate of 8.9%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Union County, as reported in Table D of the January 2018 SDR.
- The applicant’s non-Union County patient projections are based on historic utilization and patient letters of support for patients projected to transfer from Union County Dialysis.

Access

In Section C.3, page 14, the applicant states, “*By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*”

In Section L.1, page 44, the applicant projects the following payor mix during the second full fiscal year of operation (CY2020) following completion of the project, as illustrated in the following table.

Payor Category	Percent of Total Patients
Medicaid	10.8%
Medicare	37.9%
Medicare/Medicaid	10.8%
Medicare/Commercial	24.3%
VA	2.7%
Commercial Insurance	13.5%
Total	100.0%

Source: Table, page 44 of the application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application

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

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

The following table shows the projected relocation of stations from Union County Dialysis to the proposed Marshville Dialysis facility and identifies the number of patients projected to transfer from the existing facility to the proposed new facility.

Marshville Dialysis Project		
Facility	Number of Stations to be Relocated	Number of Patients Transferring
Union County Dialysis	4	13
Total Relocated and Transferred	4	13

In Section D.1, pages 20-21, the applicant explains why it believes the needs of the population presently utilizing the dialysis services to be relocated will be adequately met following completion of the project.

Union County Dialysis

According to the January 2018 SDR, there were 104 in-center patients dialyzing at Union County Dialysis and 28 certified dialysis stations for a utilization rate of 92.86%, or 3.7143 patients per station per week ($104/28 = 3.7143/4 = .9286$ or 92.86%) as of June 30, 2017.

In addition to the 28 certified stations as of June 30, 2017, Union County Dialysis was approved for a two station expansion in Project ID# F-11259-16 and a three station expansion in Project ID# F-11322-17 for a total of 33 dialysis stations (28 existing and 5 approved). The proposed project is to relocate four existing dialysis stations to Marshville Dialysis leaving Union County Dialysis with a total of 29 dialysis stations (24 existing and 5 approved).

As of June 30, 2017, of the 104 in-center patients 93 were residents of Union County and 11 were not residents of Union County. Per the letters of support of the 13 current patients of Union County Dialysis projected to transfer their care to Marshville Dialysis 10 are from Union County and 3 are from Anson County. See Section C.1, page 12 and Exhibit C.

It is assumed that the 13 in-center patients (10 from Union County and 3 from Anson County) who signed letters of support will transfer their care to Marshville Dialysis upon certification of the transferred stations which is projected to be January 1, 2019

The applicant assumes that the number of in-center patients at Union County Dialysis who reside in Union County will increase at a rate of 8.9% per year through the first two operating years of the project based on the Five Year Average Annual Change Rate (AACR) for Union County, as reported in Table D of the January 2018 SDR.

The applicant assumes that there will be no increase in the number of patients from the other counties.

In Section D.1, page 22, the applicant calculates the in-center patient census for Union County Dialysis starting June 30, 2017 through the first two operating years (CY2019 and CY2020), summarized as follows:

Union County Dialysis	In-Center Patients
Begin with Union County Dialysis's in-center ESRD patient population from Union County, as of June 30, 2017.	93
Project the Union County population forward six months to December 31, 2017, using the Five Year AACR for Union County.	$93 \times 1.0455 = 97.1385$
Project the Union County population forward one year to December 31, 2018, using the Five Year AACR for Union County.	$97.1385 \times 1.089 = 105.784$
Subtract the 10 Union County patients projected to transfer from Union City Dialysis to Marshville Dialysis. This is the projected number of Union County patients as of the beginning of the completed project on January 1, 2018.*	$105 - 10 = 95$
Project the Union County population forward one year to December 31, 2019, using the Five Year AACR for Union County.	$95 \times 1.089 = 103.455$
Add the 8 non-Union County residents: 11 non-Union County residents as of June 30, 2017 – 3 Anson county residents projected to transfer to Marshville Dialysis. $[11 - 3 = 8]$ This is the patient census at the end of OY1.	$103.455 + 8 = \mathbf{111.455}$
Project the Union County population forward one year to December 31, 2020, using the Five Year AACR for Union County.	$103.455 \times 1.089 = 112.662$
Add the 8 non-Union County residents: 11 non-Union County residents as of June 30, 2017 – 3 Anson county residents projected to transfer to Marshville Dialysis. $[11 - 3 = 8]$ This is the patient census at the end of OY2.	$112.662 + 8 = \mathbf{120.662}$

*Note: While the result in terms of in-center patient census is the same for OY1 and OY2 the applicant, in the calculations on page 21, incorrectly projected that all 13 of the patients projected to transfer their care to Marshville Dialysis were residents of Union County and subtracted 13 patients from the projected Union County patient census as of January 1, 2018. According to the letters of support in Exhibit C-1 and the statements and calculations in Section C.1, pages 12-13, 10 of the patients projected to transfer were from Union County and 3 of the patients were from Anson County. The calculations in the table above correct this issue.

Thus, on December 31, 2020, Union County Dialysis projected to have 29 certified dialysis stations with an in-center patient population of 111, which is equivalent to a utilization rate of 3.83 patients per station per week ($111 / 29 = 3.83/4 = 0.9575$ or 95.75%). In Section D.1, page 22, the applicant states that the given this projected in-center growth, the facility will be in position to add dialysis stations through the facility need methodology.

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

- The applicant projects the patient census for Union County Dialysis based on existing Union County Dialysis patients minus those patients who have signed letters expressing their intention to transfer their care from Union County Dialysis to the Marshville Dialysis facility.

- The applicant factored into projected utilization the 5 approved dialysis stations for Union County Dialysis [Project ID# F-11259-16 (add 2 dialysis stations) and Project ID# F-11322-17 (add 3 dialysis stations)] in addition to Union County Dialysis's 28 certified stations as of June 30, 2017
- The applicant's growth projections are based on an assumption that the Union County patient census will increase at an annual rate of 8.9%, which is consistent with the Five Year Average Annual Change Rate (AACR) for Union County, as reported in Table D of the January 2018 SDR.

Further, in Section D.2, page 22, the applicant states that the proposed relocation of stations will not will not adversely affect the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Conclusion

The Agency reviewed the:

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

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

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

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

CA

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

In Section E, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicant states that this is not the most effective alternative because of the need for dialysis patients who reside in Union and Anson counties to have dialysis stations in a more convenient location and closer to their homes.

Locate a Facility in a Different Location in Cabarrus County- The applicant states that this is not the most effective alternative because for a number of dialysis patients currently traveling to Union County Dialysis the Marshville Dialysis facility is a closer and more convenient location and the relocation of four dialysis stations from Union County Dialysis to Marshville Dialysis allows these patients to transfer their care to Marshville Dialysis.

On page 22, the applicant states that its proposal is the most effective alternative because the proposed project offers current Union County and Anson County dialysis patients a more convenient location which is often closer to their homes than the Union County Dialysis facility. The proposed project addresses both growth and access issues.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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. Therefore, the application is approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, DVA Healthcare Renal Care, Inc. shall relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis upon project completion.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Marshville Dialysis shall install plumbing and electrical wiring through the walls for no more than 16 dialysis stations which shall include any isolation stations.**
- 4. Upon completion of this project, DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify four dialysis stations at Union County Dialysis for a total of no more than 29 dialysis stations at Union County Dialysis.**
- 5. DVA Healthcare Renal Care, 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

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Capital and Working Capital Costs

In Section F, page 23, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$46,608
Total	\$46,608

In Section F.1, page 23, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 25-26, the applicant states that there will be no start-up costs since Marshville Dialysis is an existing facility.

Availability of Funds

In Section F.2, page 24, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total Renal Care of North Carolina	Total
Accumulated reserves or OE *	\$46,608	\$46,608
Total Financing	\$46,608	\$46,608

* OE = Owner's Equity

Financial Feasibility

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

	1 st Full Fiscal Year*	2 nd Full Fiscal Year
Total Treatments	8,077	8,522
Total Gross Revenues (Charges)	\$2,916,971	\$3,077,298
Total Net Revenue	\$2,775,880	\$2,928,466
Average Net Revenue per treatment	\$343.68	\$343.64
Total Operating Expenses (Costs)	\$2,392,702	\$2,509,127
Average Operating Expense per treatment	\$296.36	\$294.43
Net Income	\$383,179	\$419,339

*Note: Form B mislabels' CY2019 as an Interim Year. The rest of the application identifies CY2019 as OY1.

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
- Written comments
- Information publicly available during the review and used by the Agency

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

On page 365 the 2018 SMFP defines the service area for dialysis stations as “a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR there are three existing and one approved dialysis facilities in Union County, as shown below.

**Union County Dialysis Facilities
 as of June 30, 2017**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	37	Marshville	12	0	77.08%
Union County Dialysis***	DVA	104	Monroe	28	5	92.86%
Metrolina Kidney Center**	BMA	89	Monroe	21	-10	105.95%
Fresenius Kidney Care Indian Trail***	BMA	0	Indian Trail	0	10	0.00%

Source: Table A, January 2017 SDR

*Note: Union County Dialysis was conditionally approved for 5 additional dialysis stations: Project ID# F-11259-16 (add 2 dialysis stations) and Project ID# F-11322-17 (add 3 dialysis stations).

**Note: Metrolina Kidney Center submitted an application, Project F-11242-16, which was conditionally approved 11/29/2016 to add five dialysis stations for a total of 16 inpatient dialysis stations and to develop a peritoneal and home hemodialysis training program.

***Note: Fresenius Kidney Care Indian Trail, Project ID# F-11208-16, received a certificate of need dated 12/15/16, to develop a new 10-station in-center dialysis facility by relocating 10 existing in-center dialysis stations from Metrolina Kidney Center (a/k/a BMA Monroe).

As illustrated above, two of the three operational facilities in Union County are operated by DVA and the other operational facility is operated by BMA. Based on the most recent SDR, two of the three existing facilities operated in Union County operated at 80.0% utilization rate or above, and one, Marshville Dialysis, operated at a utilization rate of 77.08%. An increase of just 2 patients at Marshville Dialysis would increase utilization at Marshville Dialysis over 80.0% [39 patients/ 12 stations = 3.25/4 = 0.8125 or 81.25%], 13 patients are projected to transfer to Marshville Dialysis as part of the proposed project.

In Section G.2, page 29, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Union County. The applicant states:

“Because this application involves the transfer of stations and patients from one DaVita facility to another DaVita facility, we are not proposing to duplicate a service already present in Union County. The transfer of stations from Union County Dialysis to Marshville Dialysis will have no effect on the operation of the Fresenius owned Metrolina Kidney Center in Monroe.”

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:

- Although the proposal will not result in an increase in the number of dialysis stations in Union County, it involves the transfer of existing stations and existing in-center patients from one DaVita facility in Union County to another DaVita facility in Union County and thus does not duplicate any existing or approved dialysis services in Union County.
- The applicant adequately demonstrates that the proposed stations are needed at Marshville Dialysis.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section H.1, page 30, the applicant provides the current staffing for the facility, and states that Marshville Dialysis is projected to add one full time equivalent (FTE) position as a result of this proposal. The applicant states the facility currently staffs 10.5 FTE positions and will have a staff of 11.5 FTEs upon project completion. In addition, the applicant provides projected direct care staff in OY 2 in Section H.7, page 33.

The assumptions and methodology used to project staffing are provided in Section H.1, page 30 and Sections H.6 and H.7, page 33. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 31-32, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3, H-4 and I-3, the applicant provides supporting documentation. In Section I.3, page 35, the applicant identifies the medical director. In Exhibit I-3, the applicant provides a letter from the current medical director indicating he will continue to serve as medical director for the facility.

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section I.1, page 34, the applicant identifies the ancillary and support services necessary for the proposed services.

MARSHVILL DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Marshville Dialysis
Self-care training (in-center)	Marshville Dialysis
Home training	Charlotte East Dialysis
HH	
PD	
Accessible follow-up program	
Psychological counseling	Marshville Dialysis
Isolation – hepatitis	Marshville Dialysis
Nutritional counseling	Marshville Dialysis
Social Work services	Marshville Dialysis
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	Cabarrus County Transportation Services

On page 34, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.

In Section I, pages 35-36, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 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
- Written comments
- Information which was publicly available during the review and used by the Agency.

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not a 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 nor 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.7, page 50, the applicant provides the historical payor mix during CY 2017 at Marshville Dialysis and Union County Dialysis, as shown in the table below.

Payment Sources CY2017	Marshville Dialysis Patients as Percent of Total	Union County Dialysis Patients as Percent of Total
Medicaid	10.8%	5.9%
Medicare	37.9%	35.7%
Medicare/Medicaid	10.8%	16.9%
Medicare/Commercial	24.3%	26.3%
VA	2.7%	4.2%
Commercial Insurance	13.5%	11.0%
Total	100.00%	100.00%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Union	12%	51%	27%	10%	6%	11%
Anson	17%	47%	55%	25%	15%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The Agency reviewed the:

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 44, the applicant states

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

In Section L.6, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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

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

C

In Section L.1, page 44, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	10.8%
Medicare	37.9%
Medicare/Medicaid	10.8%
Medicare/Commercial	24.3%
VA	2.7%
Commercial Insurance	13.5%
Total	100.0%

Source: Table, page 44 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 83.8% of total services will be provided to Medicaid/Medicare patients.

On page 44, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based *“on the sources of patient payment that have been received by existing facility in the last full operating year.”*

The Agency reviewed the:

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

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

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

C

In Section L.4, page 46, 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
- Written comments
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

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

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

DVA proposes to relocate four dialysis stations from Union County Dialysis to Marshville Dialysis for a total of 16 dialysis stations at Marshville Dialysis. Marshville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

On page 365 the 2018 SMFP defines the service area for dialysis stations as “a dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

According to the January 2018 SDR indicates there are three existing and one approved dialysis facilities in Union County, as shown below.

**Union County Dialysis Facilities
 as of June 30, 2017**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Marshville Dialysis	DVA	37	Marshville	12	0	77.08%
Union County Dialysis***	DVA	104	Monroe	28	5	92.86%
Metrolina Kidney Center**	BMA	89	Monroe	21	-10	105.95%
Fresenius Kidney Care Indian Trail***	BMA	0	Indian Trail	0	10	0.00%

Source: Table A, January 2017 SDR

*Note: Union County Dialysis was conditionally approved for 5 additional dialysis stations: Project ID# F-11259-16 (add 2 dialysis stations) and Project ID# F-11322-17 (add 3 dialysis stations).

**Note: Metrolina Kidney Center submitted an application, Project F-11242-16, which was conditionally approved 11/29/2016 to add five dialysis stations for a total of 16 inpatient dialysis stations and to develop a peritoneal and home hemodialysis training program.

***Note: Fresenius Kidney Care Indian Trail, Project ID# F-11208-16, received a certificate of need dated 12/15/16, to develop a new 10-station in-center dialysis facility by relocating 10 existing in-center dialysis stations from Metrolina Kidney Center (a/k/a BMA Monroe).

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. On page 49, the applicant states:

“The expansion of Marshville Dialysis will have no effect on competition in Union 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 Healthcare Renal Care, Inc.The expansion of Marshville Dialysis ... will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this

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

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 R 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
- Written comments
- Information publicly available during the review and used by the Agency.

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

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

C

In Section A, page 5, the applicant states DaVita operates more than 75 dialysis facilities in North Carolina. Exhibit A contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 50, 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 one of these facilities, Southeastern Dialysis Center-Wilmington. The applicant provided supplemental information to the Agency that demonstrates that Southeastern Dialysis Center-Wilmington is currently back in full compliance with all CMS requirements as of March 21, 2018. The applicant provides additional documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage for the facility in Exhibit O-3. Furthermore, in Project ID#F-11452-18, the applicant, in Section O, page 56, and Exhibit O-3 states that a survey conducted on October 26, 2017, led to the identification of an Immediate Jeopardy for Goldsboro South Dialysis, that all of the problems have been corrected

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. The specific criteria are discussed below.

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new End Stage Renal Disease 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- The In Section C.1, page 12, the applicant projects to serve 56 in-center patients by the end of OY1 (CY2019) for a utilization rate of 87.5% or 3.5 patients per station per week ($56 \text{ patients} / 16 \text{ stations} = 3.5 / 4 = 0.875$ or 87.5%). 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 12-14, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.