

Liberty Healthcare



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October 31, 2023

VIA EMAIL ONLY

Micheala Mitchell, Chief, Healthcare Planning and Certificate of Need
Tanya Saporito, Project Analyst
Certificate of Need Section, NC DHSR, NC DHHS
809 Ruggles Drive
Raleigh, NC 27603

RE: Project F-12430-23, Liberty Commons Nursing and Rehabilitation Center of Matthews, LLC, Liberty Healthcare Properties of Matthews, LLC, and LRS NC, LLC d/b/a Liberty Healthcare Management Renal Dialysis (collectively, the “Applicants” or “Liberty Renal Dialysis”), Written Comments

Dear Ms. Mitchell and Ms. Saporito,

Pursuant to N.C. Gen. Stat. 131E-185(a1)(1), Liberty Commons Nursing and Rehabilitation Center of Matthews, LLC, Liberty Healthcare Properties of Matthews, LLC, and LRS NC, LLC d/b/a Liberty Healthcare Management Renal Dialysis (together, the “Applicants”) hereby submit the following comments related to the competing application filed in regard to the adjusted need determination to develop six outpatient dialysis stations located at a nursing home facility in Mecklenburg County identified in the 2023 North Carolina State Medical Facilities Plan (“SMFP”). The following competing application also seeks approval to develop six outpatient dialysis stations located at a nursing home facility in Mecklenburg County.

Project ID #	Applicant
F-12424-23	AHSNF, Inc. and The Charlotte-Mecklenburg Hospital Authority – Atrium Health Dialysis Huntersville Oaks (“Huntersville Oaks”)

Based on our analysis, the Liberty Healthcare Management Renal Dialysis application represents the most effective alternative for meeting the skilled nursing (“SNF”) dialysis patients needs of Mecklenburg County. We appreciate your consideration of our comments in your review process.

Best Regards,



Timothy Walsh
Director of Business Development

Liberty Senior Living
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(910) 332-1982

COMMENTS ON PROJECT ID# F-12424-23
ATRIUM HEALTH DIALYSIS HUNTERSVILLE OAKS

In a North Carolina competitive review, each application is reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (Agency) also conducts a comparative analysis of all the applications. The comments provided hereto follow a similar process.

REVIEW CRITERIA FOR PROJECT F-12424-23/HUNTERSVILLE OAKS

Criterion (3)

Analysis of Need

In Section C, pages 34-45, Huntersville Oaks explains why it believes the population projected to utilize the proposed services needs the proposed services, as follows:

- The adjusted need determination in the 2023 SMFP
- The need for accessible dialysis services for SNF-appropriate dialysis patients; and
- The aging and demographic factors of Mecklenburg County

However, the information is not reasonable or adequately supported based on the following:

- In August of 2023, Liberty Healthcare and Rehabilitation Services (“Liberty”), an affiliate of Liberty Renal Dialysis, submitted multiple petitions for adjusted need determinations for outpatient dialysis stations to be located within nursing home facilities or “proximate to the nursing home building” in 24 counties. One of the counties for which an application was submitted was Mecklenburg County. Atrium Health Wake Forest Baptist opposed the Mecklenburg County 2023 Summer Petition submitted by Liberty. For reference, as found in Section C of Page 32 of the Huntersville Oaks application, Atrium Health Wake Forest Baptist is a “related entity” to Huntersville Oaks, who would “leverage its experience” with Atrium Health Wake Forest Baptist. Atrium Health Wake Forest Baptist’s opposition letter can be found in **Exhibit 1** of these comments. Page 2 of the Atrium Health Wake Forest Baptist opposition letter contains the following comments:

All the SNF / ESRD residents in Mecklenburg County requiring dialysis already have their needs met at existing ESRD treatment facilities. This is further evidenced by the 71-station county surplus published in the 2023 SMFP. Based on its erroneous assumptions, Liberty goes on to form an entire need determination procedure, to quantify its projected need for a total of 59 SNF / ESRD stations.

Having a related entity to Huntersville Oaks state publicly that “all the SNF / ESRD residents in Mecklenburg County already have their needs met at existing ESRD treatment facilities” in August 2023 and then applying for a CON and stating there is “need for accessible dialysis services for

SNF-appropriate dialysis patients” in September 2023 is contradictory. Nothing in the Huntersville Oaks application, as submitted, provides reasonable and adequately supported information as to how Mecklenburg County SNF/ESRD residents went from having their needs met at existing ESRD facilities in August of 2023 to now demonstrating a need in September 2023. It should be noted, and discussed further in the next bullet point, that Health Systems Management, Inc (“HSM”), another affiliate of Huntersville Oaks, submitted an identical opposition letter to the Mecklenburg County 2023 Summer Petition.

Additionally, HSM submitted an opposition letter to the Mecklenburg County 2022 Summer Petition requesting a nursing home 6-dialysis station pilot demonstration project. Liberty’s August 2022 petition requested a nursing home pilot demonstration project of six outpatient dialysis stations in Mecklenburg County to be located at Royal Park (Royal Park) of Matthews Rehabilitation and Health Center. This 2022 Summer Petition was the basis for the county need determination for six outpatient dialysis stations at a nursing home facility in Mecklenburg County under current review. Health Systems Management, Inc opposed the Mecklenburg County 2022 Summer Petition submitted by Liberty. For reference, as found on the webpage of Health Systems Management, Inc (“HSM”), “HSM is managing the outpatient dialysis facilities owned by Atrium Health Wake Forest Baptist.” Similar to Atrium Health Wake Forest Baptist, HSM is also a “related entity” to Huntersville Oaks. HSM’s opposition letter to the 2022 Summer Petition can be found in **Exhibit 2** of these comments. On Page 2 of the HSM opposition letter, it states:

1) Mecklenburg County is home to 26 dialysis centers (existing and proposed) and 589 dialysis stations, which constitutes a 71-station surplus for the service area. The request for an adjusted need determination for Mecklenburg County would duplicate existing and approved healthcare services.

Nothing in the Huntersville Oaks application, as submitted, provides reasonable and adequately supported information as to how Mecklenburg County had “no lack of dialysis services” in August 2023 (as reflected in the above statements) but in September 2023 a need now exists.

Subsequently, the two related entities, who Huntersville Oaks has stated with whom it would “leverage its experience,” have publicly stated SNF/ESRD residents in Mecklenburg County already have their needs met and there is already a surplus of stations.

Based on that review, the Agency should conclude that the application is not conforming to criterion (3) since it cannot demonstrate the need the population to be served has for the proposed services.

Criterion (4)

The Application is not confirming to Criterion (4). An application that cannot demonstrate the need the population proposed to be served has for the proposed services cannot be an effective alternative to meet the need. Please refer to Criterion (3) above.

Criterion (6)

Please refer to the discussion regarding need found in Criterion (3) above. On Page 2 of the Atrium Health Wake Forest Baptist opposition letter, Atrium Health Wake Forest Baptist comments that Mecklenburg County has a “71-station county surplus published in the 2023 SMFP”. As noted previously, Atrium Health Wake Forest Baptist is a related entity to Huntersville Oaks. Nothing in the Huntersville Oaks application, as submitted, provides reasonable and adequately supported information as to how Mecklenburg County had a 71-station surplus in August of 2023 to now demonstrating a need in September 2023.

A proposal that cannot demonstrate the need it has to serve the population it proposes to serve cannot demonstrate that the proposal will not result in an unnecessary duplication of existing or approved services in the service area. Please refer to Criterion (3) above.

Criterion (18a)

The Application is not conforming to Criterion (18a). An application that cannot demonstrate the need the population proposed to be served has for the proposed services cannot demonstrate that the proposal would have a positive impact on cost-effectiveness. Please refer to Criterion (3) above. A proposal that does not demonstrate that it is not unnecessarily duplicative cannot demonstrate that the proposal would have a positive impact on cost-effectiveness. Please refer to Criterion (6) above.

COMPARATIVE ANALYSIS

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming, or conforming as conditioned, with all applicable statutory and regulatory review criteria cannot be approved.

The application submitted by Liberty Renal Dialysis is conforming to all applicable statutory and regulatory review criteria. The application submitted by Huntersville Oaks is not conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Scope of Services

Both applicants propose to offer the same scope of services. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Historical Utilization

Liberty Renal Dialysis does not have any existing outpatient dialysis stations and neither the Applicants nor any affiliated entities have any other outpatient dialysis stations in Mecklenburg County. It is worth noting that Liberty Healthcare Management has employed for over one year an Executive Director of Renal Dialysis with decades of experience in renal care to lead Liberty’s dialysis program in the event that Liberty’s petition is granted.

Huntersville Oaks does not have any existing outpatient dialysis stations. However, Atrium Health Wake Forest Baptist, an affiliate of Huntersville Oaks, has a total of 20 in-center ESRD facilities in North Carolina.

Therefore, regarding this comparative factor, the application submitted by Huntersville Oaks is a more effective alternative.

Access by Service Area Residents

The 2023 SMFP defines the service area for ESRD facilities as “... 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 review is Mecklenburg County.

The following table illustrates access by service area residents during the second full fiscal year following project completion.

Percentage of Service Area Residents Projected to be Served – FY 2	
Facility	% of Total Residents
Huntersville Oaks	71.9%
Liberty Renal Dialysis	100.0%

As shown in the table above, Liberty Renal Dialysis project to serve the highest percentage of service area residents during the second full fiscal year following project completion. Therefore,

regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], 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.”

Projected Medicare

The following table compares projected access by Medicare recipients in the second full fiscal year following project completion for each facility by a % of total residents.

Percentage of Medicare Residents Projected to be Served – FY 2	
Facility	% of Total Residents
Huntersville Oaks	84.1%
Liberty Renal Dialysis	100.0%

As shown in the table above, Liberty Renal Dialysis project to serve the highest percentage of Medicare residents during the second full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Projected Charity Care

Neither Huntersville Oaks nor Liberty Renal Dialysis project to provide any charity care to any of the dialysis patients they propose to serve. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Projected Medicaid

The following table compares projected access by Medicaid recipients in the second full fiscal year following project completion for each facility by a % of total residents.

Percentage of Medicaid Residents Projected to be Served – FY 2	
Facility	% of Total Residents
Huntersville Oaks	8.9%
Applicants	0.0%

As shown in the table above, Huntersville Oaks project to serve the highest percentage of Medicaid residents during the second full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by Huntersville Oaks is a more effective alternative.

Total Projected Medically Underserved Groups

The following table compares projected access by medically underserved groups in the second full fiscal year following project completion for each facility by a % of total residents. Huntersville Oaks did not provide an estimated percentage of total patients of medically underserved groups in their application. Therefore, Liberty Renal Dialysis have added the Medicare and Medicaid percentages above to create a Medically Underserved percentage.

Percentage of Medically Underserved Residents Projected to be Served – FY 2	
Facility	% of Total Residents
Huntersville Oaks	93.0%
Liberty Renal Dialysis	100.0%

As shown in the table above, Liberty Renal Dialysis project to serve the highest percentage of medically underserved residents during the second full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Therefore, regarding this comparative factor which includes looking at projected Medicare, projected charity care, projected Medicaid, and projected low income, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Competition (Access to a New or Alternate Provider)

The introduction of a new provider in the service area is generally considered to be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients.¹

¹ 1. Competitive analysis to develop a Medicare-certified home health agency pursuant to a need determination in 2023 SMFP in Forsyth

a. Winning Project was Well Care Home Health of Forsyth County (Project G-12362-23)

While all competitive projects were equally effective on competition, the verbiage of “the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients” is listed.

2. Competitive analysis to acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination in New Hanover

a. Winning Project was EmergeOrtho- Wilmington Porters Neck (Project O-12374-23)

The verbiage of “the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients” is listed. Additionally, it states “Delaney Radiology would introduce a new provider of fixed MRI services in the service area. Thus, with regard to increasing competition for fixed MRI services in the New Hanover County fixed MRI service area, the application submitted by Delaney Radiology represents a more effective alternative.”

3. Competitive analysis to develop a new 67-bed acute care hospital pursuant to the need determination in the 2022 SMFP in Buncombe

a. Winning Project was AdventHealth Asheville (Project B-12233-22)

The verbiage of “the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients” is listed. Additionally, it states “Therefore,

Liberty Renal Dialysis does not have any existing outpatient dialysis stations and neither the Applicants nor any affiliated entities have any other outpatient dialysis stations in Mecklenburg County.

Huntersville Oaks does not have any existing outpatient dialysis stations. However, Atrium Health Wake Forest Baptist, an affiliate of Huntersville Oaks, has a total of 20 in-center ESRD facilities in North Carolina. Additionally, Carolina Medical Center, an affiliate of Atrium Health and located within Mecklenburg County, currently provides dialysis services.

Therefore, regarding this comparative factor, Liberty Renal Dialysis is the more effective alternative.

Projected Average Net Revenue per Treatment

The following table compares projected average net revenue per treatment in the second full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per treatment is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Average Net Revenue Per Treatment – FY 2			
Facility	Total # of Treatments	Net Revenue	Average Net Revenue per Treatment
Huntersville Oaks	3,588	\$8,555,027	\$2,384.34
Liberty Renal Dialysis	2,808	\$2,316,684	\$825.03

As shown in the table above, Liberty Renal Dialysis projects the lowest average net revenue per treatment in the second full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Projected Average Operating Expense per Treatment

The following table compares projected average operating expense per treatment in the second full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per treatment is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Average Operating Expense Per Treatment – FY 2			
Facility	Total # of Treatments	Operating Expense	Average Operating Expense per Treatment

with regard to patient access to a new or alternate provider, the applications submitted by Novant Health Asheville Medical Center and AdventHealth Asheville are more effective alternatives, and the application submitted by Mission Hospital is the less effective alternative.”

Huntersville Oaks	3,588	\$1,059,080	\$295.17
Liberty Renal Dialysis	2,808	\$729,859	\$259.92

As shown in the table above, Liberty Renal Dialysis projects the lowest average operating expense per treatment in the second full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by Liberty Renal Dialysis is a more effective alternative.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the above Comparative Analysis.

Comparative Factor	Liberty Renal Dialysis	Huntersville Oaks
Conformity with Statutory and Regulatory Review Criteria	Yes	No
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	Less Effective	More Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Medicare Patients	More Effective	Less Effective
Access by Charity Care Patients	Equally Effective	Equally Effective
Access by Medicaid Patients	Less Effective	More Effective
Access by Medically Underserved Patients	More Effective	Less Effective
Competition (Access to a New or Alternate Provider)	More Effective	Less Effective
Projected Average Net Revenue per Treatment	More Effective	Less Effective
Projected Average Operating Expense per Treatment	More Effective	Less Effective

The Huntersville Oaks application is not an effective alternative with respect to Conformity with Review Criteria; therefore, it should not be approvable.

Nonetheless, as shown in the table above, Liberty Renal Dialysis is a more effective alternative for the following factors:

- Access by Service Area Residents
- Access by Medicare Patients
- Access by Medically Underserved Patients
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Treatment
- Projected Average Operating Expense per Treatment

As shown in the table above, Liberty Renal Dialysis is an equally effective alternative for the following factors:

- Scope of Services
- Access by Charity Care Patients

As shown in the previous table, Liberty Renal Dialysis is a less effective alternative for the following factor:

- Historical Utilization
- Access by Medicaid Patients

Therefore, based upon the Comparative Analysis above, the Liberty Healthcare Management Renal Dialysis application should be approved and the Atrium Health Dialysis Huntersville Oaks should be denied.

EXHIBIT 1



Russell M. Howerton, MD, F.A.C.S.
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Senior Vice President, Clinical Operations

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August 4, 2023

Healthcare Planning Section
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NCDHHS
809 Ruggles Drive
Raleigh, NC 27603

Re: Atrium Health Wake Forest Baptist and Health Systems Management's Comments on behalf of Wake Forest University Health Sciences Dialysis Centers Comments Regarding Liberty Healthcare's Petition to modify Chapter 9 of the 2024 State Medical Facilities Plan – Mecklenburg County

Dear SHCC Members:

On behalf of the Wake Forest University Health Sciences (WFUHS) Dialysis Centers, WFUHS presents the following observational comments regarding the petitions filed by Liberty Healthcare ("Liberty") relating to a change in need methodology for dialysis stations in North Carolina counties.

INAPPROPRIATE FILING TIME

The 2023 SMFP clearly states on page 7 the following: "**Spring petitions and proposals. Spring petitions involve requests for changes to the SMFP that have potential for a statewide effect, such as the addition, deletion or revision of policies or need determination methodologies.**" Clearly, all the petitions submitted by Liberty represent such a change and therefore are ineligible for consideration at this late date.

POLICY CHANGE REQUEST

By its own words, Liberty proposes a "**modification to Chapter 9 of the SMFP.**" Liberty's proposed modification, while being filed untimely, also violates the basic principles of CON. Liberty's petitions are clearly an attempt to circumvent the existing CON laws regulating the establishment of a new institutional health service. Particularly, Liberty is requesting the creation of a "hybrid" SNF / ESRD treatment facility, which would be subject to both SNF and ESRD rules and regulations.

RULE MAKING ESRD COMPLY WITH SNF REQUIREMENTS

Liberty's proposal asks that the special need determination require the SNF / ESRD provider to be located within or on the same campus as the SNF. If located within the SNF, Liberty asks that the SHCC establish an additional new rule that would require the dialysis unit to comply with "**federal life safety and building code requirements applicable to a nursing home.**" Such requirements are not necessarily compliant with CMS Rules for Participation relating to ESRD treatment facilities nor within the realm of authority of the SHCC to create.

EXCLUDE SNF / ESRD STATIONS FROM COUNTY STATION TOTALS

Liberty goes on to suggest that any stations developed pursuant to this new rule would be excluded from the county and facility need methodologies. However, CMS standards provide that any patient with ESRD would be able to utilize those stations. The result would be a duplication of dialysis services for SNF and

non-SNF patients. Such a rule would also violate a patient's right to choose their ESRD provider and thereby also pose a potential violation of STARK laws in regard to self-dealing.

LIMIT WHO CAN APPLY

NC CON statutes allow any Mecklenburg to apply for a published need determination, however, Liberty proposes a policy change / new policy creation that would allow **only** "a licensed nursing home facility" to apply for a SNF / ESRD need determination. To be clear, ESRD is a provider type that is separate and unique from a SNF. This ask is the equivalent of a dialysis provider requesting a special need determination to allow it to develop SNF beds in an ESRD unit.

CREATE A NEW NEED POLICY

Liberty puts forth what it calls "quantifying data" including per its petition: "Mecklenburg SNF Dialysis Data, Nursing Home ESRD Dialysis Station Need Determination by Planning Area, and Comparison to State and National Averages." Liberty references the UM-KECC ESRD patient database and how it used Medicare Dialysis Facilities Data – FY 2023, Medicare Dialysis Facilities Data Dictionary, and the 2023 SMFP to determine that Mecklenburg County has a need for 62 ESRD stations located at a nursing home. Liberty did this by suggesting that since 11.70% of patients on dialysis are SNF residents and since Mecklenburg County had 1,692 SNF residents as of 12/31/2021, there were 198 SNF residents who needed dialysis stations at a SNF in Mecklenburg County "during the year." Thus, according to Liberty, Mecklenburg County needs 62 more dialysis stations to serve the SNF residents at a SNF / ESRD provider.

All the SNF / ESRD residents in Mecklenburg County requiring dialysis already have their needs met at existing ESRD treatment facilities. This is further evidenced by the 71-station county surplus published in the 2023 SMFP. Based on its erroneous assumptions, Liberty goes on to form an entire need determination procedure, to quantify its projected need for a total of 59 SNF / ESRD stations.

FACTUAL INFORMATION

In all its petitions Liberty has never identified how many Liberty patients, specifically, required ESRD services in the past. Liberty operates 2 of the 30 SNF's in Mecklenburg County. Yet, Liberty is the only SNF provider requesting SNF / ESRD stations. Liberty is making its requests without providing how many, if any, ESRD patients it sends to dialysis during any time referenced in its petition.

Liberty fails to explain that its SNF / ESRD patients do not necessarily live at the SNF for the remainder of their lives. Thus, the overall need for ESRD treatment for SNF patients is far less than presented by Liberty. Per the 2023 SMFP, there were 1,871 ESRD patients in Mecklenburg County, which includes SNF residents receiving dialysis care. Of the 25 existing ESRD treatment facilities, only two were operating at greater than 90% utilization. The need projected by Liberty is both unwarranted and unfounded.

Liberty suggests that its request is necessary because all its prior petitions were denied. However, that is incorrect. Liberty's request for a pilot program in Mecklenburg County was granted by the SHCC. Applications for that special need determination are due to the CON Section by September 15, 2023. Thus, the pilot program allowed by the SHCC for Mecklenburg County is still in its pre-development stage and no conclusions can yet be drawn on its long-term viability.

SCHEDULING COMPLAINTS

On page 7, Liberty proposes that by providing dialysis within the nursing home, clinical patient outcomes would improve because the SNF could schedule the dialysis treatment around the patient's SNF schedule

versus scheduling SNF services around dialysis. However, there are clinical reasons patients are given dialysis on a consistent schedule (M,W,F or T,Th,S / mornings or afternoons), which may be outside the realm of understanding to those who do not possess expertise in the field of ESRD treatment. Based on more than 40 years of experience and expertise in the treatment of ESRD patients, consistency is key to patient longevity and patient quality of life.

INFECTION RISK & PATIENT SATISFACTION

On Page 8 of its petition, Liberty claims its proposal maximizes Safety and Quality because ***“it reduces the risk of infection and complications associated with offsite travel.”*** However, Liberty fails to show any evidence that the existing ESRD providers pose a risk to patient safety or an increase in the rate of infection. Liberty also fails to show how its proposal would mitigate any potential ESRD-related infection risks and offers only a subjugated opinion as evidence.

Liberty suggests that overall SNF patient satisfaction would increase. However, given Liberty’s lack of experience in the specialized care required to successfully deliver ESRD treatments patients may be less satisfied due to risk of inadequate dialysis and a reduction in their overall quality of life.

PERFORMANCE

The most recent CMS report for skilled nursing facilities found at <https://data.cms.gov/provider-data/topics/nursing-homes> indicates Liberty as well as other SNF’s may be ill-equipped to comply with ESRD CON requirements. Section O of the ESRD CON application requires all applicants to provide survey data for all commonly owned entities during an 18-month lookback period. Since Liberty is asking for a new hybrid SNF / ESRD provider type and wants the SHCC to require the ESRD portion to comply with SNF standards, it is reasonable to expect the SNF to comply with ESRD standards. Thus, the surveys conducted at every like-owned SNF would be applicable in determining if the applying SNF could be reasonably expected to safely deliver dialysis care. See **Exhibit A**.

FINANCIAL CONCERNS

Liberty states on Page 7 of its petition the adverse effects if a change is not made to allow their petition. Twice in the same paragraph, Liberty complains that taking patients to dialysis is not ***“economically affordable for the nursing facility”*** and that transporting patients to dialysis is a ***“cost burden on the nursing home.”***

Liberty suggests on page 9 that by allowing a 59-station duplication of the existing services in Mecklenburg County, access to dialysis care for SNF patients would be improved. However, Liberty **fails** to show any barriers to ESRD care for SNF patients aside from its **own financial burden** of providing transportation services to its patients suffering from ESRD. Liberty also fails to indicate how many, if any, of its patients required dialysis and transportation services during any period discussed in its petition. Perhaps, Liberty in its quest to diversify its business offerings, should develop a new transportation service exclusively for ESRD patients to and from treatment. Liberty could use that service as means to overcome the financial burden of paying another transportation provider, which Liberty continues to stress is a barrier to finding true value.

Liberty’s proposal would also limit the SNF patient’s choice by basically requiring patients to use their in-house dialysis versus allowing the patient to choose their own nephrologist who may not be affiliated with the Liberty SNF.

CONCLUSION

In Mecklenburg County the existing ESRD providers do a very good job addressing patient station needs as evidenced by the 59-station county surplus as recorded in the 2023 SMFP. Liberty sees these continued petitions as its only means by which to enter the ESRD industry and circumvent the CON requirements by which all legitimate ESRD treatment providers are bound. To allow any of Liberty's petitions would be an injustice. The existing ESRD treatment facilities and providers who have operated for decades within the boundaries of CON have spread access to dialysis services to nearly all of North Carolina's 100 counties. To this end and for the reasons mentioned above, it is our hope that the SHCC will deny all the petitions filed by Liberty for the 2024 SMFP to protect the health and safety of the ESRD patients of North Carolina.

Respectfully,

A handwritten signature in black ink, appearing to read "Russell M. Howerton MD". The signature is fluid and cursive, with a large "R" and "H".

Russell M. Howerton, MD, FACS
President Wake Forest Health Network
Senior Vice President Clinical Operations
Atrium Health Wake Forest Baptist



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August 4, 2023

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Re: Health Systems Management's Comments on behalf of Wake Forest University Health Sciences Dialysis Centers Comments Regarding Liberty Healthcare's Petition to modify Chapter 9 of the 2024 State Medical Facilities Plan – Mecklenburg County

Dear SHCC Members:

On behalf of the Wake Forest University Health Sciences (WFUHS) Dialysis Centers, WFUHS presents the following observational comments regarding the petitions filed by Liberty Healthcare ("Liberty") relating to a change in need methodology for dialysis stations in North Carolina counties.

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POLICY CHANGE REQUEST

By its own words, Liberty proposes a "**modification to Chapter 9 of the SMFP.**" Liberty's proposed modification, while being filed untimely, also violates the basic principles of CON. Liberty's petitions are clearly an attempt to circumvent the existing CON laws regulating the establishment of a new institutional health service. Particularly, Liberty is requesting the creation of a "hybrid" SNF / ESRD treatment facility, which would be subject to both SNF and ESRD rules and regulations.

RULE MAKING ESRD COMPLY WITH SNF REQUIREMENTS

Liberty's proposal asks that the special need determination require the SNF / ESRD provider to be located within or on the same campus as the SNF. If located within the SNF, Liberty asks that the SHCC establish an additional new rule that would require the dialysis unit to comply with "**federal life safety and building code requirements applicable to a nursing home.**" Such requirements are not necessarily compliant with CMS Rules for Participation relating to ESRD treatment facilities nor within the realm of authority of the SHCC to create.

EXCLUDE SNF / ESRD STATIONS FROM COUNTY STATION TOTALS

Liberty goes on to suggest that any stations developed pursuant to this new rule would be excluded from the county and facility need methodologies. However, CMS standards provide that any patient with ESRD would be able to utilize those stations. The result would be a duplication of dialysis services for SNF and non-SNF patients. Such a rule would also violate a patient's right to choose their ESRD provider and thereby also pose a potential violation of STARK laws in regard to self-dealing.

LIMIT WHO CAN APPLY

NC CON statutes allow any Mecklenburg to apply for a published need determination, however, Liberty proposes a policy change / new policy creation that would allow **only** "a licensed nursing home facility" to apply for a SNF / ESRD need determination. To be clear, ESRD is a provider type that is separate and unique from a SNF. This ask is the equivalent of a dialysis provider requesting a special need determination to allow it to develop SNF beds in an ESRD unit.

CREATE A NEW NEED POLICY

Liberty puts forth what it calls "quantifying data" including per its petition: "Mecklenburg SNF Dialysis Data, Nursing Home ESRD Dialysis Station Need Determination by Planning Area, and Comparison to State and National Averages." Liberty references the UM-KECC ESRD patient database and how it used Medicare Dialysis Facilities Data – FY 2023, Medicare Dialysis Facilities Data Dictionary, and the 2023 SMFP to determine that Mecklenburg County has a need for 62 ESRD stations located at a nursing home. Liberty did this by suggesting that since 11.70% of patients on dialysis are SNF residents and since Mecklenburg County had 1,692 SNF residents as of 12/31/2021, there were 198 SNF residents who needed dialysis stations at a SNF in Mecklenburg County "during the year." Thus, according to Liberty, Mecklenburg County needs 62 more dialysis stations to serve the SNF residents at a SNF / ESRD provider.

All the SNF / ESRD residents in Mecklenburg County requiring dialysis already have their needs met at existing ESRD treatment facilities. This is further evidenced by the 71-station county surplus published in the 2023 SMFP. Based on its erroneous assumptions, Liberty goes on to form an entire need determination procedure, to quantify its projected need for a total of 59 SNF / ESRD stations.

FACTUAL INFORMATION

In all its petitions Liberty has never identified how many Liberty patients, specifically, required ESRD services in the past. Liberty operates 2 of the 30 SNF's in Mecklenburg County. Yet, Liberty is the only SNF provider requesting SNF / ESRD stations. Liberty is making its requests without providing how many, if any, ESRD patients it sends to dialysis during any time referenced in its petition.

Liberty fails to explain that its SNF / ESRD patients do not necessarily live at the SNF for the remainder of their lives. Thus, the overall need for ESRD treatment for SNF patients is far less than presented by Liberty. Per the 2023 SMFP, there were 1,871 ESRD patients in Mecklenburg County, which includes SNF residents receiving dialysis care. Of the 25 existing ESRD treatment facilities, only two were operating at greater than 90% utilization. The need projected by Liberty is both unwarranted and unfounded.

Liberty suggests that its request is necessary because all its prior petitions were denied. However, that is incorrect. Liberty's request for a pilot program in Mecklenburg County was granted by the SHCC. Applications for that special need determination are due to the CON Section by September 15, 2023. Thus, the pilot program allowed by the SHCC for Mecklenburg County is still in its pre-development stage and no conclusions can yet be drawn on its long-term viability.

SCHEDULING COMPLAINTS

On page 7, Liberty proposes that by providing dialysis within the nursing home, clinical patient outcomes would improve because the SNF could schedule the dialysis treatment around the patient's SNF schedule versus scheduling SNF services around dialysis. However, there are clinical reasons patients are given dialysis on a consistent schedule (M,W,F or T,Th,S / mornings or afternoons), which may be outside the realm of understanding to those who do not possess expertise in the field of ESRD treatment. Based on more than 40 years of experience and expertise in the treatment of ESRD patients, consistency is key to patient longevity and patient quality of life.

INFECTION RISK & PATIENT SATISFACTION

On Page 8 of its petition, Liberty claims its proposal maximizes Safety and Quality because "***it reduces the risk of infection and complications associated with offsite travel.***" However, Liberty fails to show any evidence that the existing ESRD providers pose a risk to patient safety or an increase in the rate of infection. Liberty also fails to show how its proposal would mitigate any potential ESRD-related infection risks and offers only a subjugated opinion as evidence.

Liberty suggests that overall SNF patient satisfaction would increase. However, given Liberty's lack of experience in the specialized care required to successfully deliver ESRD treatments patients may be less satisfied due to risk of inadequate dialysis and a reduction in their overall quality of life.

PERFORMANCE

The most recent CMS report for skilled nursing facilities found at <https://data.cms.gov/provider-data/topics/nursing-homes> indicates Liberty as well as other SNF's may be ill-equipped to comply with ESRD CON requirements. Section O of the ESRD CON application requires all applicants to provide survey data for all commonly owned entities during an 18-month lookback period. Since Liberty is asking for a new hybrid SNF / ESRD provider type and wants the SHCC to require the ESRD portion to comply with SNF standards, it is reasonable to expect the SNF to comply with ESRD standards. Thus, the surveys conducted at every like-owned SNF would be applicable in determining if the applying SNF could be reasonably expected to safely deliver dialysis care. See **Exhibit A**.

FINANCIAL CONCERNS

Liberty states on Page 7 of its petition the adverse effects if a change is not made to allow their petition. Twice in the same paragraph, Liberty complains that taking patients to dialysis is not "***economically affordable for the nursing facility***" and that transporting patients to dialysis is a "***cost burden on the nursing home.***"

Liberty suggests on page 9 that by allowing a 59-station duplication of the existing services in Mecklenburg County, access to dialysis care for SNF patients would be improved. However, Liberty **fails** to show any barriers to ESRD care for SNF patients aside from its **own financial burden** of providing transportation services to its patients suffering from ESRD. Liberty also fails to indicate how many, if any, of its patients required dialysis and transportation services during any period discussed in its petition. Perhaps, Liberty in its quest to diversify its business offerings, should develop a new transportation service exclusively for ESRD patients to and from treatment. Liberty could use that service as means to overcome the financial burden of paying another transportation provider, which Liberty continues to stress is a barrier to finding true value.

Liberty's proposal would also limit the SNF patient's choice by basically requiring patients to use their in-house dialysis versus allowing the patient to choose their own nephrologist who may not be affiliated with the Liberty SNF.

CONCLUSION

In Mecklenburg County the existing ESRD providers do a very good job addressing patient station needs as evidenced by the 59-station county surplus as recorded in the 2023 SMFP. Liberty sees these continued petitions as its only means by which to enter the ESRD industry and circumvent the CON requirements by which all legitimate ESRD treatment providers are bound. To allow any of Liberty's petitions would be an injustice. The existing ESRD treatment facilities and providers who have operated for decades within the boundaries of CON have spread access to dialysis services to nearly all of North Carolina's 100 counties. To this end and for the reasons mentioned above, it is our hope that the SHCC will deny all the petitions filed by Liberty for the 2024 SMFP to protect the health and safety of the ESRD patients of North Carolina.

Respectfully,

C. Alex Kemp, II
C. Alex Kemp, II, MBA
Chief Executive Officer
Health Systems Management, Inc.

Marshia S. Coe
Marshia S. Coe, RN, BSN, MSHA
Chief Operating Officer
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EXHIBIT 2



August 9, 2022

Elizabeth Brown, Planner
Amy Craddock, Assistant Chief
Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Liberty Healthcare & Rehabilitation Services – Petition for Adjusted Need Determination for Nursing Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 SMFP

To Whom It May Concern:

The following comments are submitted on behalf of Wake Forest University Health Sciences (WFUHS) dialysis centers in North Carolina. WFUHS owns over 20 dialysis facilities in North Carolina providing in-center hemodialysis (ICH), as well as home-hemodialysis (HH) and peritoneal dialysis (PD) training and support services. Health Systems Management, Inc., has managed the WFUHS facilities for more than 30 years.

Liberty Healthcare & Rehabilitation Services (LHRS) has submitted a petition requesting an adjusted need determination for Mecklenburg County for a nursing home dialysis pilot demonstration project. The request is for 6 dialysis stations and is fundamentally flawed as discussed below:

- 1) Mecklenburg County is home to 26 dialysis centers (existing and proposed) and 589 dialysis stations, which constitutes a 71-station surplus for the service area. The request for an adjusted need determination for Mecklenburg County would duplicate existing and approved healthcare services.
- 2) In its petition LHRS uses in-center and home dialysis descriptives interchangeably. This is a direct display of LHRS's lack of dialysis industry expertise.
- 3) Given the location of the three LHRS facilities within Mecklenburg County compared to the existing and approved ESRD facilities in the county, each is within a 5 to 10-minute drive of LHRS. Thus, geographic accessibility is not an issue. See **Exhibit A**.
- 4) LHRS proposes its need for 6 stations is partially due to its inability to capture reimbursement for contracted transportation services. There are at least 20 medical transport companies in Mecklenburg County, alone, with which LHRS could contract versus their current provider. The LHRS facilities are not located in rural nor remote areas. Thus, the reliability on a singular medical transport company at a rate that is cost prohibitive to LHRS is an internal issue and not grounds for a CON Adjusted Need Determination.
- 5) LHRS states the transport to off-site dialysis is disruptive and time-consuming. Yet, Google Maps demonstrates that the closest dialysis center to Royal Park of Matthews is 2 miles and only 6 minutes away. See **Exhibit B**.

- 6) Dialysis treatment schedules do not normally vary. Thus, the claim that dialysis treatment outside of LHRS prevents patients from receiving other care at LHRS is due to scheduling of those services at the LHRS facility and of no fault of the existing dialysis providers.
- 7) LHRS's petition would have the SHCC issue an adjusted need determination for which only LHRS could apply contrary to CON Rules for adjusted need determinations for dialysis stations.
- 8) LHRS, while relying upon their failure to contract with existing dialysis providers to offer dialysis services on site as grounds for their request for 6 dialysis stations, has failed to address the costs nor cost-savings that would result from approval of their proposal.
- 9) LHRS has failed to provide details on how it could provide dialysis care cheaper and more effectively than an experienced licensed ESRD provider, while meeting the criteria for participation in the Medicare and Medicaid programs from which it would seek reimbursement.
- 10) LHRS provides an Illinois statute to support how it could provide dialysis within an SNF. However, that statute appears to give a free-pass to SNF's proposing to offer dialysis services without requiring the proponent to demonstrate how the Basic Principles of CON in North Carolina are met.

Overall, the LHRS proposal is based in whole on monetary concerns of the proponent and not an intrinsic need for the services requested. There is no lack of dialysis services in Mecklenburg County. In fact, there is a 71-station surplus. There is no lack of medical transport companies from which to contract a better transportation rate, there are 20 such providers within Mecklenburg County. It is not a long haul for patients to travel to dialysis, the closest facility is 2 miles and 6 minutes from LHRS. Geographic accessibility is not at issue. A purported disruption in care provided at LHRS to dialysis patients is solely due to scheduling at LHRS and not due to off-site dialysis treatment, which is consistently scheduled for all ESRD patients week after week.

Approval of the LHRS Petition would up-end the Basic Principles of CON, introduce a new provider into a county with no need determination, duplicate services, and put patients at risk. LHRS chooses not to contract with an existing dialysis provider for dialysis care for its patients and chooses to use a transportation service that charges \$104 a treatment. Neither choice represents nor demonstrates a need for the services proposed by LHRS.

We strongly recommend that this petition be denied.

Respectfully,



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Exhibit A

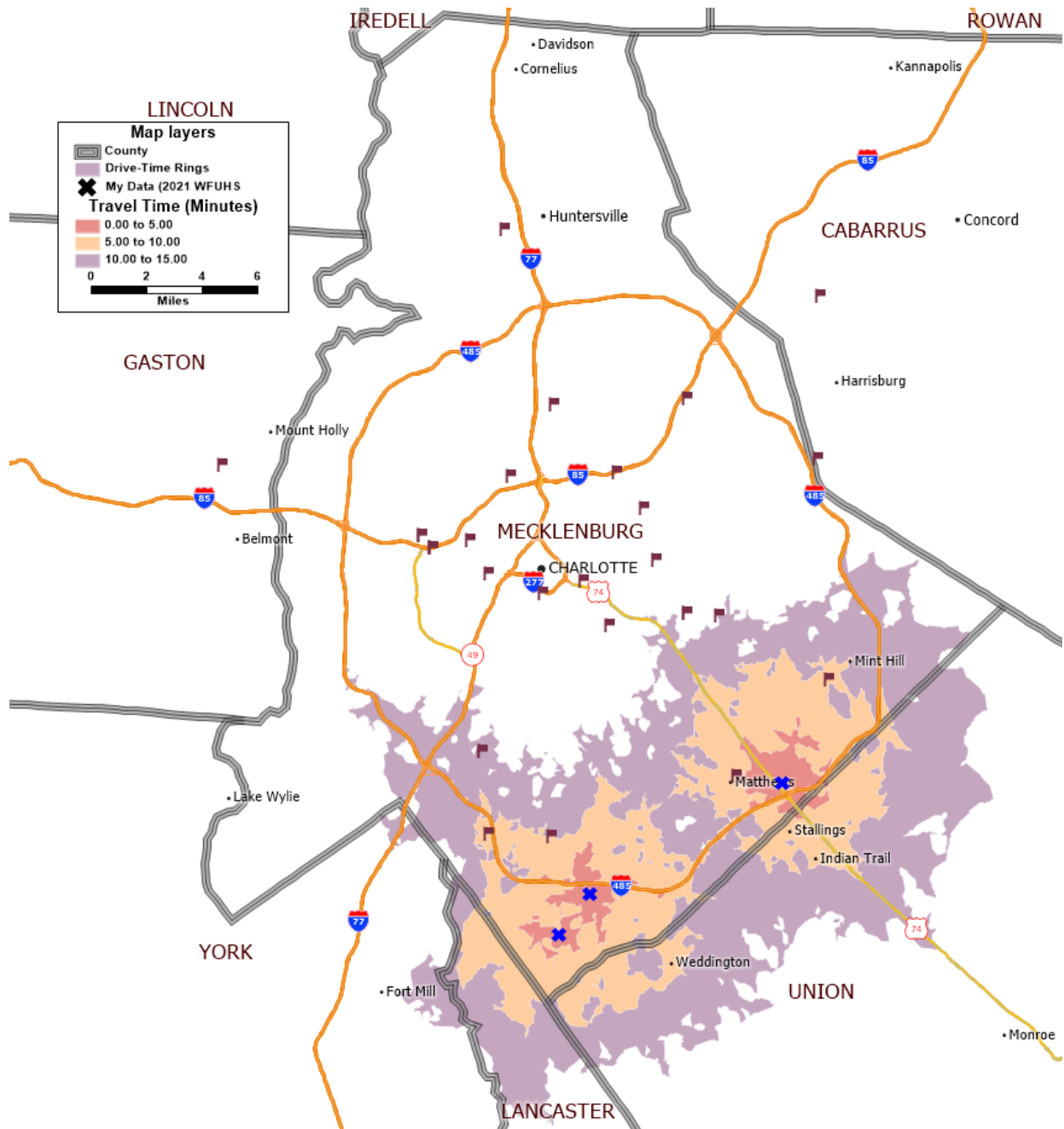


Exhibit B

The screenshot displays a Google Maps interface with a search bar at the top containing the starting point "2700 Royal Commons Ln, Matthews, NC" and the destination "Fresenius Kidney Care Matthews, 910 P...". Below the search bar, there are navigation icons for car, transit, walking, cycling, and flying. A sidebar on the left shows the search results and route options. The main map area shows a satellite view of the area with a blue route line connecting the start and end points. The route options are as follows:

Route Description	Time	Distance
via Matthews-Mint Hill Rd Fastest route now due to traffic conditions	6 min	2.0 miles
via Matthews Township Pkwy	8 min	2.4 miles
via Matthews-Mint Hill Rd and E Charles St	8 min	2.5 miles