Acute Care Services Committee
Agency Report
Adjusted Need Petition for One Additional Operating Room Each in the Pitt/Greene/Hyde/Tyrrell and Craven/Jones/Pamlico Service Areas 2019 State Medical Facilities Plan

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Petitioners:
Eastern Nephrology Associates, PLLC
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Request:
Eastern Nephrology Associates and Fresenius Vascular Care (Azura) request that the *2019 State Medical Facilities Plan* include a need determination for one additional operating room (OR) each in the Pitt/Greene/Hyde/Tyrrell and Craven/Jones/Pamlico service areas for the purpose of providing vascular access (VA) procedures for dialysis patients.

Background Information:
Chapter Two of the State Medical Facilities Plan (SMFP) provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The need methodology consists of several steps to determine the number of ORs needed in each service area. The methodology first projects the number of surgical hours by multiplying the average case times reported by each facility by the hours for inpatient and ambulatory cases for the previous year (reporting year). This result is then multiplied by the projected population change between the reporting year and four years beyond the data year (projection year). The number of operating rooms required by the projection year is the result of dividing the projected number of surgical hours for the projection year by the number of hours per OR per year for each

facility based on assumptions used in the SMFP, while accounting for outliers. The final step calculates the number of additional ORs needed by subtracting the projected total number of required ORs from the current OR inventory for each health system in the service area. Deficits for all health systems are summed to obtain the need for ORs in the service area. Underutilized and closed facilities are excluded from the calculations.

Vascular access centers (VAC) provide the procedures to create, manage and maintain end-stage renal disease (ESRD) patients' vascular accesses. They may also provide other vascular and interventional radiological services not related to ESRD. There are three types of vascular access for ESRD – catheter, arteriovenous (AV) graft, and AV fistula. The National Kidney Foundation recommends the use of AV fistulas whenever feasible because they are associated with the lowest rate of complications.[1]

The Craven/Jones/Pamlico (Craven) service area has one facility offering surgical services, CarolinaEast Medical Center, which has a surplus of 9.36 ORs in the *Proposed 2019 SMFP*. The Pitt/Greene/Hyde/Tyrrell (Pitt) service area has one hospital, Vidant Health, and one ambulatory surgical center/facility (ASC), Vidant SurgiCenter. The ASC has a deficit of 0.40 ORs and hospital has a surplus of 5.51 ORs in the *Proposed 2019 SMFP*.

This Petition is the third petition submitted by Azura and one or more of its partners. In summer 2017, Azura and several medical practices (including Eastern Nephrology) petitioned for a demonstration project to develop two ORs in each of the six Health Service Areas in single-specialty VA ASCs to provide services to ESRD patients. In spring 2018, the same petitioners sought a change in the OR methodology to exclude VA ASCs from the OR inventory. Both of these petitions were denied.

Fresenius (Azura) owns and/or operates approximately 50% of the dialysis facilities in the state. Other major providers are DaVita with 37% of facilities and Health Systems Management with 9%. Various providers account for the remaining 4% of facilities. Fresenius also operates VACs, but DaVita and Health Systems Management do not.[2]

The Agency does not have systematic data on where VA procedures currently take place in North Carolina. VACs are not licensed, and the Agency collects no data on their procedures. The Agency's annual License Renewal Applications (LRA) do not identify vascular surgical procedures in sufficient detail to ascertain the type of procedure or patient. However, the 2018 ASC LRAs indicated that only about 0.2% of the total surgical procedures performed were vascular. Hospital outpatient departments (HOPD) also reported that about 0.2% of total procedures were vascular. Note that the HOPD figures do not include ambulatory procedures performed in shared ORs in a hospital.

[1] http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm
[2] DaVita owns Lifeline VACs in other states; the closest center to NC is in Norfolk, Virginia.

Analysis/Implications:
In general, the Petitioners propose that converting VACs to ASCs is necessary to "preserve dialysis patients' access to life-saving, high-quality care…." They offer several specific reasons to support this proposal:

- Dedicated VACs achieve better outcomes for patients.
- Creation of the initial VA in an ASC is less costly and leads to better coordination of care and patient outcomes.
- VACs must become licensed ASCs to remain financially viable.

Dedicated VACs Achieve Better Outcomes for Patients
The Petition cites evidence of greater patient safety in ASCs compared to hospitals. However, data supplied by the Petitioners assumes that all ESRD patients will receive all VA services in hospitals if VACs do not convert to ASCs. This eventuality seems unlikely because the physician office-based VACs will still have procedure rooms. It is unrealistic to expect that these room will cease being used for ESRD VA procedures entirely.

Access Creation in ASCs Would Improve Care and Lower Costs
The Agency acknowledges that initial access placement would be less expensive in an ASC than in a hospital. Also, if the surgeon/team who does the initial access creation is the same surgeon/team the patient continues to see, then coordination of care is more likely.

However, based on the numbers provided in the Petition, the increase in procedures due to initial access placement would be minimal. The ESRD population in NC is growing by approximately 3.7% annually. The Craven and Pitt VACs had a combined total of 1,524 patients in 2017. The Petitioners estimate that 70% of their patients would be suitable for initial access placement in an ASC. Therefore, in the first year, about 40 patients would be likely to receive initial access placement (1,524 * .037 = 56.39 new patients. 70% of 56 = 39.47). This number would increase by only about one patient a year for the next several years.

Conversion of VACs to ASCs is Necessary for Financial Viability
This issue has been a major impetus for the two petitions previously submitted by these Petitioners. The Centers for Medicare and Medicaid Services (CMS) implemented a bundled payments structure for vascular access procedures on January 1, 2017.[3] The Society for Vascular Surgery claims that a fee-for-service system produces an inherent incentive for physicians to treat immediate problems only. The purpose of bundling is to "target the highest quality vascular access method for a given patient" and then to "set up a bundled/global payment that incorporates placement of the vascular access as well a maintenance of this access over some defined period of time."[4] Changes to the 2018 fee schedule reduced the ASC reimbursements somewhat, but not substantially.

On July 25, 2018, however, CMS proposed permanent reductions in reimbursements for two of the most commonly performed VA procedures - diagnostic angiography of the dialysis circuit (CPT code 36902) and thrombectomy of the dialysis circuit with diagnostic angiography (CPT

[3] Persons with ESRD are eligible for Medicare regardless of age. Some ESRD patients are also covered by Medicaid.
[4] https://vascular.org/news-advocacy/svs-medicare-physician-payment-plan-2013

code 36905). The new rates will reduce the reimbursement for procedures performed in ASCs such that the rates will be identical to those if the procedures were performed in an office-based setting (83 FR 37046, p. 37156). It appears that the procedures covered by these two codes account for about two-thirds of the total VA case time reported in the Petition; however, it is not possible to determine the exact proportion, because the Petition did not use CPT codes to identify the procedures reported at the Azura facilities. It is important to point out that the new rates are proposed only; they are not final. Even so, this situation does speak to the fluid nature of the CMS reimbursement policies discussed in past Agency reports as part of the rationale for denial of the previous petitions.

Summer petitions must address issues unique to a specific area of the state. The Petition accurately states that, "… the differential between physician office rates and ASC rates remains significant" (p. 8). This statement refers the reader to Exhibit C, which compares CMS Medicare reimbursements between the ASC rate and the CMS Hospital Outpatient Prospective Payment System (HOPPS) rate. This comparison does not speak to their claim, however. To show that the reimbursement system is overly burdensome in the service areas that are the subject of the Petition, the Petitioners should have shown a breakdown of procedures by CPT code, so that the reader could examine the reimbursement structure for the Pitt and Craven service areas separately.

Finally, the Agency Report prepared in Spring 2018 noted the surplus of ORs in ASCs statewide. In it, the Agency suggested that VACs could partner with existing ASCs to serve ESRD patients. In the current Petition, the Petitioners propose to convert two VACs into ASCs in two OR service areas where it is not possible to partner with an existing ASC. In the Craven service area, no ASCs exist; in the Pitt service area, the ASC does not have surplus ORs. However, both of these service areas have a substantial number of surplus ORs at the hospitals. The Petitioners provide no information to about attempts to partner with the hospitals in these service areas to relocate surplus ORs to develop a new ASC.

The Agency recognizes that the Petitioners' preferred business model is to convert their existing VACs into ASCs. Perhaps by choosing an area in which partnering with an existing ASC is not possible, one may think that the Agency's concerns have been addressed. However, the Agency also noted that Petitioners could choose to apply for CONs under the need determinations in the *2018 SMFP*. Indeed, on August 15, 2018, Fresenius Vascular Care Raleigh MSO, LLC, affiliated with Azura, and North Carolina Nephrology, PA, through a wholly-owned subsidiary, filed a CON application pursuant to the need determination in the *2018 SMFP* for six ORs in Wake County. The application proposes to turn an existing unlicensed VAC into a licensed ASC. There are eight other competing applications in Wake County.

Simply licensing a VAC as an ASC does not improve patient access to VA services. Arguably, the change would be invisible to the patient, unless the individual's co-pay increases. It would have been preferable to develop a new ASC in a part of the service area that does not currently have VAC services.

Agency Recommendation:

The agency supports the standard methodology for ORs. In previous reports, the Agency expressed clear preferences for how VACs might develop ASCs. However, this Petition did not choose any of these options that were available in these service areas. Therefore, given available information submitted by the deadline and in consideration of factors discussed above, the agency recommends denial of the petition.