

**Acute Care Committee Agency Report
Adjusted Need Petition
for Two Operating Rooms in Dedicated to Vascular Access in an Ambulatory
Surgical Center in Health Service Area VI
in the 2024 State Medical Facilities Plan**

Petitioner:

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Request:

Carolina Vascular Care (CVC) requests a special need determination for two operating rooms (ORs) dedicated to vascular access (VA) in Health Service Area VI (HSA VI) in the *2024 State Medical Facilities Plan (SMFP or "Plan")*. The request specifies that the ORs be approved for ambulatory surgical centers (ASCs) within the service area.

Background Information:

Chapter Two of the *SMFP* notes that during the summer, the Agency accepts petitions that “involve requests for adjustments to need determinations in the *Proposed SMFP*. Petitioners may submit a written petition requesting an adjustment to the need determination in the *Proposed SMFP* if they believe that special attributes of a service area or institution give rise to resource requirements that differ from those provided by the standard methodologies and policies.” It should be noted that any person may submit a certificate of need (CON) application for a need determination in the *SMFP*. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The State Health Coordinating Council (SHCC) first received a petition regarding VA centers in 2017 with a request to exclude VA ASCs from the OR need methodology; the petition was denied. Also in 2017, Eastern Nephrology Associates (ENA) and Fresenius Vascular Care (FVC) submitted a summer petition for a demonstration project. The petition proposed two centers in each of the six health service areas (HSAs; see Appendix A of the *SMFP* for a listing of HSAs). The decline in reimbursement for VA procedures performed in physician-office-based laboratories (OBL) was a major basis for the petition. The petitioners argued that ASCs were the only viable option for continued non-hospital VA care. Based on the data available at that time, it did not appear that the number of VA patients within the state could support 12 VA centers. Additionally, the SHCC opined that the appropriateness and efficacy of providing VA procedures in an outpatient setting was not in question, and thus did not need to be demonstrated.

Certificates of need were subsequently issued to two VA ASCs in response to need determinations generated by the standard need determination methodology in the 2018 SMFP. Metrolina Vascular Access Care in Mecklenburg County was licensed on April 29, 2022. RAC Surgery Center in Wake County was licensed on March 19, 2021. Each ASC has one OR.

The SHCC received a third petition in 2018 from ENA and FVC requesting an adjusted need determination for one VA ASC in the Pitt/Greene/Hyde/Tyrrell service area. These petitioners again cited reductions in OBL reimbursement as a basis for the request. The Agency observed that reimbursements were in flux and it was unclear that rates were consistently being reduced in OBLs. The SHCC denied the petition and recommended that those interested in developing VA centers apply for ORs based on standard need determinations.

In 2022, the current Petitioners presented a fourth request that again highlighted the reductions in OBL reimbursements. That petition served as the impetus for the inclusion of a need determination for one VA-dedicated OR in each of the State's six HSAs in the 2023 SMFP. However, the Agency's recommendation was borne out of its estimation of the level of need for these services:

The Agency...acknowledges that that OBLs may be at continued financial risk. However, the Agency does not recommend approval of a dedicated VA OR in Nash County in the absence of evidence of a need.¹

Agency staff calculations estimated a level of volume that would equate to 14 VA ORs across the State “if all procedures were performed in a dedicated VA OR.”¹ By recommending an adjusted need determination for six ORs, the Agency was acknowledging that hospitals and OBLs will continue to be the only reasonably accessible option in some areas. The Agency also took a conservative approach because neither facility with an existing dedicated VA OR had been in operation long enough to provide the agency with a full year of data, and thus, utilization was unknown.

Analysis/Implications:

One of the Petitioner's rationales for the current request is that HSA VI has a larger population of dialysis patients. HSA IV serves 19% of the State's dialysis patients. Similarly, five of the six HSAs serve roughly 16 – 19% of the State's dialysis patients. Last year, HSA VI was home to only 55 (or 1.5%) more dialysis patients than HSA IV. To date, of the two ACSs with dedicated VA ORs in the State, only RAC Surgery Center (RACSC) in Wake County in HSA IV has been in operation long enough to submit a full year of data on its License Renewal Application. For 2022, the facility reported an average case time of 60 minutes. They also reported having performed 2,126 VA procedures. There are 3,591 VA patients in HSA IV. If we assume that each patient will undergo two VA procedures a year, then HSA IV patients needed a total of 7,182 procedures in 2022, and RACSC's VA OR performed about 30% of those procedures.

One aspect of the OR methodology is the assumption that one OR in a separately licensed ambulatory surgical center can be available for up to 1,312 standard hours per year. In 2022,

¹ NC Division of Health Service Regulation (2022). *Acute Care Committee Agency Report Adjusted Need Petition for the Nash County Operating Room Service Area in the 2023 State Medical Facilities Plan.*

dialysis providers in HSA VI reported serving 3,194 patients. Again, assuming that each patient will need two VA procedures a year, HSA VI patients will need a total of 6,388 procedures. Hypothesizing that 30% of those total procedures are performed in a dedicated VA OR setting, and last for an average of 60 minutes, then 1.5 ORs would be needed (Table 1).

Table 1. Estimated Ambulatory Vascular Access OR Volume in HSA VI

Final Ambulatory Case Times (Hours per Case)	1.0
Estimated Surgical Cases	6,388.0
30% of Total Procedures Needed in HSA VI	1,916.4
Standard Hours for 1 OR in a separately licensed ambulatory surgical facilities not in Group 5	1,312.0
ORs Needed	1.5

As noted above, the *2023 SMFP* includes a need determination for one dedicated vascular access OR in HSA VI. The Petitioner notes the CON application review date begins November 1, 2023, and the earliest a decision would be made is March 2024. The Petitioner also acknowledges that the *2023 SMFP* offers an additional opportunity for a vascular access OR. Based on the standard need methodology for the *2023 SMFP*, there is a need determination for 3 ORs in the Pitt/Green/Hyde/Tyrrell (Pitt) service area, which is in HSA VI. Eastern Nephrology Associates has submitted a CON application for one of those ORs so that it can develop a dedicated VA OR; these applications currently are under review. The Petitioner notes that this decision will be made, at the earliest, in November 2023. Because the *2024 SMFP* will have been voted on by the SHCC and on its way to the Governor by the time decisions are made, the Petitioner is concerned that if ENA is not awarded a CON for one of the ORs for the Pitt service area, the next opportunity to obtain an adjusted need determination will not occur until Summer 2024.

In summary, while HSA VI has more dialysis patients than the other HSAs, it is by a small margin. Approving this petition would create the possibility that four vascular access ORs are developed in HSA VI although there is no evidence to support that level of capacity.

Agency Recommendation:

Given available information and comments submitted by the August 9, 2023 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to include a need determination for two VA ORs in HSA VI in the *2024 SMFP*.