Acute Care Services Committee
Agency Report
Adjusted Need Petition for
Demonstration Project for Vascular Access Ambulatory Surgery Centers for End-Stage Renal Disease Patients in the 2018 State Medical Facilities Plan

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Petitioners:
American Access Care of NC, PLLC
Eastern Nephrology Associates, PLLC
Metrolina Nephrology Associates, PA
North Carolina Nephrology, PA
Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care

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Request:
Azura Vascular Care and four medical practices, listed above, request an "…adjusted need determination for a demonstration project to develop two operating rooms in each of the six Health Services Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary…" for end-stage renal disease (ESRD) patients. A vascular access is necessary to enable the dialysis machine to access the patient's blood for filtration and return to the patient.

Background Information:
Chapter Two of the *North Carolina Proposed 2018 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 policies and methodologies in the spring. The planning process and time allow for submission of petitions requesting adjusted need determinations 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 new need methodology consists of several steps to determine the number of ORs needed in each OR service area. The methodology projects the number of surgical hours by first multiplying the average case times reported by each facility by the hours for inpatient and ambulatory cases for the previous year (data year). This result is then multiplied by the projected population change between the data year and four years beyond the data year (target year). The number of operating rooms required by the target year is the result of dividing the projected number of surgical hours for the target 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.

Vascular access centers provide the surgical creation, management and maintenance of 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 impetus for the petition is that the Centers for Medicare and Medicaid Services (CMS) instituted a bundled payments structure for vascular access procedures on January 1, 2017. 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."[2] The Petitioner asserts that because of this change, "existing physician office-based vascular access centers will no longer be sustainable if they cannot become licensed ambulatory surgical facilities and will close, forcing ESRD patients into hospitals" (page 1).

Analysis/Implications:

Impact of New Regulations on Vascular Access Centers

Medicare is the primary or secondary coverage for approximately 84% of ESRD patients.[3] CMS implemented bundled payments for dialysis services and supplies in 2011 to help control costs.[4] The specific goal of the bundled payment structure for vascular access is to have a zero percent impact on nephrology reimbursement overall.[5]

[1] http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm
[2] https://vascular.org/news-advocacy/svs-medicare-physician-payment-plan-2013
[3] United States Renal Data System. *2016 Annual Data Report.* Data as of 2014, includes patients receiving dialysis as well as those who have had kidney transplants. https://www.usrds.org/2016/view/Default.aspx
[4] https://www.usrds.org/2016/view/v2_11.aspx
[5] Riley, James B. & Greis, Jason S. (2016). Practical Considerations for Medical Practices Considering Converting their Vascular Access Centers into Medicare-Certified Ambulatory Surgery Centers. Chicago: McGuireWoods LLP.

Several sources have estimated that the potential impact of the new regulations will decrease revenue by an average of 30-40% for vascular access procedures for ESRD patients, when performed in a physician's office.[6] Moving vascular access procedures from a procedure room in a medical practice to a hospital setting will undoubtedly incur significant costs to Medicare. Doing so may also put patients at greater risk of health care-associated infection. Therefore, development non-hospital-affiliated ORs is one solution being sought.

The CMS bundled payment structure is not unique to vascular access centers. While physician practices will undoubtedly need to make adjustments, converting vascular access centers to ambulatory surgical facilities (ASF) represents only one option. For example, many vascular access centers perform procedures unrelated to ESRD. An ASF dedicated to the ESRD niche may not be the most reasonable medical or business option for these centers.

Potential Need for Dedicated Vascular Access ASF

Apart from any motivations for a demonstration project, it is necessary to consider whether the proposed ORs can be financially sustainable. The Petitioner discusses two types of care to be provided in the proposed facilities: initial vascular access and vascular access intervention. According to the Petitioner, it is standard practice to perform the initial vascular access in a hospital, because the procedure is not reimbursed in a doctor's office. The most common type of procedure in the proposed ORs would be vascular access repair. When intervention is needed, it often must occur within a day or two after an access failure or after discovery of an infection or other issue.

The Petition (page 5) notes that "the average dialysis patient experiences 2.2 to 2.5 access interventions per year." The Petition (page 7) states that Azura-affiliated practices performed 11,050 procedures on 5,823 patients in North Carolina in 2016. This represents an average of 1.9 procedures per patient. It is unknown whether 5,823 represents the total number of patients associated with these practices. While an average of two procedures per patient were performed on those patients who needed intervention, it is not possible to estimate the proportion of total ESRD patients who need intervention in an average year. Based on other information in the Petition, failure rates appear to be considerably less than 10% annually.

The Petition further states that Azura practices cover 79 of the 100 counties in the state. If coverage of 79 counties indicates inclusion of roughly 79% of the total ESRD patients, then it is reasonable to increase the 5,823 by 20% to estimate that a total of about 7,000 patients would need intervention annually, for a total of approximately 14,500 procedures (at two per patient). The Petition provides no information on the average length of vascular access procedures performed in Azura-affiliated practices. Upon initial examination, the number of prospective patients may not be sufficient to support 12 new ambulatory surgical ORs dedicated specifically to the needs of ESRD patients. The July 1, 2017 North Carolina Semiannual Dialysis Report shows that dialysis centers served 17,387 dialysis patients statewide as of December 31, 2016. An OR in an ambulatory surgical facility requires 1,312.5 surgical hours per year for full utilization. Only if most of the 17,387 ESRD patients were to require vascular access repair or replacement annually

[6] Neumann, Mark E. (2016, September 29). *Nephrology: News & Issues.* Proposed bundling in Medicare Fee Schedule could cut interventional access revenue up to 40%.

could 12 ORs be supported, assuming the procedure lasted an average of 60 minutes. The Agency did not have an enough data to answer some of the most important questions in analyzing this request. These include:

- What is the breakdown of vascular access type among ESRD patients in North Carolina?
- What proportion of ESRD patients in North Carolina are likely to require vascular access intervention in any given year?
- Among patients who require intervention, on average, how many times a year is intervention required?
- What are the most common types of interventions, and in what proportions?
- What is the average case time for interventions currently conducted in procedure rooms?
- What potential proportion of new ESRD patients may be suitable to have initial vascular access performed in an ASF?

Agency Recommendation:

The Agency supports the new methodology for OR need determination. However, before recommending demonstration projects, the Acute Care Services Committee and the SHCC carefully examine the pertinent issues and provide opportunities for input from subject area experts and the public.

Historically, the SHCC has taken one full cycle for consideration of complex planning requests. For example, before approving the Single Specialty Ambulatory Surgical Facility Demonstration Project, the SHCC established a workgroup that began consideration of the demonstration in November of 2008. The project was approved for implementation in the 2010 SMFP. More recently, consideration of the Dental Ambulatory Surgical Facility Demonstration Project began in March 2016, with implementation in the 2017 SMFP.

Sufficient time does not exist for proper consideration of the proposed demonstration project for the 2018 SMFP. With these considerations in mind and given available information and comments submitted by the August 10, 2017 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition.