

**Comments in Opposition to Carolina Vascular Care, LLC's Petition  
for an Adjusted Need Determination for Two Operating Rooms  
In ASCs Dedicated to Vascular Access in HSA VI  
in the *2024 State Medical Facilities Plan***

**COMMENTER**

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**INTRODUCTION**

Carolina Vascular Care, PLLC filed a petition on the *2024 State Medical Facilities Plan* for two additional operating rooms to be located in specialty ambulatory surgical centers dedicated to vascular access in Health Service Area VI. UNC Health Nash opposes the petition and requests that it be denied.

**UNC HEALTH NASH'S RATIONALE FOR OPPOSITION**

In many ways, the petition repeats the same arguments put forth in its petition filed in 2023. While that petition was denied, the SHCC instead determined that there was a need for one vascular access operating room in each Health Service Area (HSA) across the state. Thus far, only two of those operating rooms are under review by the Healthcare Planning and Certificate of Need Section (HPCON Section); the remaining four will begin reviews later this year, including the review for HSA VI, which begins November 1. Thus, as a foundational matter, UNC Health Nash believes it is prudent to wait until the review on the operating room allocated for HSA VI is conducted before considering allowing even more operating rooms to be developed. The SHCC has previously denied petitions requesting special need determinations for services for which a need was already in the current *SMFP*, and UNC Health Nash believes it should do so again in this case<sup>1</sup>.

Moreover, while acknowledging that there is a pending need determination for a vascular access operating room in HSA VI, the petition asserts that two additional operating rooms are needed, each of which must be developed in an ASC, and each ASC must include only one of the operating rooms. In essence, the petition is requesting that the SHCC establish a need determination for two additional ASCs in HSA VI, each with only one operating room. This approach differs considerably from the SHCC's historical need determinations, which allocated operating rooms dedicated to vascular access procedures but without dictating in what type of facility they should be developed. In fact, the need determinations in the *SMFP* only rarely specify how the allocations should be developed; MRI scanners and other

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<sup>1</sup> See, e.g., the [Agency Report](#) on Raleigh Radiology's 2019 petition for a special need determination for a fixed MRI in Wake County, during a year in which a need determination already existed in Wake County for a fixed MRI scanner. The petition was denied.

technology, for example, can be developed in freestanding facilities, physician offices, or hospitals, and need determinations do not specify a preference. In contrast, this petition requests not only the allocation of two additional operating rooms, but that the operating rooms must be developed in an ASC that is dedicated to vascular access procedures—in other words, approval of the petition would mandate the development of additional ASCs for this purpose, which is a clear departure from the way in which the SHCC typically determines need for additional services like operating rooms.

The petition also states that it is attempting to allow all of the existing OBLs in HSA VI to develop an ASC for vascular access procedures, which is potentially precedent setting. While the SHCC has responded positively to petitions for special need determinations in the past based on the need of a particular facility or group, it is certainly uncommon to have need determinations to ensure that “everyone gets one,” as this petition suggests would be the outcome if approved. Based on the need determinations in the *2023 SMFP*, UNC Health Nash notes that the SHCC determined that some additional operating rooms are needed for vascular access procedures; however, that is far short of what the approval of this petition would do, essentially establishing a need to ensure that every existing OBL in a particular Health Service Area could establish a new, licensed ASC. If this petition is approved, it would suggest to the existing OBLs in the rest of the state that the SHCC will allocate an operating room for each of them, resulting in significant additional capacity across the state.

It is also apparent, as acknowledged in the petition, that vascular access ASCs can be and are developed through the normal need determination process. One such facility exists in Wake County, developed under a previous, competitive need determination, and another was proposed for Pitt County under the need determination pursuant to the standard methodology in the *2023 SMFP*. Clearly there are other options available for such facilities to be developed, including the pending exemption process from the statutory amendments in at least two counties in HSA VI.

Finally, as expressed in comments on last year’s petition, UNC Health Nash is concerned that the SHCC may allocate a need for operating rooms in an ASC “dedicated to vascular access procedures,” only to have that facility later become a general ASC, either by the original developers or a subsequent owner. While Carolina Vascular Care may intend to develop a facility dedicated to vascular access, there are 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 lowest volume of any fixed MRI in the county, per the *Proposed 2024 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 two operating rooms for purposes of developing ASCs dedicated to vascular access procedures, it is unclear as to how the SHCC or DHSR can limit an ASC to only performing certain types of procedures, nor how it would determine what is included in “vascular access

procedures” if it could. While there are statutes defining multispecialty surgical programs, there are none that would allow the proposed ASC to be developed as anything other than a general ASC, which would appear to limit DHSRs ability to restrict the types of procedures performed there. Moreover, even if the SHCC were to attempt to limit the development of the operating rooms to a “dedicated vascular access” ASC, as the SHCC is aware, DHSR does not regulate procedure rooms, including what type of procedures can be performed in procedure rooms. In other words, if the petition is approved, Carolina Vascular Care or any other provider could propose to develop procedure rooms that would not be limited in the types of procedures they can perform, because there is no CON or Licensure restriction on procedure rooms. 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.

#### **SUMMARY**

UNC Health Nash supports the standard methodology for operating rooms and believes that no additional need determinations as proposed in this petition are warranted at this time. It is particularly concerned that the type of restrictions on the ASCs proposed in the petition are ill-defined, and based on historical precedent, likely to be short-lived at best. The SHCC has already allocated a need for additional vascular access operating rooms across the state as part of special need determinations, and another vascular access ASC is currently under CON review for Pitt County, in HSA VI. Given these factors, UNC Health Nash believes that the SHCC should deny Carolina Vascular Care’s petition.

Thank you.