

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 6, 2020

Findings Date: November 6, 2020

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: L-11933-20

Facility: Wilson Dialysis

FID #: 971340

County: Wilson

Applicant: DVA Renal Healthcare, Inc.

Project: Add no more than 7 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 39 stations upon completion of this project and Project ID #J-11743-19 (relocate 5 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. (hereinafter referred to as “DVA” or “the applicant”) d/b/a Wilson Dialysis proposes to add 7 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of 39 stations upon completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

Need Determination

Chapter 9 of the 2020 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 Table 9D, page 170, the county need methodology shows there is not a county need determination for additional dialysis stations in Wilson County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center as reported in the 2020 SMFP is at least 75 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Wilson Dialysis on page 165 of the 2020 SMFP is 78.75 percent or 3.15 patients per station per week, based on 126 in-center dialysis patients and 40 certified dialysis stations (126 patients / 40 stations = 3.15; $3.15 / 4 = 78.75\%$).

As shown in Table 9E on page 173 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at Wilson Dialysis is up to 10 additional stations; thus, the applicant is eligible to apply to add up to 10 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than seven new stations to Wilson Dialysis, which is consistent with the 2020 SMFP calculated facility need determination for up to 10 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on pages 30-31 of the 2020 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B, pages 13-16, the applicant explains why it believes its application is consistent with Policy GEN-3. On pages 15-16, the applicant states:

“For all its patients – current patients as well as those included in the projected utilization – DaVita is committed to:

- *promoting a culture of safety;*
- *ensuring industry-leading quality of care;*
- *promoting equitable access; and*
- *maximizing healthcare value.*

..., established policy and procedure will continue to guide this commitment.”

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Wilson Dialysis's projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need.

(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 7 dialysis stations to Wilson Dialysis pursuant to Condition 2 of the facility need methodology for a total of 39 stations following completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

In Section C, page 19, the applicant states it currently provides both home hemodialysis (HH) and peritoneal dialysis (PD) training and support. On page 20, the applicant projects it will continue to provide both HH and PD training and support during the first two full operating years following project completion.

In Section A, page 5, the applicant states its parent company is DaVita, Inc. The applicant uses DaVita, Inc. (DaVita) interchangeably with DVA to refer to itself or its facilities. References to DaVita should be interpreted to mean DVA unless otherwise specified.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and*

Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Wilson County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Wilson Dialysis – Current Patient Origin (as of 12/31/2019)						
	In-Center Patients		HH Patients		PD Patients	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wilson	115	88.50%	13	86.67%	50	89.29%
Nash	6	4.60%	1	6.67%	3	5.36%
Greene	1	0.80%	0	0.00%	0	0.00%
Johnston	2	1.50%	0	0.00%	2	3.57%
Wake	1	0.80%	0	0.00%	0	0.00%
Sampson	1	0.80%	0	0.00%	0	0.00%
Edgecombe	1	0.80%	0	0.00%	0	0.00%
Guilford	1	0.80%	0	0.00%	0	0.00%
Other States	2	1.50%	0	0.00%	0	0.00%
Wayne	0	0.00%	1	6.67%	1	1.79%
Total	130	100.00%	15	100.00%	56	100.00%

Table may not foot due to rounding.

Source: Section C, page 19

Wilson Dialysis – Projected Patient Origin – OY 2 (CY 2023)						
	In-Center Patients		HH Patients		PD Patients	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wilson	101	91.80%	17	89.50%	54	90.00%
Nash	4	3.60%	1	5.30%	3	5.00%
Greene	3	2.70%	0	0.00%	0	0.00%
Johnston	0	0.00%	0	0.00%	2	3.33%
Wake	0	0.00%	0	0.00%	0	0.00%
Sampson	0	0.00%	0	0.00%	0	0.00%
Edgecombe	0	0.00%	0	0.00%	0	0.00%
Guilford	0	0.00%	0	0.00%	0	0.00%
Other States	2	1.80%	0	0.00%	0	0.00%
Wayne	0	0.00%	1	5.30%	1	1.67%
Total	110	100.00%	19	100.00%	60	100.00%

Table may not foot due to rounding.

Source: Section C, page 20

In Section C, pages 20-22, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 20, the applicant states five stations were relocated to Kenly Dialysis as part of Project I.D. #L-11438-17. Kenly Dialysis was certified on February 24, 2020. Project I.D. #L-11591-18 added two stations to Wilson Dialysis after Kenly Dialysis was certified for a total of 37 stations at Wilson Dialysis after completion of both projects.

Project I.D. #J-11743-19, proposing to relocate five stations from Wilson Dialysis as part of developing Clayton Dialysis, was approved by the Agency on December 20, 2019. As part of that project, the applicant projected 17 in-center patients would transfer care to Clayton Dialysis when it becomes certified. The applicant states this would leave Wilson Dialysis with 32 stations.

The applicant states it does not project any growth in the Wilson County in-center patient population projected to continue dialyzing at Wilson Dialysis because although the Five Year Average Annual Change Rate (AACR) for Wilson County, as published in the 2020 SMFP, is 4.2 percent, the applicant states the facility's Five Year AACR is -0.09 percent. In supplemental information requested by the Agency, the applicant states it is trying to be proactive in planning to meet the needs of the patients served by the facility as a result of the recent changes to the ESRD need methodology, used for the first time in the 2020 SMFP.

According to publicly available information, Wilson Dialysis was serving 130 in-center patients on December 31, 2019. In Project I.D. #L-11438-17, the applicant projected a total of 15 in-center patients who were dialyzing at Wilson Dialysis would transfer their care to Kenly Dialysis upon its certification, which occurred on February 24, 2020. The applicant states on page 20 that as of June 30, 2020, it was serving 127 in-center patients. While there is no way to predict which patients supporting the development of a new dialysis facility will actually transfer care to that facility and there are many reasons for population changes at a dialysis facility, the applicant is currently serving 12 more in-center patients than it had projected to serve following the relocation of the five stations to Kenly Dialysis.

The information is reasonable and adequately supported based on the following analysis:

- Wilson Dialysis has previously been approved to relocate a total of 10 stations to serve Wilson County residents or its patients dialyzing at Wilson Dialysis who supported the development of additional facilities in the area.
- Wilson Dialysis has previously been approved to backfill only two of those 10 stations.
- The 2020 SMFP used an ESRD methodology different than the one which had been used for at least the previous eight years. Changes to this methodology included an annual calculation of facility need instead of a biannual calculation and a different utilization threshold requirement for facilities to generate a facility need.
- Because this is a new methodology in use for the first time, it is reasonable for applicants to be uncertain of impacts and want to be proactive in planning until the impacts of the change in need methodology are better understood.
- Despite the negative Five Year AACR for Wilson Dialysis, the applicant is currently serving 12 more patients than it projected to be serving after relocating five stations to develop Kenly Dialysis, which was certified less than a year ago.

- Developing the seven stations proposed in this application will backfill stations which had previously been relocated and will not result in a physical expansion of the facility.

Projected Utilization

On Form C and the Form C Utilization subsection in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

Wilson Dialysis – Historical Utilization (as of 12/31/2019)						
	In-Center Patients		HH Patients		PD Patients	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wilson	115	88.50%	13	86.67%	50	89.29%
Nash	6	4.60%	1	6.67%	3	5.36%
Greene	1	0.80%	0	0.00%	0	0.00%
Johnston	2	1.50%	0	0.00%	2	3.57%
Wake	1	0.80%	0	0.00%	0	0.00%
Sampson	1	0.80%	0	0.00%	0	0.00%
Edgecombe	1	0.80%	0	0.00%	0	0.00%
Guilford	1	0.80%	0	0.00%	0	0.00%
Other States	2	1.50%	0	0.00%	0	0.00%
Wayne	0	0.00%	1	6.67%	1	1.79%
Total	130	100.00%	15	100.00%	56	100.00%

Table may not foot due to rounding.

Wilson Dialysis – Projected Utilization – OY 2 (CY 2023)						
	In-Center Patients		HH Patients		PD Patients	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wilson	101	91.80%	17	89.50%	54	90.00%
Nash	4	3.60%	1	5.30%	3	5.00%
Greene	3	2.70%	0	0.00%	0	0.00%
Johnston	0	0.00%	0	0.00%	2	3.33%
Wake	0	0.00%	0	0.00%	0	0.00%
Sampson	0	0.00%	0	0.00%	0	0.00%
Edgecombe	0	0.00%	0	0.00%	0	0.00%
Guilford	0	0.00%	0	0.00%	0	0.00%
Other States	2	1.80%	0	0.00%	0	0.00%
Wayne	0	0.00%	1	5.30%	1	1.67%
Total	110	100.00%	19	100.00%	60	100.00%

Table may not foot due to rounding.

In Section C, pages 20-22, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

In-Center Projected Utilization

- The applicant begins its in-center utilization projections with the patient facility census on June 30, 2020. On page 20, the applicant states that, on June 30, 2020, its in-center patient

census was comprised of 115 Wilson County patients and 12 patients from other North Carolina counties and other states.

- Because the facility in-center Average Annual Change Rate (AACR) for Wilson Dialysis is -0.09% over the last five years, the applicant projects no growth for the in-center Wilson County patient population.
- The applicant assumes that, as part of Project I.D. #J-11743-19 (relocate five stations to Clayton Dialysis), 17 in-center patients residing in Wilson County will transfer their care to Clayton Dialysis on January 1, 2021, when Clayton Dialysis is expected to be certified.
- The applicant assumes no population growth for the patients residing in other North Carolina counties and other states dialyzing in-center at Wilson Dialysis but assumes the patients will continue to dialyze in-center at Wilson Dialysis and adds them to the calculations when appropriate.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 21, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

Wilson Dialysis In-Center Projected Utilization	
Starting point of calculations is Wilson County patients dialyzing at Wilson Dialysis on June 30, 2020.	115
Wilson County patient population is projected forward by six months to December 31, 2020, with no projected growth.	$115 \times 1.0 = 115$
17 Wilson County patients are projected to transfer care to Clayton Dialysis on January 1, 2021, when the five stations to be relocated from Wilson Dialysis (Project I.D. #J-11743-19) are projected to be certified.	$115 - 17 = 98$
Wilson County patient population is projected forward by one year to December 31, 2021, with no projected growth.	$98 \times 1.0 = 98$
The patients from other NC counties and other states are added. This is the projected census on January 1, 2022 and the starting census for this project.	$98 + 12 = 110$
Wilson County patient population is projected forward by one year to December 31, 2022, with no projected growth.	$98 \times 1.0 = 98$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2022 (OY1).	$98 + 12 = 110$
Wilson County patient population is projected forward by one year to December 31, 2023, with no projected growth.	$98 \times 1.0 = 98$
The patients from other NC counties and other states are added. This is the projected census on December 31, 2023 (OY2).	$98 + 12 = 110$

The applicant projects to serve 110 patients on 39 stations, which is 2.82 patients per station per week ($110 \text{ patients} / 39 \text{ stations} = 2.82$), by the end of both OY1 and OY 2. This exceeds

the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

There are two potential issues which may call into question whether the applicant can reasonably project to meet the minimum utilization of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b):

- In Project I.D. #J-11743-19, the applicant projected 18 patients would transfer care from Wilson Dialysis to Clayton Dialysis, not 17 patients.
- Additionally, as of the date of these findings, Project I.D. #J-11743-19 is under appeal. If the decision in Project I.D. #J-11743-19 is reversed as a result of the appeal, no patients or stations will transfer to Clayton Dialysis, which will result in a patient population of 127 in-center patients dialyzing on 44 stations at the end of the first two full operating years.

The Project Analyst performed additional calculations for both scenarios discussed above and concluded that even if 18 patients transfer care to Clayton Dialysis, or if the decision in Project I.D. #J-11743-19 is overturned and Wilson Dialysis has 127 in-center patients dialyzing on 44 stations at the end of the first full operating year, the applicant would still reasonably project to serve the minimum of 2.8 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). See the Working Papers for the Project Analyst's additional calculations.

HH and PD Projected Utilization

- The applicant begins its utilization projections with the patient facility census on January 1, 2020. On pages 21-22, the applicant states that, on January 1, 2020, its HH patient census was comprised of 13 Wilson County patients and two patients from other North Carolina counties and its PD patient census was comprised of 50 Wilson County patients and six patients from other North Carolina counties.
- The applicant assumes that both the HH patient population and PD patient population will increase by one patient per year through the second full operating year following project completion. Based on the projected patient origin on page 20, the applicant projects the new patients will be Wilson County residents.
- The project is scheduled to begin offering services on January 1, 2022. OY1 is CY 2022. OY2 is CY 2023.

In Section C, pages 21-22, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the HH and PD patient census for OY1 and OY2, as summarized in the tables below.

Wilson Dialysis HH Projected Utilization	
Starting point of calculations is Wilson Dialysis HH patients as of January 1, 2020.	15
The HH patient population of Wilson Dialysis is projected forward by one year to December 31, 2020, at a growth rate of one patient per year.	$15 + 1 = 16$
The HH patient population of Wilson Dialysis is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	$16 + 1 = 17$
The HH patient population of Wilson Dialysis is projected forward by one year to December 31, 2022, at a growth rate of one patient per year (end of OY1).	$17 + 1 = 18$
The HH patient population of Wilson Dialysis is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY2).	$18 + 1 = 19$

Wilson Dialysis PD Projected Utilization	
Starting point of calculations is Wilson Dialysis PD patients as of January 1, 2020.	56
The PD patient population of Wilson Dialysis is projected forward by one year to December 31, 2020, at a growth rate of one patient per year.	$56 + 1 = 57$
The PD patient population of Wilson Dialysis is projected forward by one year to December 31, 2021, at a growth rate of one patient per year.	$57 + 1 = 58$
The PD patient population of Wilson Dialysis is projected forward by one year to December 31, 2022, at a growth rate of one patient per year (end of OY1).	$58 + 1 = 59$
The PD patient population of Wilson Dialysis is projected forward by one year to December 31, 2023, at a growth rate of one patient per year (end of OY2).	$59 + 1 = 60$

Projected utilization is reasonable and adequately supported based on the following analysis:

- The applicant projects in-center utilization using no growth rate, which is conservative given the facility’s slightly negative historical growth rate and Wilson County’s overall Five Year AACR of 4.2 percent.
- The applicant accounts for the dialysis stations and patients projected to transfer to Clayton Dialysis as part of Project I.D. #J-11743-19.
- Even if 18 patients transfer to Clayton Dialysis, as represented in Project I.D. #J-11743-19, the applicant reasonably projects its utilization will meet the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

- Even if the outcome of Project I.D. #J-11743-19 (currently under appeal) is reversed, and no patients or stations transfer to Clayton Dialysis, the facility’s projected utilization will meet the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 24, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or [disability]. 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 those with disabilities, patients attending school or patients who work. ...

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

On pages 24-25, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table. The applicant states it assumes the estimated percentage for the medically underserved groups listed in the following table will be the same as its patient population in CY 2019 and projected patient population in CY 2023.

Medically Underserved Groups	% of Total Patients
Women	39.1%
People age 65 and older	45.0%
Medicare beneficiaries	83.1%
Medicaid recipients	8.5%
American Indian	0.5%
Asian	0.0%
Black or African-American	68.3%
Native Hawaiian or Pacific Islander	0.0%
Other Race	5.0%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Supplemental information requested by the Agency
- 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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 or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add 7 dialysis stations to Wilson Dialysis pursuant to Condition 2 of the facility need methodology for a total of 39 stations following completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

In Section E, page 30, and in supplemental information requested by the Agency, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states maintaining the status quo was not an effective alternative because of the need to proactively plan for the needs of patients currently being served as the result of changes to the ESRD need methodology.

- Relocate Stations from Another DaVita Facility: the applicant states every other DaVita facility in Wilson County is either newly certified or close to capacity; therefore, this is not an effective alternative.

The applicant states its proposal is the most effective alternative because it proactively plans to meet the needs of the patients currently dialyzing at Wilson Dialysis and unknown impacts as the result of new changes to the ESRD need methodology.

The applicant adequately demonstrates 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
- Supplemental information requested by the Agency
- 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. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 7 additional in-center dialysis stations for a total of no more than 39 in-center and home hemodialysis training stations at Wilson Dialysis upon completion of this project and Project I.D. #J-11743-19 (relocate 5 stations to Clayton Dialysis). In the event a certificate of need for Project I.D. #J-11743-19 is not issued or is issued for fewer than 5 stations, Wilson Dialysis shall have no more than 44 in-center and home hemodialysis stations upon completion of this project.**

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on April 1, 2021. The second progress report shall be due on July 1, 2021 and so forth.
- 4. The certificate holder 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 7 dialysis stations to Wilson Dialysis pursuant to Condition 2 of the facility need methodology for a total of 39 stations following completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects a total capital cost of \$69,504 to be used for medical equipment, non-medical equipment, and furniture. In Section Q, the applicant provides the assumptions used to project the capital cost. In Section F, page 33, the applicant states there are no projected start-up expenses or initial operating expenses because Wilson Dialysis is an existing and operational facility.

Availability of Funds

In Section F, page 31, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc., authorizing the use of accumulated reserves for the

capital needs and any other needs of the project. Exhibit F-2 also contains a Form 10-K Consolidated Financial Statement from DaVita, Inc., which showed that as of December 31, 2019, DaVita, Inc. had adequate cash and assets to fund the capital and working capital costs of the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
Wilson Dialysis	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	27,565	27,862
Total Gross Revenues (Charges)	\$9,140,060	\$9,248,368
Total Net Revenue	\$8,739,262	\$8,843,260
Average Net Revenue per Treatment	\$317	\$317
Total Operating Expenses (Costs)	\$4,698,199	\$4,765,262
Average Operating Expense per Treatment	\$170	\$171
Net Income/(Loss)	\$4,041,063	\$4,077,998

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital cost is 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 7 dialysis stations to Wilson Dialysis pursuant to Condition 2 of the facility need methodology for a total of 39 stations following completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Thus, the service area for this facility consists of Wilson County. Facilities may serve residents of counties not included in their service area.

There are four existing and approved facilities which provide dialysis and/or dialysis home training and support in Wilson County, three of which were operational on December 31, 2018. Information on these dialysis facilities is provided below:

Wilson County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Forest Hills Dialysis	DaVita	Wilson	31	91.13%
Kenly Dialysis*	DaVita	Kenly	0	0.00%
Sharpsburg Dialysis	DaVita	Sharpsburg	10	12.50%
Wilson Dialysis	DaVita	Wilson	40	78.75%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

In Section G, page 36, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wilson County:

“While adding stations at this facility does increase the number of stations in Wilson County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s 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 will not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant proposes to increase the number of dialysis stations in Wilson County based on Condition 2 of the facility need determination in the 2020 SMFP.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations in Wilson County.

Conclusion

The Agency reviewed the:

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

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

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

C

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

Wilson Dialysis Current and Projected Staffing		
	Current 12/31/19	Projected – OYs 1-2 (CYs 2022 & 2023)
Administrator	1.00	1.00
Registered Nurses	4.75	5.00
Home Training Nurse	1.00	1.00
Patient Care Technicians	14.00	14.50
Dietician	1.00	1.00
Social Worker	1.00	1.00
Admin/Business Office	1.00	1.00
Biomedical Tech	0.50	0.50
TOTAL	24.25	25.00

Adequate costs for the health manpower and management personnel proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 37-38, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3. In Section H, page 38, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director expressing support for the proposed project and stating an interest in continuing to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, page 39, the applicant states the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

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

The applicant provides supporting documentation in Exhibit I-1.

In Section I, page 40, the applicant describes its existing relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

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

NA

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 46, the applicant provides the historical payor mix during CY 2019 for its existing services at Wilson Dialysis, as shown in the table below.

Wilson Dialysis – Historical Payor Mix (CY 2019)						
	In-Center Patients		HH Patients		PD Patients	
Payor Source	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self Pay	1	0.8%	0	0.0%	0	0.0%
Insurance*	6	4.6%	1	6.7%	8	14.3%
Medicare*	108	83.1%	13	86.7%	45	80.4%
Medicaid*	11	8.5%	0	0.0%	1	1.8%
Other (VA)	4	3.1%	1	6.7%	2	3.6%
Total	130	100.0%	15	100.0%	56	100.0%

Table may not foot due to rounding.

*Including any managed care plans

In Section L, page 45, the applicant provides the following comparison.

Wilson Dialysis	% of Patients Served During CY 2019	% of the Population of Wilson County
Female	39.1%	52.6%
Male	60.9%	47.4%
Unknown	0.0%	0.0%
64 and Younger	55.0%	81.3%
65 and Older	45.0%	18.7%
American Indian	0.5%	0.6%
Asian	0.0%	1.3%
Black or African-American	68.3%	40.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	26.2%	55.8%
Other Race	5.0%	1.6%
Declined / Unavailable	0.0%	0.0%

Sources: DVA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 46, that Wilson Dialysis has no obligation to provide uncompensated care or community service under any federal regulations.

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against Wilson Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 47, 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.

Wilson Dialysis – Projected Payor Mix (CY 2023)						
	In-Center Patients		HH Patients		PD Patients	
Payor Source	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self Pay	0.8	0.8%	0.0	0.0%	0.0	0.0%
Insurance*	5.1	4.6%	1.3	6.7%	8.6	14.3%
Medicare*	91.4	83.1%	16.5	86.7%	48.2	80.4%
Medicaid*	9.3	8.5%	0.0	0.0%	1.1	1.8%
Other (VA)	3.4	3.1%	1.3	6.7%	2.1	3.6%
Total	110	100.0%	19	100.0%	60	100.0%

Table may not foot due to rounding.
 *Including any managed care plans

As shown in the table above, during the applicant’s second full fiscal year following project completion, the applicant projects to provide 83.1 percent, 86.7 percent, and 80.4 percent of in-center, HH, and PD services, respectively, to Medicare patients and 8.5 percent and 1.8 percent of in-center and PD services, respectively, to Medicaid patients.

On page 47, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 47-48, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 49, 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 7 dialysis stations to Wilson Dialysis pursuant to Condition 2 of the facility need methodology for a total of 39 stations following completion of this project and Project I.D. #J-11743-19 (relocate 5 stations).

On page 113, the 2020 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Wilson County. Facilities may serve residents of counties not included in their service area.

There are four existing and approved facilities which provide dialysis and/or dialysis home training and support in Wilson County, three of which were operational on December 31, 2018. Information on these dialysis facilities is provided below:

Wilson County Dialysis Facilities				
Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Forest Hills Dialysis	DaVita	Wilson	31	91.13%
Kenly Dialysis*	DaVita	Kenly	0	0.00%
Sharpsburg Dialysis	DaVita	Sharpsburg	10	12.50%
Wilson Dialysis	DaVita	Wilson	40	78.75%

Source: Table 9B, Chapter 9, 2020 SMFP; Agency records

*Facility under development or which was not operational at the time of data collection for the 2020 SMFP.

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The expansion of Wilson Dialysis will have no effect on competition in Wilson County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita.

...

..., DaVita is committed to providing quality care to the ESRD population and, by policy, works to every reasonable effort to accommodate all of its patients. The expansion of Wilson Dialysis will enhance accessibility to dialysis for current and projected 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N, and Q of the application and any exhibits)
- Quality (see Sections B, C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N 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

On Form A in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 110 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, pages 52-53, the applicant states that, during the 18 months immediately preceding the submittal of the application, an incident resulting in an Immediate Jeopardy

violation occurred in one of these facilities. The applicant states that all the problems have been corrected and the facility is back in compliance. Supporting documentation is provided in Exhibit O-2. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 110 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.*

-NA- Wilson Dialysis is an existing facility. Therefore, this Rule is not applicable to this review.

- (b) *An applicant proposing to increase the number of dialysis stations in:*
- (1) *an existing dialysis facility; or*
 - (2) *a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need;*

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C, page 21, and on Form C in Section Q, the applicant projects that Wilson Dialysis will serve 110 patients on 39 stations, or a rate of 2.82 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 20-22, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.