Acute Care Committee Agency Report
Adjusted Need Petition
for the Nash County Operating Room Service Area
in the 2023 State Medical Facilities Plan

Petitioner:
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Request:
Carolina Vascular Care requests a special need determination for one a single specialty ambulatory surgical center (ASC) with one operating room (OR) dedicated to vascular access (VA) in the Nash County service area in the *2023 State Medical Facilities Plan* (*SMFP*).

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 might 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 methodology uses growth in surgical procedures at a facility and service area population to determine needs. The Petitioner is correct that the Nash County service area is not likely to have a standard OR need determination in the foreseeable future due to both a stable population and the lack of substantial growth in procedures performed in Nash County. The only ORs in the service area are at Nash General Hospital, which has 13 shared ORs and one dedicated C-Section OR. The hospital has a surplus of 5.21 ORs in the Proposed 2023 SMFP. Even though the Petitioner proposes to locate in Nash County, they intend to serve a larger area. The Petition specifically mentions Edgecombe, Halifax, Northampton and Wilson, in addition to Nash. Taken together, these four service areas have a surplus of 23.39 ORs. (Halifax and Northampton comprise a multicounty service area because Northampton has no licensed ORs.)

The SHCC first received a petition regarding VA centers in 2017 with a request to exclude VA ASCs from the methodology; the petition was denied. The same petitioners submitted a summer petition in 2017 for a demonstration project. The petition proposed two centers in each of the six health service areas (HSA) (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 patients 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. The SHCC received a third petition in 2018 requesting an adjusted need determination for one VA ASC in the Pitt/Greene/Hyde/Tyrrell service area. The petitioner 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.

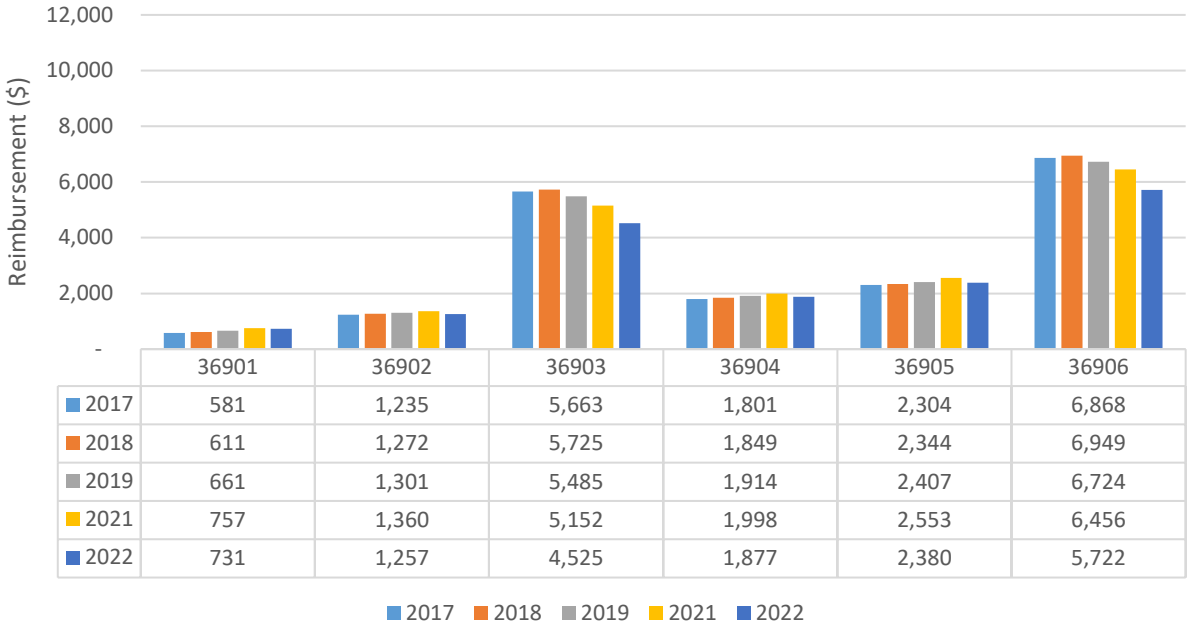
Certificates of need were subsequently issued to two VA ASCs in response to need determinations in the 2018 SMFP. Metrolina Vascular Access Care in Mecklenburg County was licensed on April 29, 2022. RAC Surgery Center in Wake County was licensed on March 19, 2021. Each ASC has one OR. Neither facility has been in operation long enough to provide a full year of data.

Analysis/Implications:
Like previous petitions, the current Petition cites reductions OBL reimbursements as a main motivation for the request. These changes began in 2017 when the Centers for Medicare and Medicaid Services (CMS) established requirements for procedures billed together more than 75% of the time to be bundled. As a result, commonly performed VA procedures experienced significant Medicare reimbursement cuts.[1] With these reductions have come increases in reimbursement for VA procedures at ASCs. These changes, however, were not consistent.

Figures 1 and 2 show changes in annual OBL reimbursement rates since 2017.[2] Rates for 2020 were not readily available. The first row of numbers below each chart shows the Healthcare Common Procedure Coding System (HCPCS) codes. The remaining rows are reported to be global national reimbursement rates for each procedure for each year. OBL reimbursement rates have remained relatively stable for most procedures. However, rates for the codes with the highest reimbursements, 36903 and 36906, have decreased by 20% and 17%, respectively. In contrast, rates for all ASC procedures except 36901 have fluctuated over this same time period. ASC reimbursement for 36903 and 36906 increased 39% and 16%, respectively.

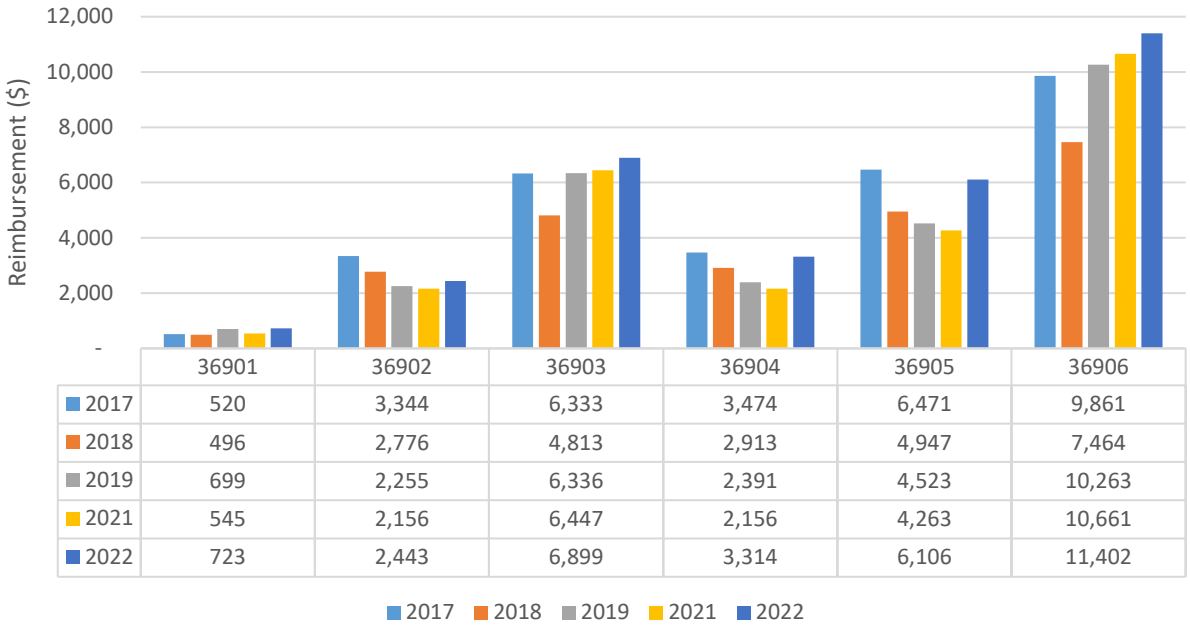
[1] McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022).
[2] *2017 and 2018 rates:* McGuireWoods (August 23, 2018). Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers. Proposed 2019 Medicare Reimbursement Changes May Negatively Impact Many Nephrologists and Dialysis Vascular Access Providers | McGuireWoods (accessed August 7, 2022). *2019 rates:* Litchfield, Terry (June 2019). Dialysis Access Coding Essentials, Recent Changes and Location Distinctions. *Endovascular Today* (18:6). Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions - Endovascular Today (evtoday.com) (accessed August 7, 2022). *2021 rates:* Greis, Jason S., Downing, Scott O., & Cilek, Jake A. (August 2021). CMS Proposes Steep Cuts to Office-Based Dialysis Vascular Access Reimbursement …Again! Bensch Healthcare+:Health Care & Life Sciences Client Bulletin. (accessed August 7, 2022). *2022 rates:* Petition.

Figure 1. OBL Reimbursement



	36901	36902	36903	36904	36905	36906
2017	581	1,235	5,663	1,801	2,304	6,868
2018	611	1,272	5,725	1,849	2,344	6,949
2019	661	1,301	5,485	1,914	2,407	6,724
2021	757	1,360	5,152	1,998	2,553	6,456
2022	731	1,257	4,525	1,877	2,380	5,722

Figure 2. ASC Reimbursement



	36901	36902	36903	36904	36905	36906
2017	520	3,344	6,333	3,474	6,471	9,861
2018	496	2,776	4,813	2,913	4,947	7,464
2019	699	2,255	6,336	2,391	4,523	10,263
2021	545	2,156	6,447	2,156	4,263	10,661
2022	723	2,443	6,899	3,314	6,106	11,402

HCPCS	Description
36901	Angiogram of Access (Fistulagram)
36902	Angiogram with Angioplasty
36903	Angiogram with Stent

HCPCS	Description
36904	Thrombectomy
36905	Thrombectomy with Angioplasty
36906	Thrombectomy with Stent

Litchfield (2019)[3] noted that

> The cut in the physician office payment was a combination of items, but the primary driver was the time for the procedure, which was significantly less than in the older codes. When the new codes came into the physician office fee schedule, it reflected that new value for the new codes. The valuation method for the ambulatory surgery center (ASC) and hospital outpatient department (HOPD) is different from that for the Physician Fee Schedule. For the HOPD, the procedures are assigned ambulatory payment classifications that are groupings of similar codes for endovascular procedures. The ASC payment is cross walked from the HOPD rate and discounted. This valuation methodology difference is why the new codes are paid very differently, and the rate increase is consistent with CMS methodology. Despite some concerns about growing utilization, this was not a signal from CMS to create ASCs nor was it a penalty for physician office surgery centers, but merely the way CMS prices new code.

Regardless of the rationale for the changes in reimbursement, the changes have, in fact, occurred. Many segments of medical care have experienced reductions in CMS reimbursement rates. It is unknown whether OBL VA procedures have received comparatively steeper reductions.

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.[4] 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.

The Agency acknowledges that access to VA services is needed throughout the state. Health Service Areas II through VI have about 3,400 dialysis patients residing in each HSA, while HSA I has about 2,000 patients.

The Agency also 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. Specifically, the SMFP does not have a need determination methodology for ASCs. Rather, need determinations in the SMFP are for ORs. CON applications specify the location of the proposed ORs (hospitals or ASC). The Petition does not indicate that Petitioner discussed access to VA services with any of the providers in the service areas they propose to serve, all of which have a surplus of ORs. We note that such a discussion does not necessarily imply that services would be provided in the manner that VA patients are currently normally seen in a hospital. Rather, a hospital may consider relocating an OR to an ASC in partnership with the Petitioner.

In considering alternatives to the Petitioner's request, the Agency investigated the potential utilization of dedicated VA ORs. In CY 2021, dialysis providers reported serving 19,302 patients. If we assume that each patient will need two VA procedures annually, NC patients will need a

[3] Litchfield, Terry. June 2019. Dialysis Access Coding Essentials, Recent Changes, and Location Distinctions. *Endovascular Today.* 18:6.
[4] Litchfield, 2019.

total of 38,604 procedures. This number of procedures calculates to 19,302 surgical hours, based on RAC Surgery Center's reported average case time of 30 minutes. The SMFP methodology anticipates that the average OR will be staffed and utilized at least 75% of the available time, for a total of 1,312 hours annually. Using this standard, it is possible that the state could potentially support 15 VA ORs (19,302/1,312 = 14.71), if **all** procedures were performed in dedicated VA ORs. This situation is highly unlikely, though, because there will always be areas where a hospital or OBL is the best or perhaps only reasonably accessible option.

Agency Recommendation:
Given available information and comments submitted by the August 11, 2021 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition to include a need determination for one VA ASC in Nash County in the *2023 SMFP*.

As an alternative to the submission of *ad hoc* petitions for VA ORs in specific service areas, the Agency recommends consideration of the following:

- Approval of one dedicated ambulatory VA OR in each of the six HSAs in the state, for a total of six VA ORs. VA ORs proposed pursuant to this need determination cannot be located in either Mecklenburg or Wake counties in light of the fact that there is a dedicated VA ASC with one OR in each of these counties. The VA OR can be located at an existing ASC, a proposed ASC, or on a hospital campus. If the OR is to be located at a hospital, it must be a dedicated ambulatory OR (i.e., in a hospital outpatient surgery department [HOPD]); and
- The VA ORs will be limited to serving dialysis patients; and
- CON-approved VA ORs and their procedures will be included in the standard OR planning inventory and methodology.