

Comments on Competing Application for Six SNF Dialysis Stations in Mecklenburg County

October 31, 2023

Competitive Comments on Mecklenburg County SNF Dialysis Stations Applications

submitted by

AHSNF, Inc. and The Charlotte-Mecklenburg Hospital Authority (CMHA)

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), AHSNF, Inc. and The Charlotte-Mecklenburg Hospital Authority (CMHA)¹ hereby submit the following comments related to the application filed by Liberty Commons Nursing and Rehabilitation Center of Matthews, LLC; Liberty Healthcare Properties of Matthews, LLC; and LRS NC, LLC (collectively referred to herein as "Liberty") to develop a six-station incenter dialysis facility at Royal Park Rehabilitation and Health Center, a licensed nursing facility in Mecklenburg County, in response to an adjusted need determination in the 2023 State Medical Facilities Plan (2023 SMFP). AHSNF, Inc. and CMHA's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards." ² See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's ease in reviewing these comments, AHSNF, Inc. and CMHA have organized their discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity relative to each issue as they relate to Liberty's application, Project ID # F-12430-23. AHSNF, Inc. and CMHA's comments include general comments regarding the review, as well as issue-specific comments on the Liberty application and a comparative analysis related to its application to develop Atrium Health Dialysis Huntersville Oaks, a six station in-center dialysis facility at Atrium Health Huntersville Oaks, a licensed nursing facility in Mecklenburg County, Project ID # 12424-23.

As detailed above, given the number of proposed in-center dialysis stations, both applications cannot be approved as proposed. The comments below include substantial issues that AHSNF, Inc. and CMHA believe render Liberty's application non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if the Liberty application was conforming, the application filed by AHSNF, Inc. and CMHA is comparatively superior to the application filed by Liberty and represents the most effective alternative for expanding access to in-center dialysis services located in a skilled nursing facility (SNF) in Mecklenburg County.

AHSNF, Inc. and CMHA are providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the application filed on September 15, 2023 by AHSNF, Inc. and CMHA (Project ID # F-12424-23).

Advocate Aurora Health, Inc. ("AAH") and Atrium Health, Inc. ("Atrium Health") formed Advocate Health, Inc. ("Advocate Health"), a nonprofit corporation, to manage and oversee AAH, Atrium Health, and their respective subsidiaries and affiliates. As part of Atrium Health, The Charlotte-Mecklenburg Hospital Authority and Wake Forest University Baptist Medical Center are now part of the Advocate Health enterprise and are managed and overseen by Advocate Health.

GENERAL COMMENTS

In response to a petition, the State Health Coordinating Council (SHCC) approved an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP). This adjusted need is for six outpatient dialysis stations located at a nursing facility in Mecklenburg County. While the adjusted need determination was in response to a 2022 Summer Petition filed by Liberty Healthcare & Rehabilitation Services as outlined below, the filing of a petition does not equate to the most effective proposal, nor does it imply that the proposal will be conforming to all Certificate of Need (CON) statutory review criteria and regulation. Furthermore, even if Liberty's application were found conforming to all CON statutory review criteria and regulations as discussed below, AHSNF, Inc. and CMHA demonstrate a significantly greater need for the dialysis stations than Liberty. The following sections outline general comments related to the applications for the dialysis stations.

The adjusted need determination described above was made by the State Health Coordinating Council (SHCC) in response to a 2022 Summer Petition by Liberty Healthcare & Rehabilitation Services for "a nursing home dialysis pilot demonstration project of six outpatient dialysis stations in Mecklenburg County in the 2023 State Medical Facilities Plan." Upon review of its petition, the Agency asserted its support of the "standard methodologies for ESRD facilities" and as such did not recommend a pilot demonstration project; however, it *did* recommend "approving a county need determination for six outpatient dialysis stations at a nursing home facility in Mecklenburg County," paired with a number of conditions outlined both in its response to Liberty's petition and in the *2023 SMFP*.

Notably, the Agency asserted in its recommendation to the SHCC that "any person may submit a CON application for this need determination." In fact, there is precedent for the petitioner of an adjusted need determination *not* being awarded the CON corresponding with that need. In Summer 2022, Rex Hospital, Inc. (UNC Rex) submitted a petition for an adjusted need determination for six-hospital designated operating rooms (ORs) in Wake County; while the Agency denied UNC Rex's requested adjusted need determination, it responded in kind by adding a need determination for two ORs, instead. UNC Rex's eventual CON application for that need determination, Project ID # J-12260-22, was denied, with the CON ultimately being rewarded to WakeMed (Project ID # J-12291-22).

[&]quot;Petition for Adjusted Facility Need Determination for Nursing Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 State Medical Facilities Plan," pp. 1-2, accessed at https://info.ncdhhs.gov/DHSR/mfp/pets/2022/summer/A09-LibertyDialysisSummerPetition.pdf.

[&]quot;Acute Care Services Committee Agency Report: Adjusted Need Petition for an End-Stage Renal Disease Facility at a Skilled Nursing Facility as a Pilot Demonstration Project in the 2023 State Medical Facilities Plan," p. 3, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2022/acsc/19_Liberty_AgencyReport_Final.pdf. Please also see 2023 SMFP, p. 135, for the conditions for the adjusted need determination.

⁵ "Acute Care Services Committee Agency Report," p. 3.

[&]quot;Petition for an Adjusted Need Determination for Six Hospital-Designated Operating Rooms in Wake County," accessed at https://info.ncdhhs.gov/DHSR/mfp/pets/2021/August11/A06-UNCREXORPetition.pdf.

[&]quot;Acute Care Committee Agency Report: Adjusted Need Petition for the Wake Operating Room Service Area in the 2022 State Medical Facilities Plan," p. 4, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2021/acsc/10 WakeUNCRexORsAgencyReport.pdf.

See "Required State Agency Findings" for 2022 Wake County Acute Care Bed and OR Review, p. 221, accessed

In short, the approval of a summer petition towards a need determination does not mandate that the petitioner also be awarded the corresponding CON for that determination. An applicant must still demonstrate conformity to all applicable review criteria, as well as establish itself as the most effective alternative to meet the determined need.

Relevant to its present application, in Summer 2023 Liberty filed 24 separate petitions, across 24 separate counties, for 369 outpatient dialysis stations to be located in a nursing home facility in the 2024 SMFP. This is an inordinately high number of summer petitions; in contrast, in Summer 2022, there were 19 petitions total, by all petitioners. 10

Liberty's significant number of petitions – which reach across numerous counties with varying healthcare needs – indicates it is pursuing a "one-size fits all" approach to the provision of dialysis services, which cannot be undertaken for such a medically taxing procedure, and in particular for a patient base that deserves the utmost in high-quality care due to the multiple comorbidities that dialysis patients often must endure – a reality cited not only in AHSNF, Inc. and CMHA's application, ¹¹ but in Liberty's application, as well. ¹²

The Agency agreed with the possibility of such a broad swath of care being unviable and ultimately diluting the quality of care across the state. In its Agency Report in response to Liberty's 24 petitions, the Agency stated that "Liberty does not explicate why the targeted counties have special characteristics that merit a different approach to assessing their need as compared to any other county in the State." The Agency also noted that the need for further dialysis services many of the counties for which Liberty submitted petitions is insufficient; for example, eight of the counties for which Liberty submitted adjusted need determinations (Alamance, Columbus, Halifax, Lee, Orange, Person, Rowan, and Watauga) have "3 or fewer dialysis patients residing at Liberty nursing facilities;" additionally, the Agency stated that "Liberty does not have facilities" in "Chatham, Durham, and Robeson counties." Not only do Liberty's petitions indicate a potential unnecessary duplication of services for multiple counties, but they also disregard cost effectiveness and the viability of establishing in-center dialysis services, given Liberty's relative inexperience in many of the counties for which it petitioned.

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https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/jan/findings/2022%20Wake%20Acute%20Care%20Bed%20and%20OR%20Review%20Findings.pdf.

These petitions can be viewed in detail on the DHSR's log of meetings for 2023, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2023/committeemeet.html#acsc. The counties for which Liberty petitioned for an adjusted need determination were Bertie, Brunswick, Buncombe, Chatham, Columbus, Cumberland, Davie, Durham, Forsyth, Franklin, Halifax, Johnston, Lee, Mecklenburg, Moore, New Hanover, Orange, Person, Robeson, Rowan, Sampson, Wake, and Watauga counties.

See "Summer 2022 Petitions and Comments," via DHSR, accessed at https://info.ncdhhs.gov/DHSR/mfp/pets/2022petitions.html.

¹¹ Project ID # F-12424-23 pp. 37-39.

Project ID # F-12430-23, pp. 30-32, which sites Diabetes, High Blood Pressure, and Hypertension as contributing factors to end-stage renal disease (ESRD).

[&]quot;Acute Care Services Committee Agency Report: Adjusted Need Petition for an End-Stage Renal Disease Facility at a Skilled Nursing Facility in Multiple Counties in the 2024 State Medical Facilities Plan," p. 3, accessed at https://info.ncdhhs.gov/dhsr/mfp/pdf/2023/acsc/14 A07-30 Liberty ESRD agencyreport final.pdf.

¹⁴ Ibid.

Put briefly, Liberty's commitment to serve the patients of Mecklenburg County is suspect. The sheer volume of dialysis services it purports to establish across the state is overly broad and aggressive, given that it currently provides no dialysis services anywhere, in Mecklenburg County or otherwise. In contrast – and as stated in their application – AHSNF, Inc. and CMHA currently provide dialysis services across 20 owned or affiliated end-stage renal disease (ESRD) facilities and also provide outpatient and inpatient dialysis services at multiple CMHA hospital campuses in Mecklenburg County. CMHA is one of the most established providers of care in Mecklenburg County, operating four acute care facilities and a wide swath of healthcare services in that county. Its depth of experience, and historical record of care for Mecklenburg County patients, establishes it as the ideal candidate to establish the unique services of SNF-based outpatient dialysis care in Mecklenburg County specifically.

Further, as also discussed throughout the application, AHSNF, Inc. and CMHA have a significant need to provide in-center dialysis care to its patients – a need that outweighs that of Liberty. CMHA currently treats a high volume of skilled nursing patients at Atrium Health Huntersville Oaks and Atrium Health Sardis Oaks, two SNFs located in Mecklenburg County which currently house numerous dialysis patients. These patients must coordinate transport to an off-site ESRD facility, which, given the condition of many dialysis patients, is a taxing process. AHSNF, Inc. and CMHA's broad dialysis patient base would greatly benefit from in-center dialysis at one of CMHA's existing SNFs; these are patients that need dialysis care today and are already patients within the larger CMHA network of care. Additionally, CMHA provides dialysis services at its four acute care facilities in Mecklenburg County; however, many of these patients, in awaiting discharge to a SNF, are often unable to be discharged, due to their specific needs requiring complex and necessary coordinated care between an SNF and a dialysis facility. In short, these patients have a need for SNF-housed dialysis care; adding dialysis services at an existing CMHA SNF would allow these patients to be discharged more quickly and conveniently, increasing access and quality of care in an appropriate setting. Liberty's application outlines no such urgent need.

Given this, Liberty's application does not sufficiently demonstrate a suitable utilization to provide Mecklenburg County with its only SNF-based outpatient dialysis service. Further, Liberty's application is also non-conforming with numerous review criteria. In contrast, AHSNF, Inc. and CMHA's application for six outpatient dialysis stations in its own SNF sufficiently demonstrates utilization, while also being based on assumptions that are conservative and founded in reliable historical evidence. AHSNF, Inc. and CMHA's application, therefore, is the best alternative to meet the need in Mecklenburg County, and should be approved.

ISSUE-SPECIFIC COMMENTS

1. Liberty's Financials Contain Errors that Renders its Application Non-Conforming

There are numerous errors and inconsistencies in Liberty's presentation of financial information – specifically regarding its capital costs, start-up costs, initial operating costs, and projected operating costs – that call into question the validity of its financials and render its application non-conforming.

Capital Costs

In Form F.1a Capital Costs, Liberty notes that its Construction/Renovation Contract(s) cost will be \$267,200, shown below.

		Column B	Column C	Column D	Column E
	Form F.1a Capital Cost	Applicant 1 Liberty Commons Nursing and Rehabilitation Center of Matthews, LLC	Applicant 2 Liberty Healthcare Properties of Matthews, LLC	Applicant 3 LRS NC, LLC	Total (Sum of Columns B-D)
1	Building Purchase Price		M. 1314 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		\$0
2	Purchase Price of Land				\$0
3	Closing Costs				\$0
4	Site Preparation				\$0
5	Construction/Renovation Contract(s)			\$267,200	\$267,200
6	Landscaping				\$0
7	Architect / Engineering Fees			\$32,000	\$32,000
8	Medical Equipment			\$302,640	\$302,640
9	Non Medical Equipment			\$15,000	\$15,000
10	Furniture			\$28,000	\$28,000
11	Consultant Fees (specify)			\$5,000	\$5,000
12	Financing Costs				\$0
13	Interest during Construction	E PLICALIST CO			\$0
14	Other (Contingency)			\$72,972	\$72,972
15	Total Capital Cost	\$0	\$0	\$722,812	\$722,812

^{*} This should match the name provided in Section A, Question 1.

Source: Project ID # 12430-23, p. 103 of electronic copy.

Liberty notes in its assumptions, included below its capital costs, that this totals \$167/square foot "for a 1,600 square foot renovation. This is consistent with a similar SNF Dialysis Den quote received from a SC General Contractor." ¹⁵

In reality, given the construction of walls, installation of a toilet, provision of water, and other amentities, this is a very low cost per square foot estimate for the renovations and relocation of services that Liberty purports as the scope of its proposed project — especially given that the renovations are being made in the greater Charlotte area, a high cost of living locale. Today's typical square foot renovation cost for medical space in the Charlotte area is between \$500 and \$1,000,

Project ID # 12430-24, p. 103 of electronic copy.

A study by *Doxo*, as cited by *The Charlotte-Observer*, noted that household expenses in Charlotte for 2023 "are 7% higher than the national average of \$2,046, and 14.5% higher than the state average of \$1,913." See https://www.charlotteobserver.com/news/state/north-carolina/article275924396.html, as well as <a href="https://www.doxo.com/doxoinsights/household-bills/North-Carolina/Mecklenburg/Charlotte/?utm_source=Iterable&utm_medium=email&utm_campaign=campaign_Follow-up:-Explorer-launch-FINAL&campaign_code=email.

based on CMHA's own experience with such projects. Given that market conditions can vary widely within the state and from state to state, and given that Liberty relies on an estimate from an architect whose offices are located in Wilmington, NC and justifies the costs by comparing them with those in South Carolina, the renovation costs to be incurred brings in to question the reliability of those costs. Therefore, Liberty fails to demonstrate whether or not adequate capital costs have been accounted for and it is therefore impossible to determine from the application as submitted whether sufficient funds are available to fund the capital costs of the project. CMHA, meanwhile, has significant experience developing projects involving both construction and renovation in the greater Charlotte area, adding a level of expertise to its estimated construction costs.

Given Liberty's outlying capital costs, its conformity with Criterion 5 should be examined.

Start-Up Costs

In Section F.3.e, Liberty provides a detailed list of its start-up costs, tabulating them to be \$73,314, as shown in the table below.

Start-Up Costs Calculation

Start-up costs represent one month of the Year 1 costs for the expenses identified in the following table, excluding administrative salaries and clinical salaries, which represent two months, and rent and utilities, which represent four months.

Туре	Costs	Months
Salaries	\$24,281	1
Taxes & Benefits	\$6,313	1
Medical Supplies	\$11,321	1
Promotions	\$5,000	1
Rent	\$16,000	8
Utilities	\$10,400	8
Total	\$73,314	

Source: Project ID # 12430-23, p. 53

Liberty notes its start-up costs account for "one month of Year 1 costs for the expenses identified...excluding administrative salaries and clinical salaries, which represent **two months**, and rent and utilities, which represent **four months**." ¹⁷ The table above, however, details salaries based on **one month** of costs. Meanwhile, taxes and benefits are less than **two months** of cost, thereby understating the value of both of these start-up expense line items.

Even if one assumes that \$16,000 in rent and \$10,400 in utilities as noted in Section F.3.e denote "four" months of these costs, there is inconsistency between this calculation and the data detailed in Form F.4 Operating Costs in Section Q. In Form F.4 Operating Costs, the cost of "Building Rent/Mortgage" is listed as \$8,000 *annually*, while the cost of "Utilities (power, water, phone, etc.)" is listed as \$4,400 for the first full fiscal year of the project and \$4,532 for the second full fiscal year of the project; like rent, both are full year values.

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¹⁷ Project ID # 12430-24, p. 53.

	1st Full FY	2nd Full FY
Form F.4 Operating Costs	F: 07/01/2025	F: 07/01/2026
	T: 06/30/2026	T: 06/30/2027
Total # of Treatments (from Form C)	2,574	2,808
Salaries **	\$291,367	\$343,793
Taxes and Benefits	\$65,558	\$77,353
Medical Director (1)	\$25,000	\$25,000
Housekeeping (2)	\$18,000	\$18,540
Maintenance (2)	\$30,000	\$30,900
Supplies	\$122,265	\$137,381
Utilities (power, water, phone, etc.)	\$4,400	\$4,532
Building Rent / Mortgage	\$8,000	\$8,000
Depreciation	\$54,373	\$54,373
Management & Other Fees (3)	\$17,180	\$18,742
Central Office Overhead (3)	\$10,308	\$11,245
Total Operating Costs	\$646,449	\$729,859
Total Operating Cost / Treatment *	\$251.15	\$259.92

Source: Project ID # 12430-23, p. 108 of electronic copy.

Beyond creating inconsistency in its financials, Liberty has understated its rent and utility costs in its calculation of net revenues. This understatement is significant: if Liberty's rent cost is in fact \$24,000 annually (\$16,000 across 8 months = \$24,000 across 12 months), and its utilities cost in in fact \$15,600 annually (\$10,400 across 8 months = \$15,600 across 12 months), this will add \$27,068 in annual expenses to its income statement (\$24,000 - \$8,000 = \$16,000; \$15,600 - \$4,532 = \$11,068; \$16,000 + \$11,068 = \$27,068). With Liberty's net income being only \$19,820 in the second full fiscal year, the additional \$27,068 in annual expenses will result in a financial loss.

According to 2023 market research, as shown below, the average cost of leasing medical office space in 2023 in the Matthews area is between \$21 and \$34 per square foot. Even the low-end of this average is greater than Liberty's rental estimates per square foot.

Summary of Medical Office Space - Matthews/CrownPoint Submarket

	Class A	Class B	Class C
Lease Rate Range / PSF	\$25.00 - \$34.00	\$21.00 - \$28.00	N/A

Source: FLI Market Research (2023).

Given that the total square footage of Liberty's proposed dialysis facility is 1,600 square feet, as noted in Section K.2, 18 the low-end of these estimates per square foot leasing costs in the Matthews area would result in a total rent cost of \$33,600 annually. This is a **\$25,600** increase in the rent stated in Form F.4 of Liberty's application (\$33,600 - \$8,000 = **\$25,600**). Again, with Liberty's net income being only \$19,820 in the second full fiscal year, the additional \$25,600 in annual expenses will result in a financial loss.

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¹⁸ Ibid, p. 70.

No matter the assumption used in the correction of rental expense, \$8,000 is remarkably low for the rental cost of medical space. Put another way, at an annual rent of \$8,000, Liberty's rent per square foot would only be only \$5 per square foot.

For its second full fiscal year, Liberty noted its net income as \$19,820, as shown in its Form F.2 income statement, below.

	1st Full FY	2nd Full FY
Form F.2 Income Statement	F: 07/01/2025	F: 07/01/2026
	T: 06/30/2026	T: 06/30/2027
Gross Revenue		
Total # of Treatments (from Form C) *	2,574	2,808
Total Patient Services Gross Revenue (from Form F.3)	\$2,061,774	\$2,316,684
Other Revenue (1)		
Total Gross Revenue (2)	\$2,061,774	\$2,316,684
Total Gross Revenue / Treatment *	\$801.00	\$825.03
Adjustments to Revenue		
Charity Care		
Bad Debt		
Contractual Adjustments	\$1,374,585	\$1,567,005
Total Adjustments to Revenue	\$1,374,585	\$1,567,005
Total Net Revenue (3)	\$687,189	\$749,679
Total Net Revenue / Treatment *	\$266.97	\$266.98
Total Operating Costs (from Form F.4)	\$646,449	\$729,859
Net Income (4)	\$40,740	\$19,820

Source: Project ID # 12430-23, p. 105 of electronic copy.

These additional operating costs, given the net income above, would result in a *negative* net income for Liberty's facility for its second full fiscal year (\$19,820 – (\$27,068 + \$25,600) = \$19,820 - \$52,668 = -\$32,848), thereby indicating that Liberty's proposed project is not financially feasible. This, therefore, renders Liberty's application non-conforming with Criterion 5.

Initial Operating Costs

In Section F.3.e, Liberty notes that its "initial operating period is 12 months and is assumed to require \$350,000 to cover the initial delay in dialysis treatment reimbursement and net income shortfall" (emphasis added).¹⁹

The CON application defines "initial operating costs" as follows:

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^{.9} Ibid, p. 53.

Initial operating costs: For the purpose of completing this application form, the term "initial operating costs" means the difference between:

- 1. total cash outflow (operating costs) during the initial operating period for the entire facility; and
- total cash inflow (revenues) during the initial operating period for the entire facility.

Initial operating period: For the purpose of completing this application form, the term "initial operating period" means the number of months, if any, during which cash outflow (operating costs) for the entire facility exceeds cash inflow (revenues) for the entire facility.

Source: Dialysis or End Stage Renal Disease Services Application, p. 9.

As shown above, Liberty states that its initial operating period for the proposed facility is 12 months, and states that it will incur a "net income shortfall" in that time period. However, Liberty's Form F.2 income statement, shown above, notes a *positive* net income within the first 12 months. In short, Liberty's initial operating period assumptions and noted net income are inconsistent, thereby understating net income and potentially financial infeasibility, which renders its application nonconforming with Criterion 5.

Projected Operating Costs

In Form F.4 Operating Costs, Liberty states that its "Supplies" cost is \$122,265 for its first full fiscal year, and \$137,381 for its second full fiscal year. ²⁰ In its Form F.4 Operating Costs Assumptions, it notes that its cost of supplies per treatment is \$47.50 for its first full fiscal year, and \$48.93 for its second full fiscal year; it offers no further explanation as to what these costs include. ²¹

Liberty's cost per treatment for supplies is very low relative to other ESRD applications. For contrast, AHSNF, Inc. and CMHA's supply cost per treatment is \$83.00. This is in-line with numerous other applications for dialysis services, as noted in the table below.

Year of Quoted Expense	2024 PY1	2026 PY1	2025 PY1	2026 PY1	2026 PY1
Application	Wake Forest University	Atrium Health Dialysis	BMA West Charlotte	Liberty	Liberty (Revised)
Application	Health Sciences ESRD	Huntersville Oaks	ESRD	Liberty	Liberty (nevised)
Application #	G-12206-22		F-12408-23		
Treatments	21,895	3,588	13,360	2,574	2,574
Pharmacy/All Supplies	\$2,085,156	\$297,843	\$972,165	\$122,265	\$187,302
Cost Per Treatment	\$95.2	\$83.0	\$72.8	\$47.5	\$72.8

Source: Project ID # G-12206-22, Project ID # F-12424-23, Project ID # F-12408-23, Project ID # 12430-23.

As shown above, Liberty's supply costs are an outlier. If these costs for Liberty equaled the next lowest total – BMA West Charlotte's supply cost per treatment of \$72.80 – Liberty would incur total supply costs of \$187,302 in project year 1 and \$204,329 in project year 2^{22} equating to a \$65,037 net increase in total operating costs in project year 1 (\$187,302 - \$122,265 = \$65,037), and a \$66,948 net increase in total operating costs in project year 2 (\$187,302 - \$137,381 = \$66,948) in project year two. Given that Liberty's net income for its second full fiscal year is \$19,820 – as shown in its Form F.2 – this new, more reasonable supply cost would result in a negative net income, thereby showing a lack of facility financial feasibility for the proposed dialysis facility (\$19,820 - \$66,948 = -\$47,128). This lack of financial feasibility renders Liberty's application non-conforming with Criterion 5.

lbid, p. 109 of electronic copy.

Revised project year 2 expenses = 2,808 total number of treatments x \$72.80. See Project ID # 12430-23, p. 105 of electronic copy.

lbid, p. 108 of electronic copy.

Finally, Liberty includes no operating costs towards Medical Records management or Pharmacy/Medications – both of which *are* included as operating costs in AHSNF, Inc. and CMHA's application.²³

Overall Financial Feasibility

The combination of Liberty's errors in its detailed financials – its start-up costs, its initial operating costs, and its projected operating costs – ultimately demonstrates a lack of financial feasibility. The table below details Liberty's financial feasibility in its second full project year as presented alongside its "revised" financial feasibility in its second full project year, given the discrepancies that have been highlighted above.

Liberty Proposed Project Financial Feasibility – Project Year 2

	,	
	2027 2nd Full FY As Submitted	2027 2nd Full FY Revised
Total Treatments	2,808	2,808
Total Gross Revenues (Charges)	\$2,316,684	\$2,316,684
Total Net Revenue	\$749,679	\$749,679
Average Net Revenue Per Treatment	\$267	\$267
Total Operating Expenses (Costs)	\$729,859	\$822,500
Average Operating Expense Per Treatment	\$260	\$293
Net Income	\$19,820	-\$72,821

Source: Project ID # 12430-23, pp. 105, 106, and 108.

Given the overall errors present in its application as well as the financial loss shown above, the Liberty application is non-conforming with Criterion 5 and should not be approved.

2. <u>Liberty does not provide sufficient detail with regards to the proposed construction and renovation</u> for its proposed services.

In Section C.1, Liberty includes two floor plan "options" for developing its proposed dialysis facility. It explains that "the nursing home areas to be renovated for the dialysis facility are currently used as storage, an office, speech therapy room, and physical therapy space."²⁴

While Liberty states that "[t]here is no capital cost associated with relocating the functions of these rooms to other areas of the nursing home," Liberty does not explain to where, and how, these vital patient resources will be located; nowhere on either of its two "options" of floor plans are the relocated areas for these services detailed – in Section C.1, in Section K, or in Exhibit C.1. As such, Liberty has not demonstrated that the proposed renovation for Liberty's proposed dialysis facility is the most reasonable alternative, nor asserted that associating no capital costs with its proposed renovations is reasonable.

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See Project ID # 12424-23, p. 118 of electronic copy.

²⁴ Project ID # 12430-23, p. 23.

lbid.

As such, the Liberty application is non-conforming with Criteria 4, 5, and 12 and should not be approved.

3. The methodology utilized by Liberty is based on unreasonable assumptions.

In its "Form C Utilization – Utilization Methodology and Assumptions," Liberty projects that it will serve 18 dialysis patients per month in fiscal year (FY) 2027, its proposed project year two. This projected total is grown from its "number of residents required to leave Royal Park [the existing nursing home facility] for dialysis treatments by month over the last two years." For FY 2023 – the most recent year of its historical totals – this total is 10 patients, averaged from a six-month period where the lowest number of dialysis patients seeking services in a month was eight, and the highest number was 12.

Utilization Methodlo	y and Ass	umption	ns																					
Step 1: Renal Dialysis Next, Renal D		ter calcu	alted th	e Compo	ounded "	6-Month	" Growth	Rate of		s require						ts using	the follo	wing calo	ulation:					
	compou	idea o ii	ionui c	IOWLII IA	ice.	10.570	- (10.00	1 1.331	(1) 3)	1														
	Compou	20:		TOWLITT	T.	10.570	- (10.00	1 1.551	(173)		022									20	023			
	S			D	J.	F	M	Α	M)22 J	A	S	0	N	D	J	F	М	20 A	023 M	J		
Residents	S 6				J 7	F 7		A 8			022 J	A 8	S 8	0	N 7	D 9	J 8	F 9	M 10	20 A 8	T	J 9	J 11	
Residents 6-Month Average Residents	S		21 N 8		J 7	F 7		A 8	M 7	20 J) J 6	A 8	S 8	0 10	7	_	J 8	F 9		20 A 8	M 12	9	J 11	1

Source: Project ID # 12430-23, p. 102 of electronic copy.

Instead of using an annual growth rate to project dialysis patients served by project year two – a more conventional method of projections – Liberty instead uses a "Compound '6-month' Growth Rate," which, for the two-year period of September 2021 through August 2023, is 10.9 percent. Utilizing this growth rate, Liberty grows its 10 dialysis patients in August 2023 to 14.64 dialysis patients in 2025, a total that it rounds up to 15 patients, accounting for the three remaining months in FY 2025. Finally, for each of the three, three-month periods remaining in FY 2026, Liberty adds one potential dialysis patient, thereby bringing its total dialysis patients at the conclusion of its FY 2026 to 18.

	2023 2024								2025															
	S	0	N	D	J	F	M	A	M	J	J	A	S	0	N	D	J	F	M	A	M	J		
Projected 6-Month Average Residents	10.73				11.90							13.20							14.64					
Calculation	= {10.0) x (1 + (10.9% x	56.7%)})		= (10.73 x (1+10.9	%))			=	11.90 x	1+10.9	%))		= (13.20 x (1 + 10.9%))							

Royal Park and/or for exsiting nursing home residents desiring to transfer to Royal Park because of the new dailysis facility. Renal Dialysis Center projects no increase in dialysis patieting during year 2

		FY2026											FY2027											
	1	A	S	0	N	D	1	F	M	A	M	J	J	A	S	0	N	D	J	F	M	A	M	J
Projected Quarterly		15.00			16.00			17.00			18.00			18.00			10.00			12.00			19.00	
Average Residents		13.00			10.00			17.00			10.00			18.00			18.00			18.00			18.00	
Calculation	= 1	14.64 + 0.	36)		= 15.0 + 1	.0		16.0 + 1	.0		17.0 + 1	.0						= 18.0	0.0 + 0					

Source: Project ID # 12430-23, p. 102 of electronic copy

AHSNF, Inc. and CMHA believe this projected growth is overly aggressive and unsupported. Further, they believe that Liberty's utilized growth rate of 10.9 percent for September 2023 through June 2025 is not a reasonable growth rate for projecting potential dialysis patients. First, Liberty's growth rate

lbid, p. 102 of electronic copy.

of 10.9 percent is based on a period of growth of only one year, a relatively short time period for which to project growth into the future. Liberty does not detail why it chooses to only provide historical dialysis patient data from September 2021, rather than further into the past, for which it would assumedly have data and therefore be able to derive a growth rate supported by additional historical data.

Second, Liberty's projected utilization is overinflated, given the historical period from which it chooses to derive its growth rate. The growth rate of 10.9 percent is selectively based on a two year – 24-month – historical period, which is then utilized to create projections for a period of two years, or 24 months. It is inconclusive that Liberty's dialysis patient growth is consistent, given the short time period, which could potentially include outliers in its data. Without a broader growth period, consistent growth of Liberty's dialysis patients is not adequately supported.

Third, Liberty does not discuss its projections of long-term stay patients versus short-term stay patients, who – as outlined in AHSNF, Inc. and CMHA's application – have very different needs in terms of dialysis services, and have very different lengths of stay that can, in theory and in practice, affect the number of dialysis patients that an SNF is able to treat.²⁷ Without this recognition and discussion of long-stay and short-stay (typically short-term rehabilitation patients) and dissemination of patients by treatment type, Liberty's projections cannot be adequately supported.

Finally, there are numerous calculations that factor into Liberty's methodology that are not adequately justified in Liberty's assumptions. Liberty's explanation of increasing its projections by one dialysis patient per year is not sufficiently supported; Liberty simply states that the dialysis facility "will increase by one patient during each of the next three quarters...due to the number of dialysis patients waiting for available space at Royal Park and/or for existing nursing home residents desiring to transfer to Royal Park because of the new dialysis facility." ²⁸ In reality, the two-year historical period of utilization shows that Liberty only treated 10 or more dialysis patients 20 percent of the time. In other words, during 80 percent of this two-year historical period, fewer than 10 patients at Liberty's facility were receiving dialysis care – thereby creating doubt as to the validity of Liberty's 18 dialysis patients at the conclusion of FY 2026. Additionally, the historical average of dialysis patients receiving care at Liberty shows that there was only an average of eight dialysis patients in the fourth quarter of FY 2021; an average of 7.5 patients in FY 2022; and an average of 9.6 patients in FY 2023. The possibility of Liberty somehow treating 15 dialysis patients at the beginning of project year one in 2025, and 18 dialysis patients at the beginning of project year two would require unprecedented growth – nearly 25 percent year over year annual growth, in fact, which Liberty has not historically experienced.

While there may indeed be patients awaiting treatment at dialysis facilities in Mecklenburg County – including Liberty's proposed facility – this assumption does not account for patient turnover: specifically, it does not account for patients who, for reasons such as overall medical improvement that no longer necessitates rehabilitation in a SNF setting, are ending dialysis treatment at Liberty's facility. Of course, without projections of long-term stay and short-term stay patients, it is impossible to discern how many patients will stop or start dialysis care at Liberty's proposed dialysis facility. By failing to provide historical data on length of stay for its SNF dialysis patients, Liberty in turn does not

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See Project ID # 12424-23, p. 39 and p. 4 of Form C Utilization – Methodology and Assumptions.

Project ID # 12430-23, p. 102 of electronic copy.

provide sufficient data to support its assumptions, thereby rendering its projections unreliable and unreasonable.

It is worth contrasting Liberty's projections with those of AHSNF, Inc. and CMHA; in particular, it is worth contrasting each set of projections with regards to the most need that can be served by each applicant. AHSNF, Inc. and CMHA utilize a compound annual growth rate (CAGR) of 1.9 percent in order to project dialysis patients through to calendar year (CY) 2027, the second year of its proposed project; on contrast, Liberty's CAGR from 2022 through 2026 – the first year of its proposed project, and the stopping point of Liberty utilizing its "Compound 6-month growth rate" to grow its proposed patient base, is 23.9 percent. This is significantly greater than AHSNF, Inc. and CMHA's CAGR, and is also a very high CAGR, which results in a virtual doubling of patient volume without sufficient explanation of how, and from where, this volume will originate.

Most significantly, AHSNF, Inc. and CMHA ultimately project its proposed outpatient hemodialysis center – Atrium Health Dialysis Huntersville Oaks – will treat 23 dialysis patients per week by its second proposed project year. In other words, <u>Atrium Health Dialysis Huntersville Oaks projects a greater patient need, despite utilizing a more conservative projection methodology.</u> Given this, an analysis of both applications' methodologies demonstrates that AHSNF, Inc. and CMHA's proposed dialysis facility will better serve the patients of Mecklenburg County.

Based on these issues, Liberty's application is non-conforming with Criteria 3, 4, 5, 6, and the performance standards for dialysis stations, and should not be approved.

4. <u>Liberty's projected payor mix is not reasonable, based on expectations regarding ESRD Medicare patients.</u>

In Section L.3.b, Liberty states that its projected payor sources for its proposed dialysis facility during the second full fiscal year of operation will be 100 percent Medicare patients – in other words, all 18 of its projected patients in FY 2026 will utilize Medicare as their payor source. In describing the assumptions to make this projection, Liberty states that "[a]II current residents living at Royal Park and receiving outpatient dialysis are Medicare recipients." ³¹

See Project ID # 12424-23, p. 3 of Form C Utilization – Methodology and Assumptions.

 $^{((16.5/8.7)^{(1/3)} - 1) = 23.9}$ percent. 16.5 is the average number of patients at the proposed facility during its first full fiscal year, noted in Form C Utilization, p. 101 of electronic copy. 8.7 is the average number of historical monthly dialysis patients at Liberty's facility from July 2022 through June 2023.

³¹ Project ID # 12430-23, p. 78.

Projected Payor Mix during the 2nd Full FY 07/01/2026 to 06/30/2027

Primary Payor	< Liberty Healthcare Management Renal Dialysis >											
Source at	In-center	Dialysis	Home Hem	odialysis **	Peritoneal Dialysis **							
Admission	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total						
Self-Pay												
Insurance *												
Medicare *	18	100.0%										
Medicaid *												
Other (describe)												
Total	18	100.0%										

Including any managed care plans.

Source: Project ID # 12430-23, p. 78.

While all current Liberty patients may in fact utilize Medicare as their payor source, Liberty's projections do not account for various contingencies in the provision of dialysis services to Medicare patients — in particular, the provision of dialysis services to *new* patients under the age of 65, for which there is a three-month waiting period. Liberty fails to consider a reasonable and adequately supported projected payor mix, given that it projects to add new patients. Given the addition of these new dialysis patients, there is potential for these patients to utilize payor sources *other than* Medicare, particularly those patients under the age of 65 who are new to dialysis and subject to a three-month waiting period for Medicare benefits.

As noted above and in Liberty's methodology, Liberty assumes that it will add dialysis patients to its existing nursing home facility. The provision of dialysis services, however, is complicated, and requires significant oversight. The initiation of hemodialysis requires (1) consultation with a nephrologist, and (2) the creation of a fistula for blood access in the arm.³² Currently, as stated in its application, Liberty cares for patients receiving dialysis services at off-site dialysis treatment centers where care is managed through oversight of the medical director of the in-center ESRD facility,³³ a position that is typically a nephrologist, unless the facility has a Centers for Medicare and Medicaid Services (CMS) waiver excusing it from this requirement, this waiver to "request another physician to serve as the medical director...must be reviewed and approved by CMS" and "[t]he facility request for waiver consideration, along with a brief resume of the alternate physician and an explanation as to why a physician who meets the requirements is not available should be submitted to the applicable SA."³⁴

Per CMS conditions of participation, the care of dialysis patients requires oversight by someone who has completed a board-approved training program in nephrology and has at least 12 months of

^{**} This is not the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

In its application, Liberty notes that "[p]roviding hemodialysis in a nursing home setting requires intricate coordination between nephrologists, dialysis professionals, nursing home staff, and potentially, family members," p. 20. It further states that "a vascular access point needs to be established [for hemodialysis procedures], often through the creation of an arteriovenous fistula (AVF), arteriovenous graft (AVG), or a central venous catheter (CVC)," p. 21.

As noted in its Form C Utilization and Methodology Assumptions, p. 102 of electronic copy.

CMS Manual System: Pub. 100-07 State Operations Provider Certification. Department of Health and Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), September 21, 2018, p. 33 of electronic copy. Accessed at https://www.cms.gov/regulations-and-guidance/transmittals/2018downloads/r181soma.pdf.

experience providing care to patients receiving dialysis, among other requirements.³⁵ Liberty's job description of its proposed facility's medical director, included in its Exhibit H.3, notes these requirements specifically as qualifications for that position.³⁶

As shown in Liberty's Exhibit I.2, the current medical director of Royal Park Rehabilitation & Health Center – the location of Liberty's proposed dialysis facility – is Thad A. Clements, MD.³⁷ There is no documentation of Dr. Clements meeting the CMS conditions as an appropriate ESRD facility medical director. If Dr. Clements does not currently have such qualifications, it will affect Liberty's ability to provide sufficient oversight for new patients receiving dialysis services at its proposed facility; in particular, it draws into question Liberty's ability to meet the conditions set forth by the SHCC to apply for Medicare certification within three years of receiving its CON.

While Liberty could receive a CMS waiver for its medical director to provide dialysis oversight, this waiver is conditional upon a "Candidate's previous experience in the care of dialysis patients." Believely has not provided evidence that it will seek, or is required to seek, this waiver, nor does it provide detailed evidence of Dr. Clements having any experience in the care of dialysis patients such that they would be successful in obtaining a waiver. The exclusion of documentation asserting the qualifications of its medical director also calls into question the existence of all necessary ancillary and support services; the replacement of this director could ultimately disrupt such vital support.

In short, these factors draw into question Liberty's ability to provide Medicare reimbursement for new patients in a timely manner. Specifically, it draws into question Liberty's projection of 100 percent Medicare patients by its second full fiscal year, given that its facility may not be able to be adequately reimbursed for Medicare, if in fact the proposed dialysis facility is not ensured of meeting all CMS certification requirements in FY 2026.

It is also unreasonable to assume that all patients at a hemodialysis center will utilize Medicare as their payor source. As noted in AHSNF, Inc. and CMHA's application, it is reasonable to expect 30 percent of commercially insured patients to transition to Medicare, based on approximately 70 percent of patients with commercial insurance maintaining existing coverage. This figure is drawn from the 2023 study "The Association of Dialysis Facility Payer Mix with Access to Kidney Transplantation," as published by the JAMA network, which further notes that this 70 percent of patients maintaining commercial insurance do so for the first 30 months through the coordination period. On the first 30 months through the coordination period.

Given this study and given that Liberty purports to add new patients to its dialysis facility, it is unreasonable to expect that *all* dialysis patients, in particular the relatively significant number of dialysis patients that Liberty will add from FY 2023 through FY 2026, will *all* utilize Medicare as their payor source. This in turn affects the financial feasibility of the proposed dialysis facility, which, if not

Project ID # 12430-23 Exhibits, p. 83 of electronic copy.

³⁵ Ibid.

³⁷ Ibid, p. 98 of electronic copy.

³⁸ *CMS Manual System: Pub. 100-07*, p. 33.

³⁹ Project ID # 12424-23, p. 88.

See Cron, David C.; Tsai, Thomas C.; and Patzer, Rachel E. "The Association of Dialysis Facility Payer Mix With Access to Kidney Transplantation." *JAMA Network Open*. 2023: 6(7). Accessed September 5, 2023, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2807134.

adequately supported by a valid payor mix, may result in inaccuracies in Liberty's financial projections detailed in Section Q.

Given this, the Liberty application is non-conforming with Criteria 5, 8, and 13 and should not be approved.

5. <u>Liberty's projections of its medically underserved population to be served is not described in suitable detail and assumes neglected access to those under age 65.</u>

In Section C.6.b, Liberty notes that 100 percent of its estimated total patients for the second full fiscal year of its proposed project will be persons 65 and older. While it does note that the proposed dialysis services will be provided "through the order of a nephrologist," and while it does state that it will "provide services to all persons...[and] all nursing home residents, including...the elderly," it does not explain the origin of its projection that all Liberty dialysis patients will be over the age of 65.

While dialysis is most commonly administered to those over the age of 65, it is not *exclusively* administered to this cohort. AHSNF, Inc. and CMHA cite an ESRD incidence rate of 118 cases per million for those between the age of 18 and 44, a statistic sourced from the United States Renal Data System's *2022 USRDS Annual Data Report*. ⁴² In other words, while ESRD incidence amongst those under the age of 65 is relatively uncommon, it is not nonexistent; Liberty's projections assume that its services will be delivered exclusively to this those over the age of 65.

While these assumptions are in part unfounded, they also reveal potential issues of access to Liberty's dialysis services. SNF services, like dialysis services, are not *exclusively* administered to those over the age of 65; this is affirmed by the CDC's memo on "Chronic Kidney Disease in the United States, 2023," included as a portion Liberty's Exhibit C.4, which notes that approximately 12 percent of people aged 45-64 have chronic kidney disease. If Liberty asserts that the *entirety* of its dialysis patients will be those over the age of 65, this in turn indicates that it will treat *no* patients under that age cohort, potentially revealing an exclusivity of services, and resulting in a non-positive impact upon access to the services provided in the service area.

Liberty's application is thereby non-conforming with Criteria 13 and 18a and should not be approved.

In summary, based on the issues detailed above, the Liberty application should be found non-conforming with the review criteria established under N.C. GEN. STAT. § 131E-183, specifically Criteria 3, 4, 5, 6, 8, 12, 13, 18a, and the performance standards for dialysis stations. The Liberty application should not be approved.

⁴¹ Project ID # 12430-23, p. 39.

Project ID # 12424-23, pp. 38-39; also see United States Renal Data System. 2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease. 2022. Accessed August 21, 2023, https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities.

Project ID # 12430-23 Exhibits, p. 51 of electronic copy.

COMPARATIVE ANALYSIS

The Liberty application (Project ID # F-12430-23) proposes to develop six outpatient dialysis stations located at a Mecklenburg County nursing home facility based on an adjusted need determination in the 2023 SMFP. Given that two applicants propose to meet the entirety of the need for the six outpatient dialysis stations in Mecklenburg County, both cannot be approved.

As stated above, both Liberty and AHSNF, Inc. and CMHA's proposed applications are in response to an adjusted need determination for six outpatient dialysis stations to be located at a nursing home facility, the first such need determination in the State of North Carolina. Given the uniqueness of this adjusted need determination and the medical frailty of the proposed patient population, AHSNF, Inc. and CMHA believe that continuity of care, ESRD facility experience, the qualifications of each application's proposed medical director, and the total need met should be considered when evaluating both applications. Additionally, the comparative factors must account for (1) the relatively low numbers of patients treated by the proposed project, and (2) the lack of SNF-provided dialysis services by either applicant, given that no such services are currently provided in North Carolina. As such, AHSNF, Inc. and CMHA considered the following comparative factors in their assessment of both applications:

- Conformity with Review Criteria
- Medical Director Qualifications
- Geographic Accessibility
- Access by Service Area Residents
- ESRD Facility Experience
- Meeting the Need
- Competition (Patient Access to a New Provider)
- Access by Underserved Groups
 - o Projected Medicare
 - Projected Medicaid
- Projected Average Net Revenue per Treatment
- Projected Average Operating Expense per Treatment
- Continuity of Care

AHNSF, Inc. and CMHA believe that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Review Criteria

As discussed in the application-specific comments above, the Liberty application is non-conforming with multiple statutory and regulatory review criteria. Specifically, the Liberty application is non-conforming with Criteria 3, 4, 5, 6, 8, 12, 13, 18a and the performance standards for dialysis stations. In contrast, the AHSNF, Inc. and CMHA application conforms with all applicable statutory and regulatory review criteria. Therefore, regarding conformity with statutory and regulatory review criteria, the AHSNF, Inc. and CMHA application is the most effective alternative.

Medical Director Qualifications

Both AHSNF, Inc. and CMHA and Liberty propose to develop a hemodialysis facility located within a SNF, as specified in the adjusted need determination in the 2023 SMFP. However, as noted above, and as shown in Liberty's Exhibit I.2, the current medical director of Royal Park Rehabilitation & Health Center — the location of Liberty's proposed dialysis facility — is Thad A. Clements, MD, a family medicine doctor with no documentation of experience treating dialysis patients. Without an experienced doctor trained in the treatment of dialysis patients, Liberty's scope of services in the offering of dialysis services is severely compromised. Additionally, without sufficient oversight of patients receiving dialysis services at its proposed facility, not only are current residents at risk, but the acceptance of new patients may not be viable. There is no documentation of Dr. Clements meeting the CMS conditions as an appropriate medical director for the in-center dialysis facility that Liberty is proposing. If Dr. Clements does not currently have sufficient qualifications for the medical oversight of dialysis patients, it will affect Liberty's ability to provide sufficient oversight for new patients receiving dialysis services. As such, regarding this comparative factor, AHSNF, Inc. and CMHA's application is more effective.

Geographic Accessibility

AHSNF, Inc. and CMHA's proposed dialysis facility – Atrium Health Dialysis Huntersville Oaks – will be located at Atrium Health Huntersville Oaks, a SNF. Atrium Health Huntersville Oaks is located in Huntersville, which is on the northern side of Mecklenburg County. In contrast, Liberty's proposed dialysis facility – Liberty Healthcare Management Renal Dialysis – will be located at Royal Park Rehabilitation and Health Center, an existing SNF that is located in Matthews, on the southeastern side of Mecklenburg County.

As noted above, both proposed projects represent the establishment of the first outpatient dialysis center located in a Mecklenburg County SNF. The two proposed facilities are a comparable, similar distance from the center point of the county. As such, the geographic accessibility comparative factor is inconclusive.

Access by Service Area Residents

As noted in Section C.3.b of both applications, AHSNF, Inc. and CMHA project that 71.9 percent of their patients in fiscal year two of their proposed project will originate from Mecklenburg County; Liberty projects that 100 percent of its patients in fiscal year two of its proposed project will originate from Mecklenburg County. While Liberty does project a greater percentage of patients to originate in-county, its projections are questionable. Liberty asserts that "[t]he projected patient origin is based on the current patient origin of the nursing home facility residents who receive outpatient dialysis treatments. All current dialysis patients at Royal Park are Mecklenburg County residents;"⁴⁴ however, this assumption — which it also uses for its 100 percent projection of patients over the age of 65 — is not properly supported. Liberty's projections do not account for various contingencies in the provision of dialysis services to *new* patients such as those being discharged from the hospital who may originate from a county other than Mecklenburg — a factor that is taken into consideration by the AHSNF, Inc. and CMHA application; given that Liberty projects its total dialysis patients to nearly *double* over a two-year period, its historical volumes cannot be relied upon for accurate patient origin projections. As such, the AHSNF, Inc. and CMHA application is more effective for this comparative factor.

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⁴⁴ Project ID # 12430-23, p. 28.

ESRD Facility Experience

Both AHSNF, Inc. and CMHA and Liberty propose to establish new outpatient hemodialysis centers. As detailed in its application, CMHA and related entities currently own or operate 20 ESRD facilities in the Triad of North Carolina. Additionally, CMHA currently provides outpatient and inpatient dialysis services at Carolinas Medical Center (CMC), as well as inpatient dialysis services at Atrium Health Mercy, Atrium Health Pineville, Atrium Health University City, and Atrium Health Carolinas Rehabilitation. All four of these facilities are located in Mecklenburg County. Finally, CMHA operates two SNFs in Mecklenburg County – Atrium Health Huntersville Oaks and Atrium Health Sardis Oaks – both of which frequently coordinate care for dialysis patients with outside ESRD facilities. Liberty, meanwhile, currently does not operate dialysis services in Mecklenburg County. Given the uniqueness of this adjusted need determination and the SHCC's concerns regarding provision and oversight of dialysis care at a SNF, AHSNF, Inc. and CMHA feel dialysis experience is a more appropriate and relevant comparative factor than historical utilization, which has been excluded from the comparative factors evaluated by AHSNF, Inc. and CMHA. Given that CMHA has experience providing complex dialysis services, AHSNF, Inc. and CMHA are therefore the more effective applicants for this comparative factor.

Meeting the Need

In the second full fiscal year of its proposed project, Liberty projects to treat 18 total dialysis patients. AHSNF, Inc. and CMHA, in the second full fiscal year of their proposed project, project to treat 23 total dialysis patients. This greater quantitative need (23 > 18) makes AHSNF, Inc. and CMHA a more effective applicant for this comparative factor; additionally, Liberty's projected volumes are not adequately supported through its methodology and assumptions. As stated previously, the two-year historical period of utilization shows that Liberty only treated 10 or more dialysis patients 20 percent of the time. In other words, during 80 percent of this two-year historical period, fewer than 10 patients at Liberty's facility were receiving dialysis care - thereby creating doubt as to the validity of Liberty's 18 dialysis patients at the conclusion of FY 2026. Additionally, the historical average of dialysis patients receiving care at Liberty shows that there was only an average of eight dialysis patients in the fourth quarter of FY 2021; an average of 7.5 patients in FY 2022; and an average of 9.6 patients in FY 2023. The possibility of Liberty somehow treating 15 dialysis patients at the beginning of project year one in 2025, and 18 dialysis patients at the beginning of project year two would require unprecedented growth - nearly 25 percent year over year annual growth, in fact, which Liberty has not historically experienced. With this in mind, Liberty's application is not approvable based on its determination of need, and AHSNF, Inc. and CMHA's application is the more effective applicant for this comparative factor.

Competition (Patient Access to a New Provider)

As stated above, both AHSNF, Inc. and CMHA and Liberty are applying for an adjusted need determination for six outpatient dialysis stations at a SNF. The provision of dialysis services in a SNF is a unique service and as noted in both applications, there are currently no outpatient dialysis services provided in North Carolina SNFs, making the eventual development of the proposed project the first of its kind in the state. As such, no competition currently exists for the proposed services and both providers would be new providers in the delivery of dialysis services in a SNF, thereby making the comparative factor of competition inconclusive.

Access by Underserved Groups

The following table shows the percentages of Medicare and Medicaid as gross revenue in the second year of operation based on the information provided in Section L.3.a of each application.

Medicare and Medicaid Percentage as Gross Revenue – Project Year 2

Applicant	Medicare % of Total	Medicaid % of Total
AHSNF, Inc. and CMHA	84.1%	8.9%
Liberty	100%	0%

Source: Section L.3.a of the respective applications.

As Liberty states that 100 percent of its 18 patients in project year two will be Medicare patients, 100 percent of its revenue, therefore, is derived from Medicare recipients. Conversely, AHSNF, Inc. and CMHA project that 8.9 percent of its gross revenue will be derived from Medicaid recipients, in contrast to no such revenue derived for the Liberty application.

However, Liberty's projections of the number of patients it will treat that are Medicare recipients is not reasonable, as stated in the issue-specific comments above. As such, Liberty's application is nonconforming with Criteria 5 and 13, rendering it unable to be approved.

Additionally, in their respective Sections L.4.b, AHSNF, Inc. and CMHA state that they will provide care to the medically indigent or low-income patients at a reduced cost; Liberty, however, states that it will not provide such care. 45 This thereby makes the AHSNF, Inc. and CMHA application more effective in the provision of charity care, thereby adding to its effectiveness in providing access to underserved groups.

Regardless, given that the Liberty application is non-conforming with Criteria 5 and 13, it is unable to be approved, while AHSNF, Inc. and CMHA's application is conforming to these criteria and thereby approvable.

Projected Average Net Revenue per Treatment

The following table shows the projected net revenue per patient treatment in the second year of operation for both applicants, based on the information provided in each applicant's pro forma financial statements (Form F.2).

Average Net Revenue per Treatment – Project Year 2

Applicant	Net Revenue	# of Treatments	Net Revenue per Treatment	# of Patients	Net Revenue per Patient
AHSNF, Inc. and CMHA	\$1,173,425	3,588	\$327	23	\$50,062
Liberty	\$749,679	2,808	\$267	18	\$41,649

Source: Forms C and F.2 of respective applications.

45 Project ID # 12424-23, p. 89; and Project ID # 12430-23, p. 78.

Although Liberty's proposed dialysis facility has a lower average net revenue per treatment than that of AHSNF, Inc. and CMHA, it is non-conforming with Criterion 5, as stated in the issue-specific comments. Given this, AHSNF, Inc. and CMHA's application is the only approvable application.

Projected Average Operating Expense per Treatment

The following table shows the projected average operating expense per patient treatment in the second year of operation for both applicants, based on the information provided in each applicant's pro forma financial statements (Form F.3).

Average Operating Expense per Treatment – Project Year 2

Applicant	Operating Expense	# of Treatments	Expense per Treatment	# of Patients	Expense per Patient
AHSNF, Inc. and CMHA	\$1,059,080	3,588	\$295	23	\$45,184
Liberty	\$729,859	2,808	\$260	18	\$40,548

Source: Forms C and F.3 of respective applications.

Although Liberty's proposed dialysis facility has a lower average operating expense per treatment than that of AHSNF, Inc. and CMHA, it is non-conforming with Criterion 5, as stated in the issue-specific comments; specifically, Liberty appears to have understated several expenses, including its proposed annual rent expenses, which are not in-line with leasing costs per square foot in the Matthews area. Given this, AHSNF, Inc. and CMHA's application is the more effective and only approvable application.

Continuity of Care

As detailed above, AHSNF, Inc. and CMHA operate a wide range of medical facilities, both outside of and within Mecklenburg County. Additionally – as further explained in their application – due to dialysis patients often having multiple comorbidities, SNFs must provide a robust and comprehensive plan of care for these patients that can frequently involve care at other medical facilities, including acute care facilities. Given CMHA's multiple in-system care options, a dialysis patient receiving care at Atrium Health Huntersville Oaks can receive any and all care required exclusively at Atrium Health facilities. This includes not only SNF care, but also emergency and acute hospital care necessitated by and related to their multiple comorbidities. Further, the management of patients' medical records and internal protocols can be far more easily coordinated between members of the larger CMHA team, leading to a higher quality of care than a patient might experience utilizing a non-Atrium Health facility. Given that Liberty is solely a provider of SNF services and does not operate a comprehensive network of medical facilities, AHSNF, Inc. and CMHA are the more effective option for this comparative factor.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the competing applications.

Comparative Factor	AHSNF, Inc. and CMHA	Liberty	
Conformity with Review Criteria	Yes	No	
Medical Director Qualifications	More Effective	Less Effective	
Geographic Accessibility	Inconclusive	Inconclusive	
Access by Service Area Residents	More Effective	Most Effective, But Not Approvable	
ESRD Facility Experience	More Effective	Less Effective	
Meeting the Need	More Effective	Less Effective	
Competition (Patient Access to a new provider)	Inconclusive	Inconclusive	
Access by Underserved Groups	More Effective	Most Effective, But Not Approvable	
Average Net Revenue per Treatment	More Effective	Most Effective, But Not Approvable	
Average Expense per Treatment	More Effective	Less Effective	
Continuity of Care	More Effective	Less Effective	

SUMMARY

In summary, AHSNF, Inc. and CMHA believe that their application represents the most effective alternative for the six outpatient dialysis stations to be located in a nursing home facility in Mecklenburg County. AHSNF, Inc. and CMHA are also fully conforming to all applicable statutory and regulatory review criteria and are comparatively superior on the relevant factors in this review. As such, the AHNSF, Inc. and CMHA application should be approved.

Please note that in no way do AHSNF, Inc. and CMHA intend for these comments to change or amend their application filed on September 15, 2023. If the Agency considers any of these comments to be amending the AHSNF, Inc. and CMHA application, those responses should not be considered.