

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 25, 2019

Findings Date: September 25, 2019

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: O-11712-19

Facility: Brunswick Community Hospital, LLC

FID #: 061342

County: Brunswick

Applicant(s): Brunswick Community Hospital, LLC

Novant Health, Inc.

Project: Provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Brunswick Community Hospital, LLC and Novant Health, Inc. collectively referred to as the “applicant” or “NHBMC” propose to add inpatient dialysis services through a service agreement with Total Renal Care, Inc. utilizing no more than two portable inpatient dialysis units upon project completion. The applicant serves as the lessee and DaVita, Inc. serves as the lessor. Brunswick Community Hospital, LLC is located at 240 Hospital Drive NE in Bolivia, Brunswick County.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2019 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2019 SMFP which are applicable to this review.

Conclusion

The applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2019 SMFP. There are no policies in the 2019 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

Patient Origin

The 2019 SMFP does not define a service area for inpatient dialysis services. The applicant defines its primary service area in Section C, page 29, as Brunswick County. Facilities may also serve residents of counties not included in their service area. The applicant projects patient origin based on the inpatient services and not the entire facility.

The following table illustrates current and projected patient origin.

County	1 st Full FY 1/1/2020 TO 12/31/2020		2 nd Full FY 1/1/2021 TO 12/31/2021		3 rd Full FY 1/1/2022 TO 12/31/2022	
	#of Patients	% of Total	#of Patients	% of Total	#of Patients	% of Total
Brunswick	206	100.0%	212	100.0%	217	100.0%
Total	206	100.0%	212	100.0%	217	100.0%

Source: Section C, page 29

In Section C, page 29, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 30, the applicant states:

“Adding inpatient dialysis machines at NHBMC makes it possible for local residents on dialysis to receive inpatient care at NHBMC, rather than having to travel to Wilmington, NC or Myrtle Beach, SC (the two closest cities with inpatient dialysis services) and interrupting their care at NHBMC and incurring additional expenses (e.g., ambulance charges) and inconvenience.”

In Section C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

On pages 30-37, the applicant identifies three key factors used to project utilization and support the need for inpatient dialysis services at NHBMC as discussed below:

- Brunswick County Population Growth
- Brunswick County ESRD Growth
- Common Comorbidities in people with Chronic kidney disease

Brunswick County Population Growth

On page 31, the applicant discusses Brunswick County population growth using projections from the North Carolina State Budget and Management (NCSBM). The applicant states from 2014 to 2019, the population of Brunswick County grew by 17.3 percent. By demographics, the 45-64 age population grew by 11.0 percent and the 65+ age population grew by 34.3 percent. The applicant states that the NCSBM projects the 45-64 age population will increase by 8.1 percent from 2019 to 2024. The 65+ age population will increase by 20.5 percent from 2019 to 2024 to become 32.7 percent of Brunswick County's population. The applicant assumes with the increase in the Brunswick County population, particularly the 65 + age population, there will be an increase in patients with chronic kidney diseases and related deaths.

Brunswick County ESRD Growth

On page 31, the applicant discusses the increase in the number of in-center patients receiving dialysis services in Brunswick County. The applicant references data from the January 2013 SDR through the January 2019 SDR, as shown in the table below. Starting in 2013, the data indicates the total number of dialysis patients increases from 80 patients in 2013 to 123 in 2018. This includes a significant increase from 2016 to 2017. The applicant assumes with the increase in patients receiving dialysis services in Brunswick County, more patients will require some level of care as an inpatient at NHBMC during the period that they are receiving ESRD.

Common Comorbidities in people with chronic kidney disease

On pages 32-37, the applicant discusses the common comorbidities in people with chronic kidney disease. These comorbidities include diabetes, high blood pressure, cardiovascular disease and congestive heart disease. Referencing the North Carolina Trend Report, February 2019, the applicant reports that between 2013 and 2017, Brunswick County experienced an increase in death rates related to these comorbidities. The applicant states that based on the data, the population of Brunswick County is more likely to be hospitalized for conditions related to chronic kidney disease. The applicant states that as the population ages and these comorbidities become more prevalent in Brunswick county, the more likely these patients will need access to dialysis services.

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

- Providing dialysis services during an inpatient stay will avoid transportation expenses to a dialysis facility without interrupting the patient care at NHBMC.
- The applicant demonstrates the need for inpatient dialysis services based on the growth of the population and ESRD patients in Brunswick County.
- The applicant demonstrated the need for inpatient dialysis services based on the increased need for inpatient services for common comorbidities for patients with chronic kidney disease.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the tables below. The applicant applies three methods to identify the most conservative home and in-center dialysis patient projections: Linear trending, annual growth, and population growth.

Linear Trending Method-The applicant's data is based on the home and in-center dialysis patient usage for the last four semiannual data points (6/2017 through 12/2018) trending forward eight periods (6/2019 through 12/2022). The semiannual totals were averaged to obtain the average annual number of dialysis patients.

Annual Dialysis Patient Growth Method-The applicant states the average annual number of total dialysis patients for 2017 and 2018 was used to determine the patient growth rate. The patient growth rate between 2017 and 2018 was 6.944% $[(154/144)/144 = 10/144 = .0694 \times 100 = 6.94]$. The 6.94 annual growth rate was used to project patient growth through 2022.

The Population Projection Growth Method- The applicant states the average annual number of total dialysis patients for 2017 and 2018 was used to determine the population growth rate. The applicant used the 5-year population growth rate of 13.5% for Brunswick County's 18 and over residents. The 2018 average annual number of dialysis patients was multiplied by 1 + growth rate (1.1350) to project the 2023 dialysis patients. The tables below reflect the projections of the three methods:

Linear Trending												
	2017		2018		2019		2020		2021		2022	
	June	Dec										
Home	24	24	29	31	34	36	39	41	44	47	49	52
In-Center	115	124	123	125	129	132	135	138	141	144	146	149
Total	139	148	152	156	163	168	174	179	185	190	196	201
Annual Average	144		154		165		176		187		198	

Source: Section Q, page 98

Annual Dialysis Patient Growth								
	2017		2018		2019	2020	2021	2022
	June	Dec	June	Dec				
Home	24	24	29	31				
In-Center	115	124	123	125				
Total	139	148	152	156				
Annual Average	144		154		165	176	188	201

Source: Section Q, page 98

Population Projection Growth								
	2017		2018	2019	2020	2021	2022	2023
	June	Dec						
Home	24	24						
In-Center	115	124						
Total	139	148						
Annual Average	144		154	158	162	166	171	175

Source: Section Q, page 99

The applicant chose to use the population growth method because it is the most conservative. Project utilization is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the projected growth of the Brunswick County ESRD population and how this growth will result in more dialysis patients requiring inpatient care in NHBMC during the period that they are receiving ESRD treatments.
- The applicant adequately demonstrates how this project allows NHBMC to offer inpatient dialysis services while reducing cost and interruption of care due to transporting a patient to another facility providing dialysis.

Access

In Section C, page 42, the applicant states:

“NHBMC will provide services to all persons regardless of race, age, religion, creed, disability, national origin or ability to pay because Novant Health facilities and programs do not discriminate against any persons, or other medically underserved persons, regardless of their ability to pay.”

In Section L, page 76, the applicant projects the following payor mix during the first full fiscal year of operation following completion of the project, as illustrated in the following table.

1st Full FY (1/1/2020-12/31/2020)	
Payor Source	NHBMC
Self-Pay	1.6%
Charity Care	9.8%
Medicare	52.0%
Medicaid	12.5%
Insurance	21.5%
Workers Compensation	0.3%
Tricare	1.9%
Other (BH and other)	0.3%
Total	100.0%

The projected payor mix is reasonable and adequately supported.

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 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.

NA

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

- (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 provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

In Section E, page 52, 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:

- Operate an Inpatient Dialysis Service without a Hospital Service Agreement-The applicant states that this alternative was not effective because NHBMC would be responsible for acquiring and maintaining the dialysis equipment as well as providing the service. The applicant states that the service will not generate the volume of treatment for the staff to remain proficient in the provision of the service.
- Operate an Inpatient Dialysis Service with a Hospital Service Agreement-The applicant states that this was the least costly and most effective method. The applicant states that contracting with the largest provider of dialysis services in Brunswick County would save in costs such as purchasing and maintenance of medical equipment and training NHBMC staff while not compromising services to dialysis patients.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Brunswick Community Hospital, LLC and Novant Health, Inc. shall materially comply with all representations made in the certificate of need application.**

- 2. Brunswick Community Hospital, LLC and Novant Health, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**
 - 3. Brunswick Community Hospital, LLC and Novant Health, Inc. shall provide the Agency clarifying information on why the project's Facility or Service Accredited date is four years from the date of the services offered, prior to issuance of the certificate of need.**
 - 4. Brunswick Community Hospital, LLC and Novant Health, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

Capital and Working Capital Costs

In Section F.1, page 54, the applicant states that NHBMC is not projecting any capital costs for this project. The applicant states that NHBMC upfitted a room to accommodate the hemodialysis equipment. NHBMC spent a total of \$2,550 which is not included in the pro forma financial statements in Section Q (see page 27).

In Section F.3, page 56, the applicant states that this project will not involve start-up or initial operating expenses.

Financial Feasibility

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

NHBMC	Operating Year 1 CY 2020	Operating Year 2 CY 2021	Operating Year 3 CY 2022
Total Procedures	487	500	512
Total Gross Revenues (Charges)	\$414,596	\$428,791	\$443,474
Total Net Revenue	\$103,201	\$106,872	\$110,674
Average Net Revenue per procedure	\$211.91	\$213.74	\$216.16
Total Operating Expenses (Costs)	\$90,766	\$93,834	\$97,006
Average Operating Expense per procedure	\$186.37	\$187.67	\$189.46
Net Income	\$12,435	13,038	\$13.668

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to provide inpatient dialysis services through the lease of no more than two portable inpatient dialysis units upon project completion.

The 2019 SMFP does not define a service area for inpatient dialysis services. The applicant defines its primary service area in Section C, page 29, as Brunswick County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 60, the applicant states there are no existing or approved facilities that provide inpatient dialysis services in Brunswick County. The applicant identifies the two closest hospitals outside of the service area that provide inpatient dialysis services.

County	City	Facility
New Hanover	Wilmington	New Hanover Regional medical Center
Horry County, SC	Myrtle Beach, SC	Grand Strand Medical Center

Source: Section G, page 60

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Brunswick County. The applicant states:

“As previously stated, no existing or approved facilities exist that provide inpatient dialysis services in Brunswick County. Brunswick County residents receiving outpatient dialysis treatments who require inpatient admissions must travel to or be transported to either Wilmington or Myrtle Beach for their inpatient admission.”

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:

- The proposal would not result in an increase in inpatient dialysis services.
- There are no existing or approved facilities that provide inpatient dialysis services in Brunswick County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q, page 115, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
		2 nd FY (1/1/2021 to 12/31/2021)
Register Nurse	0	0.5
Housekeeping	0	0.1
Office Support	0	0.1
TOTAL	0	0.7

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 62 and 63, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 66, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibit H.3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, page 65, the applicant states that the following ancillary and support services are required for the proposed services and are currently provided by NHBMC or Novant Health Corporate Services:

- Billing, Accounts Payable, and General Accounting
- Business Office/Admitting
- Facility Management
- Human Resources/Wage and Benefits

- Information Management
- Legal Services
- Materials Management
- Medical Record Services
- Planning and Marketing
- Precertification and Insurance
- Purchasing
- Quality Management and Infection Control
- Risk Management and Utilization Review
- Scheduling
- Staff Education

In Exhibit I.1, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, pages 66-67, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the

project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to 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 75, the applicant provides the historical payor mix during the last full fiscal year for the proposed services, as shown in the table below.

**NHBMC Payor Mix
 FY 10/1/2017 to 9/30/2018**

Payor Source	Percent of Total Patients
Self-Pay	1.6%
Charity Care	9.8%
Medicare (includes managed care plans)	52.0%
Medicaid (includes managed care plans)	12.5%
Insurance (includes managed care plans)	21.5%
Workers Compensation	0.3%
Tricare	1.9%
Other (BH and Other)	0.3%
Total	100.0%

Source: Section L, page 75

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Brunswick	31%	52%	18%	14%	13%	15%
Statewide	16%	51%	37%	15%	10%	12%

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

* Excludes "White alone, not Hispanic or Latino"

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

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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

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

The Agency reviewed the:

- Application
- Exhibits to the application
- 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, page 75, the applicant states:

“NHBMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.”

In Section L, page 75, 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

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 76, the applicant projects the following payor mix for the proposed services during the first full fiscal year of operation following completion of the project, as shown in the table below.

**NHBMC Payor Mix
FY 1/1/2020 to 12/31/2020**

Payor Source	Percent of Total Patients
Self-Pay	1.6%
Charity Care	9.8%
Medicare (includes managed care plans)	52.0%
Medicaid (includes managed care plans)	12.5%
Insurance (includes managed care plans)	21.5%
Workers Compensation	0.3%
Tricare	1.9%
Other (BH and Other)	0.3%
Total	100.0%

Source: Section L, page 76

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.6% of total services will be provided to self-pay patients, 9.8% to charity care patients, 52% to Medicare patients and 12.5% to Medicaid patients.

On page 76, 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 for the following reasons:

- The applicant assumes no changes from the current hospital payor mix
- The applicant states that inpatient dialysis service is based on data from the Congressional Research Service, Medicare Coverage of End-Stage Renal Failure (ESRD), August 16, 2018.

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.

In Section L, page 78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 80, 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.1.

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 2019 SMFP does not define a service area for inpatient dialysis services. The applicant defines its primary service area in Section C, page 29, as Brunswick County. Facilities may also serve residents of counties not included in their service area.

County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	1/1/2020 TO 12/31/2020		1/1/2021 TO 12/31/2021		1/1/2022 TO 12/31/2022	
Brunswick	206	100.0%	212	100.0%	217	100.0%
Total	206	100.0%	212	100.0%	217	100.0%

Source: Section C, page 29

In Section N, page 82, 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 82, the applicant states:

“Currently, inpatient dialysis services are not provided within Brunswick County. With the development of inpatient dialysis services at NHBMC, Brunswick County residents receiving outpatient dialysis treatments will have access to inpatient care within the county.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section N and 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

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.

In Section A, page 10, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred in any of these facilities. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 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.

NA

The applicant proposes to provide inpatient dialysis services through the addition of no more than two portable inpatient dialysis units upon project completion. There are no administrative rules that are applicable to proposal to add inpatient dialysis services to Brunswick Community Hospital, LLC through a service agreement with DaVita, Inc.