



July 31, 2023

Gregory F. Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Via Email

RE: Comments regarding competing Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC's Operating Room CON Application (Q-12397-23)

Dear Mr. Yakabowski:

Enclosed please find comments prepared by Pitt County Memorial Hospital, Inc. d/b/a ECU Health Medical Center (hereinafter "EHMC" or "ECUH Medical Center") regarding the competing Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC's (hereinafter "ENAASC") CON application to develop a new ambulatory surgical facility (ASF) with one operating room and three procedure rooms within the Pitt, Greene, Hyde and Tyrrell County Operating Room Service Area to meet the need identified in the *2023 State Medical Facilities Plan (SMFP)*. We appreciate your consideration of these comments regarding the applicants' CON application during your review of the applications. If you have any questions about the information presented here, please contact me at 252-847-3631 or jshoveli@ecuhealth.org.

Sincerely,

Jeff Shovelin
Vice President – Business Planning and Strategy
ECU Health

**COMMENTS ABOUT COMPETING NOVANT HEALTH NEW HANOVER
REGIONAL MEDICAL CENTER CERTIFICATE OF NEED APPLICATION**

Submitted by ECU Health Medical Center
July 31, 2023

In accordance with N.C.G.S. §131E-185(a.1)(1), Pitt County Memorial Hospital, Inc. d/b/a ECU Health Medical Center (hereinafter “EHMC” or “ECUH Medical Center”) submits these written comments regarding the competing Eastern Nephrology Associates ASC, LLC and Fresenius Vascular Care Greenville MSO, LLC’s (hereinafter “ENAASC”) CON application (Project ID Q-12397-23) to develop a new ambulatory surgery facility (ASF) with one operating room and three procedure rooms within the Pitt, Greene, Hyde and Tyrrell County Operating Room Service Area to meet the need identified in the 2023 State Medical Facilities Plan (SMFP). The discussion below describes how ENAASC’s application does not conform to all the Certificate of Need review criteria and applicable operating room administrative rules.

Specific comments regarding the ENAASC application (Q-12397-23)

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

ENAASC does not adequately demonstrate the need for the proposed project, fails to demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP, and did not show that its proposal is not unnecessarily duplicative of existing resources. The discussions regarding analysis of need and maximizing value, in Criterion (3) and unnecessary duplication in Criterion (6), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the ENAASC application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (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.*

ENAASC describes the scope of their proposal as “to develop a licensed ambulatory surgical facility (ASF) with one operating room and three procedure rooms, focused on vascular access procedures for patients with end-stage renal disease (ESRD) as well as select non-ESRD

*vascular treatment procedures.*¹ Since ENAASC's application was filed in response to a need determination for operating rooms in the 2023 SMFP, the applicant would have to prove how their proposal would best meet the identified need for operating rooms. While ENAASC throughout their application provided information related to the benefits and needs for "vascular access centers" and "coordinated vascular access care", they failed to provide any valid and defensible information to prove a dedicated vascular access ASF is necessary to address the need. Therefore, the application is nonconforming to Criterion 3.

For the discussions below, it is important to recognize and maintain the distinction between a "vascular access center" (VAC) and a "vascular access ASF". Azura Vascular Care (related entity to applicants) defines a VAC on their own website as *"an outpatient facility that provides critical care and maintenance to those with a dialysis access and provides state-of-the-art minimally invasive treatments for people with other vascular diseases – diseases of the blood vessels and lymphatic system. Some vascular centers also provide vascular surgery."*² Most VACs are considered "Office Based Laboratories" (OBLs) in a physician office setting. In July 2018, the applicants file a Petition for Adjusted Need Determination (Exhibit 1) where they repeatedly described "vascular access ASFs" as a licensed single-specialty ambulatory surgical facility *"for the purpose of providing vascular access procedures for dialysis patients, including the surgical creation, management and maintenance of patients' vascular accesses"* (p.2). By the applicants' own definitions from publically available sources, a VAC and a vascular access ASF are two different things. ENAASC's application confirms this statement in this current application by stating, *"To improve quality of and access to cost-effective care, the recent trend has been for office-based vascular access centers to move towards licensed ASFs."*³ This OBL/VAC versus ASF designation distinction is important to the discussion below. It is the addition of the one operating room, not the three procedure rooms, proposed in this application that moves a facility from OBL to ASF.

In Question C.4 of the application, ENAASC identified several reasons for the need to create a vascular access ASF. While many of the points support the expansion of VACs and even VAC procedure rooms built to ASF standards, there is not a single valid and supported reason provided in the application that supports a new vascular access ASF. Specifically, (in order of identification in ENAASC's application)

Rational 1: Increasing Incidence of Chronic Kidney Disease (CKD) and End State Renal Disease (ESRD)

ENAASC provided a significant amount of good incidence, clinical, and outcome information related to CKD and ESRD and the benefits of coordinated care for vascular access creation and maintenance in an ambulatory environment. ECU Health recognizes this and is not immune to the kidney disease challenges in eastern NC. However, the applicant did not show how a licensed ASF addresses the need. ENCASC specifically stated,

¹ ENAASC CON Question A.5.a p.19

² <https://www.azuravascularcare.com/infodialysisaccess/what-is-a-vascular-access-center/>

³ ENAASC CON Question C.4 p.45

*“Historically, dialysis access creation and maintenance required inpatient surgery, and the creation of vascular accesses is still performed primarily in a hospital setting. But since the early 2000s, dedicated, **physician office-based vascular access centers** [emphasis added] have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within hours.”⁴*

In the next paragraph, the applicant attempts to make the connection between the success of “physician office-based vascular access centers” and “vascular access ASFs” by stating,

“Licensed, vascular access ambulatory surgical facilities (“vascular ASFs”) are necessary to preserve access to timely, cost-effective care. Moreover, providing care in a licensed ASF enables vascular ASFs to create vascular accesses -- which are currently done in hospitals -- in a less-expensive ambulatory setting, and continue to keep overall healthcare spending on ESRD patients down by avoiding unnecessary hospital admissions.”⁵

ENAASC makes the jump from office based VACs, essentially OBLs, in one paragraph to a licensed ASC in the next without discussing or proving why the connection can be made. Clearly, the need and benefit of more procedures rooms in a new or existing office-based VAC is needed to address the growing incidence of CKD and ESRD, but no information was provided that directly supported the need for a dedicated operating room and new ASF. Therefore, the applicants failed to prove why an ASF is needed to address the needs of CKD and ESRD patients. ENAASC’s other statements regarding cost and hospital care will be discussed in more detail in other topics below.

Rationale 2: Change in Reimbursement for Vascular Access Services in OBLs

It is important to note, while the proposed new vascular access ASF would be a new facility, the applicants are existing providers of the services proposed in the application. The two existing VAC locations in Greenville and New Bern identified in the application (d/b/a of one of the co-applicants) are performing OBL vascular access and maintenance procedure today. In fact, ENAASC specifically states,

“Co-applicant Eastern Nephrology Associates ASC, LLC (ENAASC) is a new entity, but its sole member Eastern Nephrology Associates, PLLC d/b/a Vascular Care of Greenville (VCG) and Vascular Care of New Bern (VCNB) has a longstanding presence in Pitt County, serving the needs of vascular access end-stage renal disease (ESRD) and other non-ESRD patients needing vascular treatment. VCG and VCNB have combined with Azura Vascular Care (AVC) to

⁴ ENAASC CON Question C.4.a p.42

⁵ ENAASC CON Question C.4.a p.42

provide -for many years -office-based vascular access services in Pitt County and Craven County via a management services organization (MSO) arrangement.”⁶

“AVC is the nation's largest operator of ASF-based ESRD vascular access services, operating approximately 72 locations throughout the United States. AVC has successfully obtained 10 Certificates of Need (CONs) for ASFs in multiple states, including two North Carolina licensed ambulatory surgical facilities (Raleigh Access Center in Wake County, and Metrolina Vascular Access Care in Mecklenburg County). AVC currently operates over 45 licensed and accredited ASFs in 23 states and Puerto Rico (including two in North Carolina)”⁷

“Currently, Vascular Care of Greenville and Vascular Care of New Bern provide office-based vascular access procedures and vascular care treatment for patients, including the minimally invasive treatment of uterine fibroids, varicoceles, varicose veins, peripheral artery disease (PAD) and dialysis access management as described above.”⁸

Why is this important? The reality is the ENAASC proposed project boils down to the ability to create an ASC and move existing patient procedures from an OBL reimbursement model at VCG and VCNB to a significantly higher ASC reimbursement model. The applicants even stated,

“While an OBL is a practical and safe location for vascular access procedures and maintenance of existing grafts, the recent changes in reimbursement legitimately threaten the viability of OBLs like VCG and VCNB. The physician practice operations have subsidized the financial loss of the vascular access center; however, the recent and continued reductions to OBL reimbursement significantly threaten long-term viability. Development of ENAASC will facilitate financial viability and, more importantly, ensure that dialysis patients maintain access to critically necessary, lifesaving vascular access services.”⁹

Even during the planning for the 2023 SMFP, in response to a petition for a special needs determination for a vascular access ASF, the DHHS Healthcare Planning Section’s Agency Report (hereinafter “Agency Report”) to the Acute Care Subcommittee of the State Health Coordinating Council (SHCC) stated, *“Like previous petitions, the current Petition cites reductions OBL reimbursements as a main motivation for the request.”* (Exhibit 2).

In addition, it is important for the CON Section to understand the mechanism as to why a shift from OBL to ASC promotes financial viability. The North Carolina Division of Health Service Regulation (“DHSR”), Certificate of Need (“CON”) Section no longer (a) regulates which cases need to be performed in a licensed operating room (“OR”) as opposed to a procedure room; or (b) forbids procedure rooms from being constructed to

⁶ ENAASC CON Question A.6.a p.22

⁷ ENAASC CON Question A.6.a p.23

⁸ ENAASC CON Question C.1 p.33

⁹ ENAASC CON Question C.4 p.43

OR standards. Therefore, while ENAASC proposes to construct its one operating room and three procedure rooms to ASC standards, there is no statutory distinction between the two. Currently, to be licensed as an ASC in North Carolina, a facility has to have at least one licensed operating room and/or at least one licensed endoscopy room.

An ASC is not prohibited from using procedure rooms that are properly equipped and staffed and constructed to OR standards for surgical procedures that would otherwise be performed in a licensed OR. Therefore, the delineation between the two categories of rooms largely boils down to whether a payer will pay for a case in a procedure room when it cannot be identified on a bill/claim to the payer as having been performed in an OR. This would include, for example, not using any CPT/HCPCS codes or diagnosis codes on the ANSI ASC X12N 837P/CMS-1500 or ANSI ASC X12N837I/UB-04 or revenue codes on the 837I/UB-04 that identify a service as having been performed in an OR.

Claims to Medicare FFS (88.1% of ENAASC's patients) for surgical procedures performed in a licensed and certified ASC are billed on the 837P/CMS-1500 with an ASC place of service code (POS 24). CMS publishes annually a list of covered surgical procedures for which an ASC may be paid, with certain updates made on a quarterly basis. This list is developed based on the regulation that describes surgical procedures that are covered in an ASC. Per 42 C.F.R. § 416.166:

(a) Covered surgical procedures. Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) General standards. Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the Federal Register and/or via the internet on the CMS website that are separately paid under the OPPIs, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(c) General exclusions. Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that:

- (1) Generally result in extensive blood loss;*
- (2) Require major or prolonged invasion of body cavities;*
- (3) Directly involve major blood vessels;*
- (4) Are generally emergent or life-threatening in nature;*
- (5) Commonly require systemic thrombolytic therapy;*

- (6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;
- (7) Can only be reported using a CPT unlisted surgical procedure code; or
- (8) Are otherwise excluded under § 411.15 of this chapter.

There is not anything in this regulation stating that to be covered by Medicare FFS, the procedures must be performed in a licensed OR. The mere fact that a surgical procedure was performed in a Medicare certified ASC in a properly equipped and staffed procedure room built to OR standards but not licensed as an OR does not mean it is not reimbursable at ASC rates by Medicare. In fact, there is no place on a Medicare claim form to distinguish the type of room (OR vs. Procedure Room). The reimbursement defaults to the place of service (Office-Based (11), ASC (24), Hospital OP (22), Hospital IP (21), ED (23), etc.) and reimbursement for ALL procedure performed at that site are reimbursed at that level, regardless of the type of room. This actually INCREASES the cost of care to payers and patients in order to provide more revenue to the applicants to ensure financial viability. Since this section is an argument of financial viability, a more detailed response on the actual impact the ENAASC proposal has on cost is discussed below where more appropriate. The more important fact is the proposal will move ALL of the proposed patients from an OBL model to a more expensive ASC model, and that is solely the mechanism to promote “financial viability”.

While ECU Health recognizes the importance Vascular Access Centers have in the coordination of care of dialysis patients, and would fully support any facility serving the patients in our region that was financially challenged, ENAASC did not provide any historical information to back up its claims of threatened long-term financial viability or the overall impact of the decreased reimbursement changes over time. As an existing VAC provider with a “longstanding presence in Pitt County”, the applicants would surely have historical financial statement or analyses to back up the claims. Instead, ENAASC used a report from the American Society of Diagnostic and Interventional Nephrology (ASDIN) that stated 20% of OBLs closed as a result of the 2017 rate reductions. However, this statement was reviewed by the Healthcare Planning Section this year and they determined in the Agency Report that,

“Anecdotal information claims that OBLs can no longer afford to operate. The American Society of Diagnostic and Interventional Nephrology (ASDIN) reported that nearly 20% of OBLs closed as a result of the 2017 rate reductions. The Agency attempted to verify this data but could not do so. The 20% figure appears to be based on a survey of ASDIN members. It is unknown what proportion of OBLs in the country are represented in the ASDIN membership. It is also unknown what proportion of survey recipients responded to the survey. The Agency could not locate more recent data on subsequent closures.”
(Exhibit 2 p. 4)

Without providing any historical information to support financial claims and solely relying on a study that even the State could not verify, ENAASC failed to prove it

“needs” to convert to an ASC in order to survive. Therefore, a need for an operating was not established either.

Rational 3: Better quality, access and cost-effectiveness of Vascular Access and Vascular Treatment Care in Licensed ASF Setting

Dedicated Vascular Access ASFs Will Achieve Better Outcomes

ENAASC states in their application, “An ASF focused on select vascular treatment procedures such as those described in Section C.1 will also provide better coordination of patient care, specialization of services, with a resulting positive impact on quality of care and cost effectiveness.”¹⁰ To support this, ENAASC provided data and statistics from four studies. It is important for the CON Section to understand the methodology and age of the studies when reviewing the application. Since ENAASC did not provide the full abstracts of the study in their application, they are provided in Exhibit 2. ECU Health’s comments on the studies are found below.

- Associations between coordinated vascular care visits and decreased rates of hospitalizations and mortality in hemodialysis patients.
 - The data is over a quarter century old (1995-2002). Healthcare has changed a lot since then.
 - The findings were related to the impacts of a new VAC in Phoenix, AZ when there was not one already in the market. As previously stated, the applicants are existing providers and already operate a VAC in Greenville, NC. The applicants did not provide any information related to the two markets being comparable nor any expectations that similar results would be achieved. The study even concluded that, “Further studies are necessary to demonstrate this effect in other communities.”
 - Even assuming the results of the study are still valid today and applicable to the Greenville market, the study was still based on VACs, not vascular access ASCs. As stated above, there is a distinct difference. The applicants made no attempt to prove how a VAC study translates to an ASC, thereby again proving the need for procedure rooms and coordinated vascular access and maintenance care, but not an operating room.
- Associations between coordinated vascular care visits and decreased rates of hospitalizations and mortality in hemodialysis patients
 - Even though the data was more recent (2014), the study was still based on VACs, not vascular access ASCs. As stated above, there

¹⁰ ENAASC CON Question C.4 p.45

is a distinct difference. The applicants made no attempt to prove how a VAC study translates to an ASC, thereby again proving the need for procedure rooms and coordinated vascular access and maintenance care, but not an operating room.

- Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries.
 - The data is almost 15 years old (2006-2009)
 - Even assuming the results of the study are still valid today, once again the study is comparing VACs, not ASC. The study even states as such when it says, “*Small-scale studies have suggested that DVA care in a FOC **[freestanding office-based centers]** results in favorable patient outcomes and lower costs.*” Again, the applicants made no attempt to prove how a VAC study translates to an ASC, thereby again proving the need for procedure rooms and coordinated vascular access and maintenance care, but not an operating room.
- What is the best setting for receiving dialysis vascular access repair and maintenance services?
 - The data is almost 10 years old (2010-2013)
 - Just like the previous studies, even assuming the results of the study are still valid today, the study is comparing VACs, not ASC. The study even states as such when it says, “*This study compares patient outcomes of receiving DVA services in the **freestanding office-based center** (FOC) to those of the hospital outpatient department (HOPD).*” Again, the applicants made no attempt to prove how a VAC study translates to an ASC, thereby again proving the need for procedure rooms and coordinated vascular access and maintenance care, but not an operating room.

Even if one can reasonably argue that the benefits shown in the studies between a VAC and a hospital would be equal to or greater in an ASC, the proposed project will not allow a significant number of incremental new patients to realize these benefits, as the majority of the patients proposed to be served are the applicants existing office based patients, not hospital patients. In Section Q of the application, ENAASC provides volume assumptions used to project future volume. The applicants specifically state that,

“To project the utilization at the proposed Greenville ASF (ENAASC) during the initial three project years, the applicants assume that during each of the initial three project years (CY2026 - CY2028), a percentage of

procedures will shift from the office-based VCG and VCNB to the licensed ENAASC ambulatory surgical facility. Specifically, for the first project year (CY2026), the applicants assume a shift from VCG of 75%, followed by a shift of 80% in CY2027, and a shift of 85% in CY2028 (third project year). For the first project year (CY2026), the applicants assume a shift from VCNB of 35%, followed by a shift of 40% in CY2027, and a shift of 45% in CY2028 (third project year).”¹¹

Also in Section Q of the application (page 130-131), the applicants identify the incremental new fistula creation procedures the ASC will be able to do that it can’t do today and the subsequent incremental new follow up vascular maintenance procedures. The table below combines the projected existing volume proposed to shift as well as the proposed incremental new procedures as presented in the application. The table clearly shows that **94%** of the projected volume in the proposed new ASC **WILL NOT** come from shifting volume from a hospital. Therefore, the argument that the ASC will improve outcomes over a hospital setting for 94% of the proposed patients to be served is not applicable or valid. This argument would only apply to 6% of the proposed patients, which equates to 241 total patients, or about 1 per day of proposed operation (5 days a week x assumed 50 weeks per year to account for holidays = 250 days). As it pertains to the operating room need, as presented in Question C.1 on page 29 of the application, only the fistula creations, stents, and thrombectomy are identified to be performed in the operating room. The other procedures will be done in the procedure rooms. Therefore, the operating room itself will only benefit an incremental 150 patients per year, or about 0.6 patients per day.

ENAASC even recognizes the proposed project will have almost no impact to hospital volume. In response to Question G.2.a (p. 88), ENAASC states,

	FY26	FY27	FY28
Existing Volume Shift	3,432	3,715	4,000
New Volume*	240	241	241
Fistula Creations	120	120	121
Stents	21	21	21
Thrombectomy	9	9	9
Angioplasty	79	79	80
Fistulogram	12	12	12
TOTAL VOLUME	3,672	3,956	4,241
% New Volume	6.5%	6.1%	5.7%

**Numbers may not foot due to rounding*

Source: ENAASC CON Application Section Q p.130-131

“Vascular access maintenance procedures do not require a hospital setting and are mostly performed in physician offices now. Consequently, very few of the procedures that ENAASC projects to perform are not usually provided in hospitals unless under emergency circumstances. Projected patient volume is based on procedures previously performed in

¹¹ ENAASC CON Section Q p.129

the office-based setting. Thus, the proposed Greenville ASF will not adversely affect hospital surgical utilization.”

Therefore, since it is clearly the intent of the applicants to have almost no impact on the volume of hospital based patients, any argument in the application that states the benefits of an ASC over a hospital as a justification for need is inaccurate and cannot be considered. In addition, no rational argument can be made or considered that proposes a need for an operating room is justified to only shift 0.6 patients per day from the hospital to an ASC setting.

Licensure of Vascular Access/Treatment Centers as Ambulatory Surgical Facilities is Necessary to Preserve Access to Care

ENAASC argues that,

“To improve quality of and access to cost-effective care, the recent trend has been for office-based vascular access centers to move towards licensed ASFs. As previously discussed, without vascular access centers, vulnerable dialysis patient populations are left with only one option: vascular access created in the hospital setting. Hospitals are critical to the health and well-being of North Carolinians. However, given the broad scope of care they provide, hospitals are a less efficient, less effective environment for these services because they are not designed to respond to the unplanned, though non-emergent nature of hemodialysis access procedures. In a hospital environment, ESRD patients in need of vascular access maintenance do not typically present as emergent cases, which can result in delays in which they cannot dialyze, and their condition deteriorates while waiting to receive necessary maintenance procedures.”¹²

While this might be true, the proposed project does not intend to meaningfully address this issue. As stated above, the proposed project is intended to primarily shift existing patients in the applicants’ existing office based environment to an ASC environment, not from a hospital environment. As it was shown above, this applies to 94% of the proposed population to be served by the proposed project. This argument may only be true for about 1 patient per proposed operating day (0.6 for the operating room only). At that volume, no rationale argument can be made that the proposed project will have any meaningful impact on shifting patients from a hospital setting to an ASC.

Furthermore, ENAASC also argued that,

“Specifically, in the experience of Azura-affiliated physicians, ESRD patients in the hospital environment often are not seen "urgently" due to competing priorities of the hospital Interventional Radiology (IR)

¹² ENAASC CON Question C.4 p.45

department - the service typically tasked with treating these issues. Urgent ESRD cases are typically scheduled at the end of the day in hospital IR departments as inpatients so that more critically ill patients from the Emergency Department (ED) and Intensive Care Units (ICUs) can be accommodated first, along with previously scheduled IR outpatients. Further delaying care for this fragile population is the fact that many hospital IR departments also require a potassium level be drawn. Furthermore, owing to their competing responsibilities, hospital IR departments often only temporize an urgent or emergent clotted fistula or graft merely by placing a catheter, until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization and the deleterious sequelae of using a catheter for dialysis. Not only can this put the patient's health at risk, but it also compounds the already vast investment of time the ESRD patient must commit to life-sustaining dialysis.”¹³

Without commenting on the specific experience of the applicants, in the statement above, ENAASC clearly indicates the issue regarding delays in care and inpatient admissions resides in the Interventional Radiology department, not operative services. Yet the applicants claim a new ASC with operating rooms is needed to prevent these delays without mentioning (even in Section E) why developing a new interventional radiology suite at the current office location was or was not a viable option. Therefore, the claims an operating room is needed to preserve access to care by addressing delays in care at the hospital is not a viable argument.

Dedicated Vascular Access/Treatment Ambulatory Surgical Facilities Reduce the Cost of ESRD Care

ENAASC argues that,

“Without approval of this project, ESRD patients and vascular treatment patients of Pitt County and surrounding eastern North Carolina counties may be forced into hospitals for their vascular access/treatment care, at an overall greater cost to the healthcare system but without the specialization or coordination of care that a vascular ASF can provide. Moreover, it would unnecessarily consume limited hospital capacity and resources. Approval of this project as proposed will ensure that the vulnerable patients who are suffering from ESRD, as well as non-ESRD vascular treatment patients, have coordinated care, improved outcomes, and lower cost than receiving the same care in a hospital setting.”¹⁴

To support this claim, ENAASC provides ASC versus hospital based reimbursement rates and shows the impact of shifting 50% of volume from one setting to the other will

¹³ ENAASC CON Question C.4 p.45

¹⁴ ENAASC CON Question C.4 p.48

have in reducing the total cost of ESRD care. While this is a valid argument, as stated above, the project as proposed is not intending to shift a meaningful number of patients from the hospital setting to the ASC setting. As stated above, and repeatedly referenced in the application, 94% of the applicants’ population proposed to be served will go from a lower reimbursement (OBL) to a higher reimbursement (ASC). Since someone’s revenue is someone else’s cost, another way to state it is 94% of the applicants’ population proposed to be served will go from a lower cost of care (OBL) to a higher cost of care (ASC). In fact, the minimum delta between the cost savings 6% of cases shifting from hospital to ASC will experience versus the reimbursement/cost increases for 94% of cases shifting from OBL to ASC is a net **INCREASE** in cost of \$3.5M. Below describes the conservative methodology used to arrive at that figure.

Cost Savings Achieved from Shifting 6% of Projected Volume from Hospital to ASC

On page 47 of the ENAASC CON, the applicants’ provide a chart comparing ASC reimbursement rates to hospital rates. Without going into the healthcare industry debate as to all the reasons why hospital rates are higher, ECU Health assumed the reality that there is a difference in reimbursement rates. On the chart, all the CPT codes listed have a delta of \$3,702 per procedure except CPT code 36821 which has a delta of \$2,285. **NOTE:** CPT code G2170 and G2171 were deleted January 1, 2023 and are no longer valid. Without complicating the analysis with CPT code volume distributions and weighted averages, the most conservative, worst case scenario is to apply the \$3,702 delta to all of the incremental volume identified in the application (241 cases – three year average annual/OR + PX Room). This nets a potential reduction in costs over hospital reimbursement rates of approximately \$0.9M.

Increased Reimbursement (Cost) from Shifting 94% of Projected Volume from OBL to ASC

During the planning for the 2023 SMFP, in response to a petition for a special needs determination for a vascular access ASF, the DHHS Healthcare Planning Section’s Agency Report (hereinafter “Agency Report”) to the Acute Care Subcommittee of the State Health Coordinating Council (SHCC) did an analysis of OBL versus ASC rates for common vascular access and maintenance CPT Codes (Exhibit 2 p.3). The table below shows the comparison and delta between the two sites of service based on that information.

CPT Code	OBL	ASC	Difference	% Dif
36901	\$ 731	\$ 723	\$ (8)	-1.1%
36902	\$ 1,257	\$ 2,443	\$ 1,186	94.4%
36903	\$ 4,525	\$ 6,889	\$ 2,364	52.2%
36904	\$ 1,877	\$ 3,314	\$ 1,437	76.6%
36905	\$ 2,380	\$ 6,106	\$ 3,726	156.6%
36906	\$ 5,722	\$ 11,402	\$ 5,680	99.3%

Without complicating the analysis with CPT code volume distributions and weighted averages, the most conservative, best case scenario is to apply the lowest delta (\$1,186 – excluding CPT 36901 which has a higher reimbursement in OBL) to all of the projected volume to shift identified in the application (3,716 cases – three average annual/OR + PX Room). **NOTE:** As previously stated, the mechanism for financial viability is ALL procedures, not just ones done in operating rooms, would be reimbursed at ASC rates. Therefore, this nets a potential increase in cost over OBL reimbursement rates of approximately \$4.4M.

Therefore, the net effect as a result of the proposed project related to the average annual cost of ESRD care is an **INCREASE** of approximately \$3.5M. Given the highest possible savings was compared to the lowest possible increase, it is reasonable to assume this figure would be higher. This analysis is based on payer reimbursement and does not even account for the increased costs a patient will bear in the form of higher co-payments, co-insurance, and/or deductibles related to office-based care versus ASC settings. While the payers will absorb most of the burden in the increase in costs, the patients will experience some of the burden as well. Based on this, none of the arguments or claims ENAASC makes in their application regarding the need of an operating room to provide a lower the cost of care is accurate and should not be considered.

Rationale 4: Ambulatory Surgery Trends and Cost Effectiveness of Outpatient Surgery in ASFs

On page 48-51 of the ENAASC CON application, the applicants attempt to prove the need for their proposed project citing several sources related to the shift in care from hospitals to ASC. ENAASC specifically states, *“This project to establish a Greenville ASF is responsive to the growing demand for outpatient surgery services in an ambulatory surgery facility setting, when clinically appropriate.”*¹⁵

First, as stated above, the proposed project is not anticipating a meaningful number of patients to move from the hospital setting to the ASC setting. As detailed above, ENAASC is proposing 94% of the proposed population to be served to move from an OBL setting to an ASC.

Second, ENAASC states,

“ASFs also offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same outpatient services; surgeries performed at ASFs cost about 60% of what they would cost in a hospital outpatient setting. ASFs provide cost-effective care that can save the patient, government, and third-party payors money for appropriate outpatient cases.”

and

¹⁵ ENAASC CON Question C.4 p.48

“A greater number of individuals nationwide are enrolled in consumer-directed health plans that use high deductibles to encourage patients to choose lower cost options for their care. Patients with these plans will be more likely to choose a freestanding ASF than a hospital for their outpatient surgical care and seek physicians and facilities that offer those lower costs. In addition, healthcare insurance plans are increasingly structured to steer physicians and patients toward lower cost options for care.”¹⁶

While this may be true, as proven above, the proposed project moves the majority of their patients to a HIGHER cost of care. As a result, the proposed project INCREASES costs by well over \$3.5M per year. Therefore, the argument that the ASC proposed in this application will reduce costs is inaccurate and should not be considered.

Thirdly, the applicants did not attempt in their argument to connect the recent trend of all types of outpatient surgeries to their proposed narrowly focused single specialty operating room and what impact it would have. ENAASC tried to make a correlation using Sg2 information related to general surgery by stating, *“For example, for general surgery, Sg2 forecasts a 3% decline in inpatient procedures and a 10% increase in outpatient procedures over the next decade.”¹⁷* While this might be true for general surgery, the example has no bearing on the applicants’ proposed project. Exhibit 4 provides current information from Sg2 and provides the most recent projections of IP/OP splits as well as Sg2’s disease states considered under each service line. The information clearly shows the primary population to be served in the ENAASC application (chronic kidney disease and end stage renal disease) does not fall in the “general surgery” service line, but rather the “nephrology” service line. According to Sg2, while outpatient nephrology is projected to increase 23.4%, inpatient is also expected to **INCREASE** 4.2%. Therefore, the argument that the ASC proposed in this application will address the need for a decrease in inpatient care and increase in outpatient care is inaccurate since **BOTH IP AND OP** are projected to increase for the proposed population to be served by the applicants and should not be considered.

Rationale 5: Service Area Demographics

ENAASC provides a lot of good information about the demographic, socioeconomic, and health incidence of eastern NC residents. ECU Health, which also serves the health care needs of the region, fully understands and appreciates the complex make up of the rural region we serve. However, as stated above, the proposed project is not intended to meaningfully impact the number of new patients served in the region, with 94% of the population proposed to be served coming from the applicants’ existing OBL facilities.

Also, ENAASC cites the drive time to the Raleigh Access Center (RAC) in Wake County (a related entity of the applicants – Azura Vascular Care) as a need for the proposed project. However, in the applicants’ own volume projections, there was no assumed volume shift from this facility. As a related entity to the applicants, there would surely be patient origin data at this

¹⁶ ENAASC CON Question C.4 p.50

¹⁷ ENAASC CON Question C.4 p.50

facility to show the volume of patients from eastern NC that went to RAC. Yet the applicants' did not provide any information to substantiate their claim. In fact, the proposed project will subject **MORE** patients to travel a substantial distance for care. In Section Q of the application (p. 129), ENAASC identifies the projected volume for the first three operating years (FY26-28) at their New Bern (Craven County) facility. The applicants assume that 35%, 40% and 45% of the New Bern facility location would shift to the proposed new ASC in Greenville (Pitt County). That equates to 600, 688, and 776 patients receiving care today in New Bern that will then have to travel to Greenville for care. By the third year of operating, that's 3 a day based on a 250 day normal operating year. The drive time distance between the two locations is 56 minutes according to MapQuest. Therefore, the proposed project will ultimately subject hundreds of existing patients currently receiving care close to home to an hour travel time to receive care. The claims that the proposed project will keep care close to home and reduce the need for travel is inaccurate and should not be considered.

In conclusion, ENAASC's application failed to prove a "need" for an operating room and the subsequent designation as an ASC. Specifically the application:

- Proved the need for more vascular access centers and better coordinated vascular maintenance and creation services (procedure rooms), but did not correlate the benefits to an ASC (operating room),
- Repeatedly cited the benefits of an ASC over hospital based services as proof of need, when in fact the overwhelming majority (94%) of the population to be served are the applicants' existing office based patients today,
- Ultimately has an incremental impact that is at best 241 patients per year (about 1 per day),
- Repeatedly cited the reimbursement disparities between OBL and ASC, which will actually increase the cost of CKD and ESRD care by \$3.4M per year minimum,
- Will increase the burden of travel on patients and reduce the ability for hundreds of patients to receive care close to home, and
- Repeatedly cites the applicants' experience in providing the proposed services, yet used the fact the proposed ASC is a "new facility" to not provide any actual historical information or facts to back up its claims, but instead relied on old studies based on VACs not ASCs.

Therefore, the ENAASC application should be found nonconforming with Criterion (3).

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

In Question G.2.a, ENAASC provided information to show the proposed project would not be duplicative of the existing providers in the service area. While the arguments may be true, the applicants did not address the duplication the proposed project has with a special need for dedicated vascular access operating rooms that is identified in the 2023 SMFP (Table 6C).

During the planning for the 2023 SMFP, in response to a petition for a special needs determination for a vascular access ASF, the DHHS Healthcare Planning Section, in their Agency Report to the Acute Care Subcommittee of the SHCC, created a methodology to determine the need for dedicated vascular access ORs in NC (Exhibit 2 p. 4-5). Specifically, the Agency Report determined that there was a need for one (1) dedicated vascular access operating room in each of the six (6) HSAs. The CON for the identified special need for HSA VI is October 16, 2023. It is reasonable to assume, that since the original petitioner for which the special need was identified is located in Rocky Mount (Nash County), that at least one CON application will be filed and approved to serve HSA VI.

The State clearly identified a need for one dedicated vascular access operating room in the proposed service area, yet approval of the proposed project would inevitably create two such centers. The applicants did not address the implications this unnecessary duplication of resources would create or why this proposal would meet a different need above and beyond the special need that was identified. Therefore, the application is not conforming to Criterion (6).

Criteria (18a) “The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”

ENAASC’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. As discussed in Criteria (3) above, the proposed project will increase the cost of care and subject hundreds of patients to additional travel cost. Therefore, the application is not conforming to Criterion (18a).

SECTION .2100 - CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

In Section Q, on page 132, ENAASC provided the following table to demonstrate the need for the number of operating room proposed (1).

Projected ENAASC Operating Room Need
CY2026 – CY2028

Year	2026	2027	2028
Total OP Surgery Cases	632	671	711
Average Case Time (Hours)	1.095	1.095	1.095
Total Surgical Hours	692	735	779
Group 6 Facility Standard Hours/OR	1,312	1,312	1,312
ORs Needed	0.53	0.56	0.59
ORs Needed (Rounded)	1.0	1.0	1.0

Totals may not foot due to rounding.

ENAASC calculated the need based on the assumption that since the ASC was technically a “new facility”, it could assume the 65.7 minute Group 6 Facility average case time without providing any information as to why this would accurately apply. As stated above and repeatedly throughout the application, the applicants’ demonstrate their “long standing” experience in providing the proposed services. So while the ASC designation might be “new”, even by their own volume assumptions, the majority of the patients will be existing patients from VCG and VCNB. The applicants did not attempt to provide the historical case times of existing patients to compare to the assumed 65.7 minutes.

For comparison, AVC cited two other NC facilities in NC to demonstrate experience in the proposed services as well as use as similar examples to the proposed project. These facilities are listed on Form O. The chart below shows the publically available 2023 Final and 2024 Draft SMFP. The table clearly shows that the two other facilities in NC that are comparable to the proposed project have average case time less than 65.7 minutes. In fact the weighted average case time is about half that at 36 minutes.

Facility	2023 SMFP (FY21 Data)		2024 Draft SMFP (FY22 Data)	
	Cases	Ave Times	Cases	AVC Times
Metrolina Vascular Access Center (MVAC)	-	-	260	60
Raleigh Access Center (RAC)	134	30	2,126	33
TOTAL	134	30	2,386	36

Clearly, this information is publically available and could have been used to justify using the 65.7 minute group average. However, the information shows that a lower average should have been used in the OR need methodology. Even the State assumed a 30 minute average case time based on RAC's 2023 SMFP average when determining the special need of dedicated vascular access operating rooms, not 65.7 minutes (Exhibit 2 p.5). Therefore, applying a more comparable case time of 36 minutes to the OR need methodology would not yield a need for an OR (see below). Therefore, the application is not conforming with 0A NCAC 14C .2103 Performance Standards.

Year	2026	2027	2028
Total Op Surgical Cases	632	671	711
Average Case Time (hrs)	0.60	0.60	0.60
Total Surgical Hours	379	403	427
Group 6 Facility Standard Hours/OR	1,312	1,312	1,312
ORs Needed	0.29	0.31	0.33
ORs Needed (Rounded)	-	-	-