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Re: Comments on Competing Application for a Certificate of Need for Vascular Access Operating Room HSA  
III: Project ID **F-12423-23**, Applicant, Vascular, PLLC, **Iredell County**

Dear Ms. Faenza:

On behalf of Iredell Health, thank you for the opportunity to comment on this CON application for a dedicated Vascular Access Operating Room located in a new ambulatory surgery center in Iredell County. We understand that your time is limited, so we have focused comments on issues important to Iredell Health.


This application makes two requests, first, a new ambulatory surgery center in Iredell County, and second, a dedicated vascular access operating room. We believe that the proposed new ambulatory surgery center is not needed and that the proposed operating room may intend to offer services beyond the scope of intent associated with the special need.

Because the State's Certificate of Need ("CON") award must be based upon the statutory review criteria in G.S. 131E-183, we organized our comments according to the criteria, and believe that the application is non-conforming to several. However, should you disagree with us and recommend approval, we ask that, at minimum, you condition the project to offering only vascular access procedures associated with ESRD patients.

This is an important issue for Iredell County and Iredell Memorial Hospital is an affected party because the project proposes to replace procedures done at IMH. Therefore, we ask that you conduct a public hearing as provided in GS 131I-185(a)2).

Thank you for the time and attention you and your staff give to reviewing these important and detailed documents. Please do not hesitate to contact me should you have any questions.

Sincerely,



Joshua Self  
Vice President

Attachment(s)

**ATTACHMENTS**

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- A. Competitive Review of F-12423-23, Vascular Access Operating Room HSA III.....A
- B. Travel time Huntersville to Mecklenburg Vascular Access Center ..... B

**COMMENTS RELATED TO STATUTORY REVIEW CRITERIA IN GS 131E-183: DEDICATED VASCULAR ACCESS OR AMBULATORY SURGICAL FACILITY HSA III/ PROJECT ID F-12423-23**

**SUMMARY**

This CON application requests a new ambulatory surgery center (“ASC”) with one vascular access operating room. The proposed facility would be located at 2603 Davie Avenue, Suite B in Statesville. Neither the applicant nor a related party owns or operates an Office Based Laboratory (“OBL”) in Statesville or elsewhere. This application proposes an entirely new program that would unnecessarily duplicate services offered at Iredell Memorial Hospital (“IMH”), a safety net hospital. The following paragraphs summarize why this CON application should be found non-conforming to statutory criteria: 1,3, 3a,4,5,6,7,8, and 12.

**CON REVIEW CRITERIA**

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

The number of procedures required to make the proposed Vascular Access ASC financially viable is based on speculative, unrealistic, and unsupported assumptions about patient willingness to travel to the proposed Statesville facility from within a 30-mile radius. The map on page 39 includes Hickory, Huntersville, Salisbury, and Wilkesboro. As demonstrated in discussions of Criterion 3 and 6 in these comments, this is not realistic. Thus, the volume forecast is not realistic; and the project should be found non-conforming with Policy Gen-3, which states:

*“... A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

This shortcoming should make the application non-conforming to Criterion 1.

- 3. The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

The application defines a 30-mile radius of the proposed ASC address as the “patient convenience” area (page 39). However, the narrative and methodology in Section Q fail to tie

the forecast patients to the population residing in that 30-mile radius. Instead, the Methodology in Section Q claims an arbitrary market share of dialysis patients in the 10 counties touched by that radius. In fact, Step 1 of the methodology at pdf page 128 shows most proposed patients originating from Mecklenburg County. Patient Origin tables on pages 39 and 40 mask that fact.

The 30-mile map on page 39 includes areas south of Huntersville in Mecklenburg County. According to Google, Huntersville is only 18 minutes away from Metrolina Vascular Access Center (“MVAC”) in Charlotte, an ASC that provides vascular access services. The application provides no information about traffic congestion in the 30-mile radius. According to Google, a noon-time trip from Mooresville to Statesville in Iredell County can take 45 minutes. People in Mecklenburg County would have to go through Mooresville to reach the proposed Statesville facility.

People with ESRD who are on routine hemodialysis need vascular access procedures to maintain their dialysis access points and keep them alive. The Vascular PLLC application makes no attempt to discover or explain where dialysis patients in the proposed 30-mile radius currently obtain vascular access services. Iredell Health identified several such places:

- Iredell Memorial Hospital (“IMH”) provides vascular access procedures, both AV fistulas and access maintenance procedures. A vascular surgeon, William B. Newton, MD, does the procedures and IMH schedules all patients without regard to ability to pay. IMH internal data show 94 percent of its vascular access patients in the last 11.5 months originated from within an 18-mile service area. None came from Mecklenburg County.
- Moreover, IMH and freestanding surgery centers in Iredell County less than 10 minutes away from IMH, have surplus operating room capacity. See more discussion in Criterion 6.
- Wallace Tarry, MD, is a vascular surgeon located in Mooresville, Iredell County who does vascular access procedures at hospitals in Concord, Cabarrus County and Lake Norman, Iredell County<sup>1</sup>. According to Dr. Newton, he, too, accepts referrals for vascular access procedures from IMH nephrologists,
- Metrolina Nephrology Associates has three nephrology offices in 30-mile radius. All are associated with the MVAC in Charlotte, which offers these services and has two interventional nephrologists<sup>2</sup>.
  - Huntersville, Mecklenburg County has three nephrologists,
  - Concord in Cabarrus County has six nephrologists,
  - Salisbury, Rowan County has five nephrologists.
- Optum Business Advisor database indicates that Randall Bast, MD, who is associated with a vascular access OBL called Foothills Dialysis Access in Lenoir, Caldwell County, did 649 vascular access outpatient procedures in the past year. His OBL is only 18 miles from Hickory in Catawba County, much closer than the 28 miles from Hickory to the proposed new Vascular ASC.

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<sup>1</sup> Optimum Business Advisors.

<sup>2</sup> <https://www.metrolinanephrology.com/Contact/#locations>

- Catawba Valley Medical Center also has a Vascular Access Team in Hickory, Catawba County.

The application does not explain the need that the population it proposes to serve has for the additional services proposed, therefore it should be found non-conforming to Criterion 3.

- 3a. **In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.**

Letters in Exhibit C.4 of the application indicate that the proposed facility will involve replacing services provided by IMH, a licensed acute care hospital. The application fails to show how reducing some or all these vascular access services at IMH might affect access to healthcare for low-income individuals, racial and ethnic minorities, women, people with disabilities, and other underserved groups, as well as the elderly who require essential healthcare services.

The application fails the demonstration requirement and should be found non-conforming to Criterion 3a.

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

Vascular access procedures require a C-arm, space for procedures, preparation and recovery space. They can be done in angiography laboratories that are properly organized and staffed. IMH has such an angiography laboratory, where a vascular surgeon and interventional radiologists work together to provide catheter and AV fistula vascular access maintenance procedures. IMH Vascular Surgeon Thomas Newton, MD also creates dialysis catheter and AV fistula access points in IMH operating rooms, because these complex procedures require more support. Most of the catheter insertions were inpatients. The AV fistulas were primarily outpatients.

The Vascular PLLC application fails to address these existing IMH services. Letters of support in Application Exhibit C.4 mention only 250 dialysis patients. Some people on home dialysis will not require vascular access. Internal records show that IMH provided 257 fistulas, fistulagrams, and catheter exchanges in 11.5 months year to date.

The proposed new ASC address is only three minutes from another freestanding facility, Iredell Surgical Center. The application requests approval for a new ambulatory surgery center. However, application Section G, which addresses this statutory criterion, fails to identify ambulatory surgery centers in Iredell County or in HSA III. The application also fails to address why proposed vascular procedures cannot be done in existing freestanding ambulatory surgery centers that have excess capacity. The list of procedures on application page 35 includes

“creation of AV fistulas.” These are complex surgical procedures, and they are currently done by vascular surgeons in hospitals in the proposed 30-mile radius.

The application’s failure to demonstrate that existing alternative methods of meeting the need are less effective, hence the application should be found non-conforming to Criterion 4.

5. **Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs, as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.**

Because the counties of patient origin are unrealistic, and the application provides only hypothetical data relating the 30-mile area to the projected procedures, the forecasted 1,311 procedures on Form C.4 for Years 2 and 3 cannot be verified. Hence, the financial projections are not reasonable. Hence the project should be found non-conforming to Criterion 5.

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

The proposed project will result in unnecessary duplication of existing or approved health services facilities and capabilities.

- 2023 SMFP Chapter 6 page 47 defines “operating room service areas” as a single or multi-county grouping shown on Figure 6.1 and delineated on page 48. For this Vascular PLLC application, the service area is Iredell County. The Vascular PLLC application provides no information about operating rooms or ambulatory surgical facilities in Iredell County. The 2023 SMFP Table 6.C on page 71 shows a surplus of 15.24 operating rooms in Iredell County, and 8.91 of the surplus operating rooms are associated with freestanding ambulatory surgical centers.
- The Vascular PLLC application fails to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. The application demonstrates no evidence of attempts to work with any of these existing facilities.
- In addition to vascular access procedures, IMH provides both inpatient and outpatient renal hemodialysis services. IMH operates a distinct part unit skilled nursing facility. Because it provides in-house hemodialysis, IMH is the local go-to nursing home for dialysis patients. IMH provides outpatient vascular access procedures for these nursing home patient with no transportation cost. The proposed ASC is unlikely to successfully move nursing home vascular access procedures to the proposed Vascular ASC. Doing so would require expensive ambulance transport to and from the nursing home to the proposed Vascular ASC.
- The proposed facility would clearly duplicate services at the above-mentioned MVAC in Mecklenburg County, because the methodology associated with Form C.1 in Section Q (pdf page 128) indicates that most patients of the proposed new Vascular PLLC ASC

would originate from Mecklenburg, Rowan, and Lincoln counties, which are closer to MVAC than to Statesville..

On this topic, the Vascular PLLC application narrative on page 83 is misleading. It states that MVAC is 43 miles away from the proposed Vascular ASC, hence is inaccessible to the proposed catchment area. As illustrated in the Attachment B screenshot, Mecklenburg, Lincoln, and Rowan counties are closer to MVAC than to the proposed new Vascular PLLC ASC.

The application fails to demonstrate that the existing approved MVAC cannot adequately serve a significant portion of the proposed catchment area for this proposed Vascular PLLC project. For these reasons, the application should be found non-conforming to Criterion 6.

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

Unlike prior CON requests for vascular access surgery centers, this project does not propose to convert services from an existing OBL to an ASC. It proposes an entirely new service.

No physician listed in the application as proposing to do procedures at the new facility is an interventional nephrologist located in Iredell County. Fernando E. Ariza, MD, the proposed Director, is in Winston Salem, Forsyth County. On July 6, 2023, he obtained privileges at IMH for dialysis and “temporary placement of vascular access.” Dr. Ariza has worked one or two weekend days at IMH since then.

Dr. Ariza, MD, is a General Nephrologist,. His LinkedIn site indicates that he is currently completing a fellowship in interventional nephrology in Brooklyn, NY. It identifies him as a COVID director in Charlotte and Greensboro and associated with SUNY Downstate Medical Center.<sup>3</sup> It does not indicate that he is board certified in interventional nephrology. He provides no information to demonstrate that he has worked in or is familiar with operations of a renal dialysis vascular access center.

A letter in Exhibit C.4 from a vascular surgeon at Park Slope Vein & Vascular Center references a July 2023 Letter of Engagement, which is not included in the CON application. The August 1, 2023, letter to Michaela Mitchell, which is included, indicates:

*“[Park Slope Vein and Vascular] has 30 years of expertise in managing Peripheral Arterial Disease (PAD), large vessel diseases, such as Aortic Aneurysms [emphasis added] and Dialysis Vascular Access including the creation of Grafts and Fistulas with subsequent management of complications and routine maintenance. The timely creation of dialysis access has been a priority of Nephrology professional organizations for years and has been included in quality metrics for dialysis centers by CMS. We welcome the opportunity to enhance the care of this very vulnerable population and offer our expertise to Vascular PLLC.”*

<sup>3</sup> <https://www.linkedin.com/in/fernando-ariza-md-rdms-51844a10>

This letter does not identify a physician who would staff the proposed Vascular ASC. The letter cites a wide range of procedures; Park Slope Vein and Vascular is in Brooklyn, NY.

Exhibit C.4 includes a letter from Interventional Nephrologist, Danny Issa, MD, who is employed by In-House Doc, Inc., UNC Chapel Hill, and VA Medical Center in Salisbury. He offers only “as needed” back up services, as does a letter from Karn Gupta, MD.

Because the day-to-day physician coverage of the proposed procedures is not clear and no experienced vascular center manager is identified, the application should be found non-conforming to Criterion 7.

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

The response to Question I.1.(b) is incomplete. It references a letter from Dr. Ariza which says his PLLC will provide ancillary services. However, Vascular PLLC has no employees.

The procedures listed on page 35 include percutaneous AVF creation. These are complex procedures that may require anesthesiology services. The application provides no information about anesthesia coverage. Presently, Certified Registered Nurse Anesthetists are in short supply.

For these reasons, the application should be found non-conforming to Criterion 8.



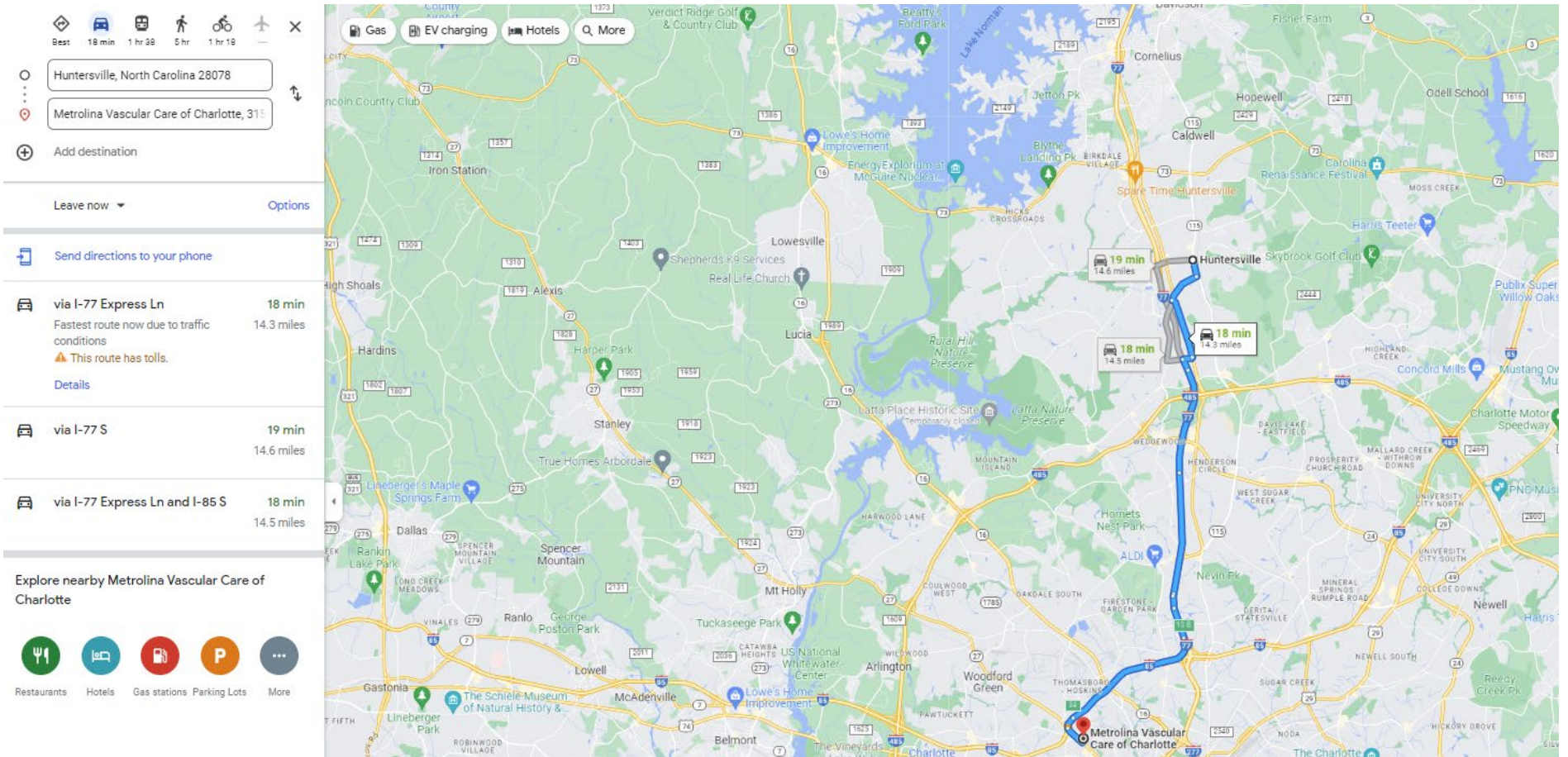
12. **Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project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

This project involves capital expenditures of more than \$4 million to develop a service that duplicates existing services. Two letters of support identify possible sources of only 250 of the forecast 624 second-year patients; and those letters acknowledge that dialysis maintenance care is provided by the local hospital. (See pdf page 129 for proposed patients by year).

IMH is accountable as the county hospital. Its board has a mandate to provide care for all county residents regardless of ability to pay. IMH turns no patients away. Yet, IMH provided only 257 vascular access procedures in the past 11.5 months. Both IMH's actual experience and the letters of support for Vascular PLLC suggest that residents of the 30-mile radius who will actually utilize the proposed new ASC may require just 268 vascular access procedures annually ( $258 / 11.5 * 12 = 268$ ).

The proposed capital expenditure for construction will unduly increase the cost of providing health services. It will not only be inefficient, but the proposed facility will only survive by directing procedures and staff away from a safety net hospital. IMH will still need to provide the services to inpatients but IMH's unit cost of providing services to inpatients and patients of the nursing home will go up.

For these reasons, the application should be found non-conforming to Criterion 12.



Google Maps accessed 9/26/2023. 2PM