DELIVERED VIA EMAIL AUGUST 10, 2017

August 7, 2017

Christopher Ullrich, M.D., SHCC Chair
Sandra Greene, Dr.P.H., Acute Care Service Committee Chair
North Carolina State Health Coordinating Council and Acute Care Service Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

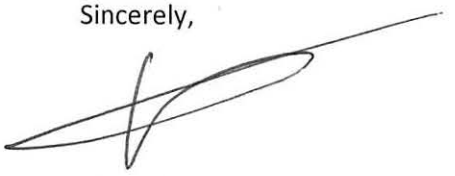
Re: Surgical Care Affiliates, Inc. Comments Regarding the Petition for an Adjusted Need Determination for 2018 State Medical Facilities Plan Demonstration Project – Vascular Access Ambulatory Surgery Center for ESRD Patients

Dear Dr. Ullrich and Dr. Greene,

Surgical Care Affiliates, Inc. (SCA) appreciates the opportunity to comment on the Petition submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, North Carolina Nephrology, PA, and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (the Petitioner) for an adjusted need determination for a demonstration project to develop two operating rooms in each of the six Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients' vascular accesses.

During your review, I urge you to consider the unwarranted and unsupported need for operating rooms dedicated to vascular access procedures currently served in physician office settings.

Sincerely,



Cory Hess
Vice President, Operations
Surgical Care Affiliates, Inc.

Attachment(s)

Request to Deny Petition for an Adjusted Need Determination for *2018 State Medical Facilities Plan* Demonstration Project – Vascular Access Ambulatory Surgery Center for ESRD Patients

Surgical Care Affiliates (SCA) is urging the State Health Coordinating Council (SHCC) to deny this Petition. The petition provides no evidence to support the need for any single specialty freestanding ambulatory surgical centers (ASC) dedicated to vascular access in North Carolina. Moreover, the petition has multiple other unsupported claims.

No Evidence to Support Need for Demonstration Project

The Petition fails to provide any clinical evidence to support the claim that vascular access procedures currently performed in office-based settings, now require a licensed operating room (OR). In fact, The Petition points to the success and efficiency of office-based vascular access centers serving end-stage renal disease (ESRD) patients:

> *"…since the early 2000s, dedicated, physician office-based vascular access centers have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within hours." (p5)*

As stated by the petitioner, the care required to maintain a patient's existing vascular access can be performed in a physician's office.

The only discussion provided to support the Petition's request is the decline in Medicare reimbursement payments for office-based vascular access procedures. Any procedure performed in a freestanding ASC is reimbursed a "facility fee." The Petition is effectively asking for an offsetting increase in reimbursement for Fresenius Vascular Care, Inc and four nephrology practices. The Petition provides no detail on the financial impact of the recent reduction in Medicare payment. It provides no reasons why the petitioners could not apply for operating rooms already included in the Proposed 2018 SMFP. The Petition alludes to four existing centers and indicates that approval would "also enable the development of new centers in areas not yet served." (p5) It provides no data to support the need for those new centers or to describe where they would be located.

The Petition does not explain why North Carolina needs two operating rooms in each of Health Service Area.

Misleading Claims

In addition to providing no evidence that vascular access procedures currently performed in office-based procedure rooms, now require a licensed OR, the Petitioner also makes several speculative assertions.

The Petition claims vascular access office-based procedure rooms are no longer sustainable:

> *"…office-based vascular access centers, and existing office-based centers will ultimately close." (p8)*

However, the Petition provides no evidence that a decline in Medicare reimbursement is the direct cause of the closure of vascular access centers in other states. The Petitioner implies that insurance companies will support the relocation of vascular access procedures currently performed in office-based procedure rooms to an ASC OR and would pay the facility fee. The Petition provides no supporting documentation. The Petitioner includes no information regarding how insurance companies would cover these procedures in an ASC OR.

The Petitioner also suggests that existing ASCs cannot accommodate these procedures:

> *"Further, traditional non-ESRD focused ASCs suffer from many of the drawbacks of hospitals, and are therefore not a viable alternative for providing vascular access care. Non-vascular ASCs are less accessible to ESRD patients (which are approximately 80% Medicare and/or Medicaid) because ASCs typically rely on a high percentage of higher-reimbursing commercially insured patients and frequently have treatment criteria that rule out this patient population. For example, many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. Critically, traditional ASCs also schedule cases well in advance and cannot accommodate the urgent presentation of dialysis vascular access cases." (p8)*

This is completely unfounded. As mentioned by the Petitioner, a majority of ESRD patients are Medicare beneficiaries which the Petition implies, reimburses enough for these cases to be attractive to an ASC. Ambulatory surgery centers do accommodate work-in cases. SCA facilities regularly accommodate add-on cases. In certain situations, if a vascular ESRD surgeon performs procedures regularly, SCA would dedicate a procedure room to vascular access procedures. Moreover, the Petitioner claims non-ESRD focused ASCs are less accessible to ESRD patients, yet it provides no evidence; no documentation showing refusal of access was included with the Petition.

The petition is confusing:

> *"…Petitioners' patients' vascular accesses are surgically created at hospitals – not because the services require a hospital setting or inpatient-level care, but because vascular access creation procedures are generally not reimbursed in the office setting." (p7)*

Overall, the Petition makes a poor distinction between the creation of the access and the maintenance and repair of the access. On one hand, they say creation only happens in hospitals, on the other, is says is can be performed in ASC. The Petition does not address why the Petition's affiliates are not currently performing vascular access creation procedures in ASCs.

By discounting freestanding ASCs as a viable option for these patients, the Petitioner is completely disregarding existing ASCs with available capacity. SCA has ASCs in HSA IV, V, and VI, all of which have capacity for accommodating vascular access procedures in addition to their current caseloads. The Petition also fails to take into account the 30 ORs in the 2018 SMFP, which will add capacity in HSA I, II,

and III. Between SCA facilities, and the need for more ORs in the 2018 Plan, there is ample capacity for these procedures, which permits an alternative other than the hospital.

The creation of a vascular access by a vascular end-stage renal disease (ESRD) specialist requires common surgical center equipment (i.e., x-ray and fluoroscopy C-arms) and trained physicians/staff, but it rarely requires a licensed operating room. General anesthesia is often avoided during the creation of a patient's vascular access due to the prevalence of comorbid conditions within the ESRD patient population.[1] A patient with multiple co-morbidities requiring general anesthesia is best served in a hospital setting. As a result, local anesthesia is commonly used during vascular access.[2] A procedure room outfitted for vascular access procedures can support a vascular access procedure that requires local anesthesia. The Petition fails to make a persuasive argument to justify up to 12 new ORs in NC. Thus, the need for specialized ESRD ASCs across the state is unjustified.

[1] http://jasn.asnjournals.org/content/14/12/3270.full.pdf+html
[2] https://academic.oup.com/bjaed/article/14/3/119/341072/Anaesthesia-for-vascular-surgery-of-the-upper-limb