



October 31, 2023

Via Email (DHSR.CON.Comments@dhhs.nc.gov and tanya.saporito@dhhs.nc.gov)

Ms. Tanya Saporito, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

**RE: Bio-Medical Applications of North Carolina, Inc. Public Written
Comments on AHSNF, Inc. and The Charlotte-Mecklenburg Hospital
Authority CON Application**

Project ID#: F-12424-23
Facility: Atrium Health Dialysis Huntersville Oaks
Project Description: Develop no more than six in-center dialysis stations at a nursing facility pursuant to an adjusted need determination in the 2023 SMFP
County: Mecklenburg
FID#: 230802

Dear Ms. Saporito:

Fresenius Medical Care Holdings, Inc. (parent company of the Fresenius Medical Care related entities¹) d/b/a Bio-Medical Applications of North Carolina, Inc. (**BMA**), submits the following written comments on the September 15, 2023, CON application filed by AHSNF, Inc. and The Charlotte-Mecklenburg Hospital Authority (**Atrium**) to develop no more than six (6) in-center dialysis stations at a nursing facility pursuant to an adjusted need determination in the 2023 SMFP (Project ID# F-12424-23) (Application, pp. 15). BMA submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1)(b and c) to discuss whether, considering the material contained in the application and other

¹ Bio-Medical Applications of North Carolina, Inc., Bio-Medical Applications of Fayetteville, Inc., Bio-Medical Applications of Clinton, Renal Care Group of the South, Inc., RAI Care Centers of North Carolina II, LLC and several joint venture operations in North Carolina: Carolina Dialysis, LLC, FMS ENA Home, LLC, Fresenius Medical Care of Lillington, LLC, Independent Nephrology Services, Inc., Fresenius Medical Care of Morrisville, LLC, Fresenius Medical Care of Rock Quarry, LLC, and Fresenius Medical Care of White Oak, LLC.

relevant factual material, the application complies with the relevant review criteria, plans and standards.

BACKGROUND

Liberty Healthcare petitioned the State Health Coordinating Council (SHCC) four times regarding the provision of outpatient dialysis services at a nursing home:

- In March 2022, Liberty's first petition sought the addition of Policy ESRD-4 to the 2023 SMFP. The proposed policy would have allowed for the development or expansion of a kidney disease treatment center at a skilled nursing facility. The Agency recommended denial of the petition and the SHCC voted to accept the Agency's recommendation and deny the Petition.
- In July 2022, Liberty's second petition sought SHCC approval of a nursing home pilot demonstration project of six (6) outpatient dialysis stations in Mecklenburg County to be located at Royal Park of Matthews Rehabilitation and Health Center based on the dialysis facility need determination methodology. The Agency denied the petition as written but recommended a county need determination for six outpatient dialysis stations at a nursing home facility in Mecklenburg County with six stipulations, which are listed in the 2023 SMFP. The SHCC voted to accept the Agency's alternative recommendation and deny the Petition as written.
- In March 2023, Liberty's third petition sought the creation of Policy ESRD-4 to develop or expand a kidney disease treatment center at a skilled nursing home facility. In its petition, Liberty asserted that by developing Policy ESRD-3, the Agency and the SHCC set a precedent for the establishment of Proposed Policy ESRD-4. The Agency recommended denial of the petition and the SHCC approved the Agency's recommendation.
- In July 2023, Liberty's fourth petition sought the creation of 24 county need determinations for outpatient dialysis stations at nursing home facilities across the state. The Agency recommended denial of the petition and the SHCC approved the Agency's recommendation.

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§ 131E-183(a) states, *"The Department 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."*

BMA believes the Agency should consider the following information when determining conformity of Atrium's CON Application with the relevant review criteria outlined in § 131E-183(a):

Criterion Three (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

Demonstration of Need and Projected Utilization

- Table 9A: Inventory of Dialysis Stations and Calculations of Utilization Rates in Chapter 9 of the Proposed 2024 SMFP shows that Mecklenburg County is home to 22 existing in-center dialysis facilities where the patient population that Atrium has identified in its application is already being served. Table 9B: ESRD Dialysis Station Need Determinations by Planning Area in Chapter 9 of the Proposed 2024 SMFP shows the Mecklenburg County Projected Total Available Stations is 598 stations, which constitutes a surplus of 94-stations for the service area.

At least one facility, Huntersville Dialysis is located less than 5-miles from the Huntersville Oaks nursing facility. Atrium does not address how the needs of the population identified in its application are not adequately being met given the existing availability and accessibility to dialysis services already being provided in proximity of the proposed facility in the service area.

- The 5-Year Average Annual Change Rate (5-Year AACR) in Table 9B: ESRD Dialysis Station Need Determinations by Planning Area in the 2020, 2021, 2022, 2023 and the Proposed 2024 SMFP has been declining over the last five years at a rate of 4.2%, 3.1%, 2.1%, 2.3% and 1.1% respectively. The Chapter 9: Dialysis Data by County of Patient Origin report also shows that the Mecklenburg County in-center hemodialysis patient population has decreased from 1,642 patients in FY 2020 to 1,596 patients in FY 2022, or by 2.8%. Atrium does not address this decline anywhere in its application even though this is publicly available data that the Agency routinely relies on for projecting the need for dialysis services.

Criterion Four (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.

In Section E pages 59-60 of the application, Atrium describes the alternative methods of meeting the need for the proposal including: maintaining the status quo of transferring ESRD patients offsite for dialysis services, develop the dialysis stations at a different nursing facility or develop fewer than six (6) stations. However, Atrium does not provide any substantive data as to its current costs for transporting patients to and from dialysis services versus the cost of operating a dialysis facility on one of its facility campuses, and

employing the specialized staff and equipment required to ensure quality patient care while meeting the criteria for participation in the government programs from which it would seek reimbursement. Thus, it is unclear how the Project Analyst is supposed to make a determination that the proposed project is the least costly or most effective alternative the need.

Criterion Six (6)

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

- Table 9A: Inventory of Dialysis Stations and Calculations of Utilization Rates in Chapter 9 of the Proposed 2024 SMFP shows that Mecklenburg County is home to 22 existing in-center dialysis facilities, as shown in the table below.

Name of Facility	Certified Stations as of 12/31/2022	Number of In-center Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022	Patients per Station	Stations to be (+) or (-)
BMA Beatties Ford	41	90	54.88%	2.1951	2
BMA Nations Ford	28	90	80.36%	3.2143	
BMA of East Charlotte	32	105	82.03%	3.2813	
BMA West Charlotte	29	87	75.00%	3.0000	
FMC Charlotte	48	88	45.83%	1.8333	
FMC Matthews	21	80	95.24%	3.8095	
FMC of North Charlotte	40	136	85.00%	3.4000	
FKC Mallard Creek	12	20	41.67%	1.6667	
FKC Regal Oaks	17	56	82.35%	3.2941	4
FKC Southeast Mecklenburg	17	49	72.06%	2.8824	
FMC Aldersgate	16	51	79.69%	3.1875	
FMC Southwest Charlotte	26	67	64.42%	2.5769	
Brookshire Dialysis	11	40	90.91%	3.6364	9
Charlotte Dialysis	33	79	59.85%	2.3939	-10
Charlotte East Dialysis	34	102	75.00%	3.0000	
Huntersville Dialysis	27	65	60.19%	2.4074	
Mint Hill Dialysis	21	56	66.67%	2.6667	
North Charlotte Dialysis Center	33	94	71.21%	2.8485	-10
South Charlotte Dialysis	27	72	66.67%	2.6667	
Sugar Creek Dialysis	21	39	46.43%	1.8571	
DSI Charlotte Latrobe Dialysis	24	70	72.92%	2.9167	
DSI Glenwater Dialysis	42	88	52.38%	2.0952	
TOTAL	600	1,624	67.67%	2.7067	

As shown in the table above, the utilization of existing dialysis stations in Mecklenburg County as of December 31, 2022, was only 67.67%.

➤ Table 9B: ESRD Dialysis Station Need Determinations by Planning Area in Chapter 9 of the Proposed 2024 SMFP shows the Mecklenburg County Projected

Total Available Stations is 598 stations, which constitutes a surplus of 94-stations for the service area.

- At least one facility, Huntersville Dialysis is located less than 5-miles from the Huntersville Oaks nursing facility. Atrium does not address how developing new stations in such close proximity to an existing dialysis facility is not an unnecessary duplication of existing or approved health service capabilities or facilities.
- While Condition #5 of the need determination outlined in Chapter 9 Table 9C of the 2023 SMFP states that the six (6) stations to be developed pursuant to this need determination are excluded from the planning inventory in the SMFP and excluded from the county and facility need methodologies, the nursing facility patients are included in the total number of patients used to calculate the need for additional dialysis services in the county. Inclusion of their numbers in the county growth rate and county need determination while excluding the stations provided for them by a nursing home dialysis facility would result in the duplication of dialysis services.

Summary

BMA and its affiliates asks that the CON Section take into consideration these comments for the reasons discussed above, in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to ensure that the material contained in the application along with any other relevant factual material complies with the relevant review criteria, plans and standards.

Respectfully,



Fatimah Wilson
Director, Certificate of Need
Fresenius Medical Care