Comments in Opposition to Carolina Vascular Care, LLC's Petition for an Adjusted Need Determination for a Single Specialty ASC Dedicated to Vascular Access in Nash County in the *2023 State Medical Facilities Plan*

COMMENTER

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INTRODUCTION

Carolina Vascular Care, PLLC filed a petition on the *2023 State Medical Facilities Plan* for a single specialty ambulatory surgical center dedicated to vascular access in Nash County. While Nash UNC Health Care ("Nash UNC") understands the needs of the particular patient population the petition purports to serve, it nevertheless contains a series of unfounded conclusions or, in some instances, lacks sufficient analysis or supporting information. As such, Nash UNC opposes the petition and requests that it be denied.

NASH UNC'S RATIONALE FOR OPPOSITION

Nash UNC believes there are numerous reasons to deny Carolina Vascular Care's petition. Most importantly, there is no evidence that the existing methodology fails to appropriately evaluate operating room need in Nash County, which shows no need for additional operating rooms, and to the contrary, a significant surplus of operating rooms. Approval of an additional operating room to be located in an ASC would be contrary to the standard need methodology and contrary to the purpose of CON Law, which recognizes that the development of unnecessary health care services "results in costly duplication…with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services," as stated in NCGS § 131E-175(4). While additional reasons for the denial of Carolina Vascular Care's petition are explored below, the SHCC's decision to deny the petition should ultimately rest on the lack of quantitative evidence of need for a vascular access ASC in Nash County.

1. **No Demonstrated Need in Nash County**

   In its petition, Carolina Vascular Care states that "there are small geographies, like the one centered around Nash County, that can support a specialized vascular access center." This claim is unsupported, given that the other two North Carolina ASCs dedicated *specifically* to vascular access are located in Wake and Mecklenburg counties, the two most populous counties in the state, according to the North Carolina Office of State Budget and Management. Nash County, meanwhile, is only the **30th** most populous county in the state.

County	Population	Rank
Wake	1,134,824	1
Mecklenburg	1,118,182	2
Guilford	542,255	3
Forsyth	383,274	4
Cumberland	334,776	5
Durham	325,751	6
Buncombe	270,224	7
Union	239,266	8
Gaston	228,618	9
Cabarrus	227,304	10
New Hanover	225,730	11
Johnston	217,723	12
Onslow	204,842	13
Iredell	187,694	14
Alamance	171,980	15
Pitt	170,059	16
Davidson	169,180	17
Catawba	160,924	18
Orange	149,013	19
Rowan	147,281	20
Randolph	144,359	21
Brunswick	137,530	22
Harnett	133,834	23
Wayne	116,989	24
Henderson	116,495	25
Robeson	115,863	26
Craven	100,534	27
Moore	100,126	28
Cleveland	99,779	29
Nash	95,027	30

Source: NC OSBM, July 2020 Estimate

More importantly, however, the two existing vascular access ASCs – Metrolina Vascular Access Care in Mecklenburg County, and RAC Surgery Center in Wake County – were both approved through standard need determinations in the *SMFP*[1]; in other words, the methodology showed a need for more operating rooms, and as such, both facilities were approved as part of meeting that need. In contrast, as Carolina Vascular Care itself points out, Nash County shows a surplus of 5.21 ORs in the *2023 SMFP*, and the Halifax/Northampton County service area shows a surplus of 4.05 ORs. In fact,

[1] RAC Surgery Center's CON application was approved in 2018; Metrolina Vascular Access Care's CON application was approved in 2019.

every facility in every county in Carolina Vascular Care's proposed service area shows capacity for additional surgical cases, with no need for the capacity proposed in the petition.

Furthermore, the physicians supporting the approved ASCs were already performing a significant number of office-based surgical cases and used that case volume as support for their respective ASCs, thereby further justifying the need. In contrast, in its petition, Carolina Vascular Care gives no data with regard to how many vascular access surgeries it has performed on patients from Nash or the surrounding counties. Indeed, the petition even states that "Carolina Vascular Care, PLLC has not investigated need in other geographies." Given this lack of data, Nash UNC believes that there is no basis for the SHCC to determine need for the petitioner's request.

Additionally, while the SHCC has created need determinations in the past specific to ASCs, such as the single-specialty demonstration projects in the *2010 SMFP*, few, perhaps none, have been created in rural areas of the state. These demonstration projects were limited to the three major metro areas of the state, specifically to prevent creating unnecessary duplication in rural areas and harming rural safety net providers. To that end, the SHCC entertained numerous petitions from a provider in Buncombe County, which is nearly three times as large as Nash County, for a special need for a single specialty ASC, but repeatedly denied the petitions[2]. The list of counties shown above includes many counties larger than Nash in which there are no ASCs, some of which are more than twice as large as Nash. Even if the SHCC were to determine that an ASC is needed in Nash County—which would be virtually unprecedented—it is not reasonable to believe that the most effective option is to create a limited specialty, one-OR ASC to serve the residents of Nash and the surrounding area. The petition simply provides no credible basis for creating a need for a vascular access ASC in Nash County.

2. Errors and Inconsistencies

Carolina Vascular Center's petition contains multiple incorrect or inconsistent statements:

- The petition states that "no hospital has offered to joint venture its excess inventory." Nash UNC has never been asked by Carolina Vascular Center whether it would consider a joint venture, and to the contrary, in discussions with Nash UNC's administration, Dr. Gupta indicated that he would receive better reimbursement in his own facility than in working with Nash UNC, which may reflect Dr. Gupta's financial interest, but not the need of the patients.
- The petition incorrectly states that Nash UNC has closed its outpatient Day Hospital ORs. While this was true during the height of the COVID-19 pandemic in order to prepare that space for a surge of COVID patients, Nash UNC's Day Hospital has since reopened and will continue to expand services there as operations warrant.
- The petition cites the need for a "trained, skilled vascular access nephrologist or a vascular surgeon who regularly performs the procedures," yet also acknowledges that "[t]here is no vascular access specialist in Nash and surrounding counties." This indicates a likely lack of success of the project, even if the petition were to be granted. Of note, however, general surgeons are trained in and regularly perform vascular access cases as needed.

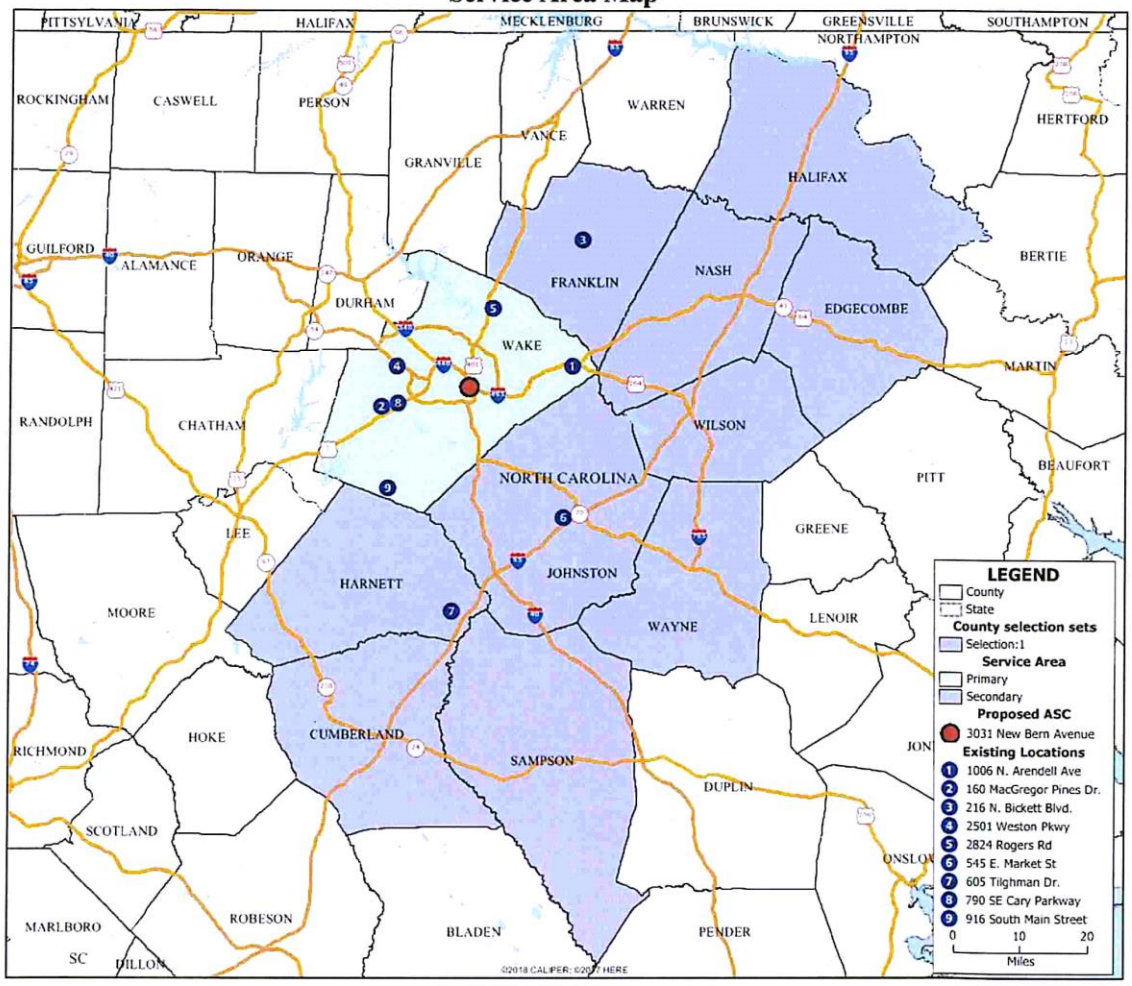
[2] https://info.ncdhhs.gov/dhsr/mfp/pets/2011/acs/0803_blueridge.pdf and https://info.ncdhhs.gov/dhsr/mfp/pets/2012/acsc/0802_buncombe_amsu.pdf and https://info.ncdhhs.gov/dhsr/mfp/pets/2013/acs/0801_amsu_petition.pdf and https://info.ncdhhs.gov/dhsr/mfp/pets/2014/acs/0731_buncombeamsu_pet.pdf and https://info.ncdhhs.gov/dhsr/mfp/pets/2015/acs/0803_buncombe_ssamsu_petition.pdf

- The petition attempts to make the case for a particular special need in Nash County; as noted above, however, there are only two ASCs dedicated to vascular access in the entire state. As such, 98 of the 100 counties in North Carolina are in the same situation as Nash County, many of which are much farther away from the two existing centers than Nash.
- The petition argues against using available ORs at Nash General Hospital, stating that they are "not designed to respond to the unplanned, though non-emergent nature of the dialysis vascular access procedures." Hospitals are, in fact, precisely equipped to respond to unplanned, though non-emergent procedures, and, as evidenced by the methodology in the *2023 SMFP,* Nash General Hospital currently has the available capacity to do so. Moreover, unlike an ASC or a physician office, a hospital is the only facility that provides 24/7 emergency care as needed; Dr. Gupta has asked for a transfer agreement with Nash UNC specifically to enable transfers in case of emergencies. Since Dr. Gupta has elected not to seek privileges at Nash UNC, patients with an emergency would be cared for by general surgeons or other specialists on staff, as they would with or without the proposed ASC.
- Finally, the petition claims that "[e]astern North Carolina has no health facility that offers vascular access procedures in an ambulatory surgical setting. The nearest is in Raleigh." Nash County is contiguous with Wake County; thus, even if the petition provided data to support the need for the facility in "eastern North Carolina," a location in a county that did not border a county with an existing vascular access ASC would be a more effective choice.

3. Sufficient Capacity in Wake County

As noted above, the closest existing dedicated vascular ASC is RAC Surgery Center, located in Wake County. RAC began serving patients in FFY 2021, and staffs five interventional nephrologists, one OR, and three procedure rooms. In its CON application, RAC included Nash County in its service area, and was approved, based on its initial projects, to serve a broad region, which includes the counties listed in Carolina Vascular Care's petition. The service area map from page 26 of the RAC application is shown below.

Figure 1
RAC Surgery Center, LLC
Service Area Map



However, despite being approved based on projections of serving 1,076 patients from Nash, Wilson, Edgecombe, Halifax, and Northampton counties in its operating and procedure rooms by its third year, RAC served only 10 patients from these five counties combined in FY 2021[3], or less than one one-thousandth (10 out of a projected 1,076) of the cases it projected from Nash and the other service area counties. Additionally, like Nash County, RAC Surgery Center also has an OR surplus (0.94 ORs), according to the *2023 SMFP.* Of note, the facility has only one OR, so it effectively has its entire OR capacity available for the patients the petition proposes to serve. The petition fails to demonstrate why it is reasonable to assume that patients from a broad service area would travel one hour or more from Halifax or Northampton counties to the proposed facility in Nash County, but patients from Nash County cannot drive less than one hour to the existing, underutilized facility in Raleigh that was approved, in part, on the premise that it would serve Nash and other counties in the region. In short, there is no evidence, as discussed above, that patients in the service area proposed in the petition lack access to vascular access surgery in an approved facility with available capacity.

[3] https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/05-Facility_Ambulatory-2022.pdf

4. Insufficient Responses to Questions from SHCC Members

The petition includes responses to a series of questions from SHCC members asked of Dr. Gupta. The petitioner's responses to these questions are inadequate, and do not support approval of this petition.

- Dr. Sandra Green asked "[h]ow many procedures/patients will you need to break even?" The petitioner responded that "[a]pproximately 600 patients visiting for 3 procedures per year."
    - No response was given regarding the financial feasibility of this number of procedures. Additionally, the petition provides no data to demonstrate that the facility can actually achieve 600 patients/1,800 procedures.
- Dr. Lyndon Jordan asked about emergency care for patients, specifically "after hours." The petitioner responded that patients "will be fit in the very next day if there's an emergency after hours."
    - Nash UNC already provides emergency services 24/7/365 to all patients in need of care, and the petition provides no evidence that the practice would provide emergency access for patients. Moreover, since Dr. Gupta has elected not to seek privileges at Nash UNC, he would not be able to care for those patients until after their discharge.
- Dr. Robert McBride asked if the ASC setting was "more economic than an OBL [office-based lab]? Will you provide other services/procedures?" The petitioner responded that ASCs "are more financially viable for vascular access procedures."
    - This response does not answer the question that Dr. McBride asked. As documented in the petition itself, the cost to patients and payors is higher in the ASC than in an office setting. Furthermore, there is available capacity in Wake County (at RAC Surgery Center, discussed above), within 45 minutes of Nash County residents, and the petitioner has not even attempted to establish an OBL in Nash County.
- Mr. John Young asked about capacity in the "hospital" (Nash General Hospital), specifically regarding "OR need." The petitioner responded that there is no specialist available at the hospital and that "busy scheduling puts patients at risk when they have to wait multiple days for treatment." Dr. Gupta himself is a specialist yet has not applied for privileges to perform cases at Nash UNC. In fact, Nash UNC understands that Dr. Gupta does currently hold privileges to practice *anywhere* within the proposed service area of the ASC, including Nash County.

5. Inability to Ensure Limited Scope of Services

Carolina Vascular Care's petition asserts that the special needs adjustment is *specifically* for an ambulatory surgical center "dedicated to vascular access." While Nash UNC does not question the validity of Carolina Vascular Care's intentions, there are nevertheless numerous examples of additional equipment, services, and facilities resulting from petitions requesting limited need determinations that are no longer limited in their scope as initially approved. A need determination for a multi-position (upright) MRI Scanner in HSAs IV, V, and VI, approved for Durham County is now a general MRI scanner (J-8107-08). A statewide need determination for a linear accelerator focused on prostate cancer in African-American men is now a general linear accelerator, located in Wake County. A demonstration project for an extremity MRI is now a 3.0T general use MRI in Wake County (J-7605-06); it has the second-lowest volume of any fixed MRI in the county, per the *2023 SMFP*.

There are additional examples specific to ASCs, as well. Previous petitions were approved for demonstration projects for ASCs limited to dental surgery, based on the assumption that such ASCs would not be approved in a normal, competitive CON application project. During the demonstration period, a three-year period, a dental-focused ASC was approved in Wake County, where one of the demonstration ASCs is located, through a regular, competitive CON review (Valleygate Surgery Center). Despite the assertions in the petition for a demonstration project for a dental-focused ASC, limited specialty ASCs can and are approved through the normal CON process – when there is a need for additional ORs in the service area.

While the petition requests the allocation of one operating room for purposes of developing its project, it should be noted that DHSR does not regulate what type of procedures can be performed in procedure rooms. In other words, if the petition is approved, Carolina Vascular Care could propose to develop an ASC with the restricted OR, but also with procedure rooms that would not be limited by the need determination or by DHSR, as they are not regulated like ORs are. Even if the approved applicant did not pursue this option, nothing would prohibit the approved applicant from, for example, selling the ASC to a provider who would then use the ASC for other types of cases, as described above. Given the numerous examples provided above of limited scope projects approved by the SHCC that are now available for general use, this scenario is not improbable.

6. Need for Special Consideration for Existing Providers in Rural Areas

The petition states that the proposed project would "place a life-saving service closer to a large number of rural residents." By its own admission, therefore, the ASC in question is intended to serve a rural area. The Access Basic Principle of the *SMFP*, however, specifically discusses the rationale for treating rural areas differently, stating:

> "*The needs of rural and small communities that are distant from comprehensive urban medical facilities merit special consideration. In rural and small communities, selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services. For this reason, methodologies that balance value, quality, and access in urban and rural areas may differ quantitatively."*

As stated above, the other two vascular access ASCs in the state of North Carolina are located in Wake and Mecklenburg counties, the two largest counties in the state. These are the two most "urban" counties, and are the only ones with approved vascular access ASCs. Given this, and given the Access Basic Principle outlined above, the rationale that led to the approval of vascular access ASCs in Wake and Mecklenburg counties should not govern the allocation of a similar facility in Nash County.

Additionally, certain points of the Findings of Fact in the CON Act warn against the development proposed in Carolina Vascular Care's petition. Specifically:

- Finding of Fact 4, which states: *"That the proliferation of unnecessary health service facilities results in <u>costly duplication and underuse of facilities</u>, with the <u>availability of excess capacity</u> leading to unnecessary use of expensive resources and overutilization of health care services"*
- Finding of Fact 6, which states: "*That <u>excess capacity of health service facilities</u> places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers."*

Given the special consideration merited in rural communities like Nash County against the type of selective competition proposed by the petition, and the example of the existing vascular access ASCs in Wake County, which, even as the largest county in the state, still has excess capacity, the petition would lead to unnecessary duplication of existing resources and excess capacity. As such, it is not warranted.

SUMMARY

Nash UNC supports the standard methodology for operating rooms and believes that it correctly shows no need for additional OR capacity in Nash County at this time. A need determination for a single specialty ASC in Nash County, particularly a vascular access ASC, would duplicate services that already exist in both Nash County (at Nash General Hospital), and nearby Wake County (at RAC Surgery Center LLC). Both of these facilities are easily commutable for anyone within the petition's proposed service area, and both facilities have a surplus of ORs as noted in the *2023 SMFP*. Furthermore, Carolina Vascular Care has provided no evidence or analysis that proves it currently or will in the future treat patients from its proposed service area; it remains unclear, in fact, whether its own providers have established a practice in the area. Nash UNC provides essential healthcare services as a safety-net provider to a rural population, and per the Basic Principles in the *SMFP*, needs special consideration of the impact this type of need determination would have on the hospital. Given these factors, the SHCC should deny Carolina Vascular Care's petition.

Thank you.