August 9, 2018

Sandra Greene, D.Ph., Chair Acute Care Committee
North Carolina State Health Coordinating Council
c/o NC Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704
DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Re: **Azura Petition for Vascular Access Ambulatory Surgical Facilities**

Dear Dr. Greene and members of the Committee:

The North Carolina Healthcare Association represents 130 hospitals and health systems in North Carolina, and we thank you for the opportunity to comment on the Petition from Eastern Nephrology Associates and Azura. The petitioner requests adjustments to the operating room need methodology in the Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico service areas, requesting a need determination for one operating room in each service area to provide Vascular Access Procedures. NCHA recommends disapproval of the petition for the following reasons:

- The Fresenius Seamless Care of Central North Carolina website lists Eastern Nephrology Associates, PLLC as participants in an ESRD Seamless Care Organization (ESCO) in the Medicare Comprehensive ESRD Care model. According to CMS' Comprehensive ESRD Care Model, *ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their aligned ESRD beneficiaries*. The movement of vascular procedures from office settings to ambulatory surgery centers contradicts the cost-savings goal of the program and is inconsistent with participation in the ESCO.

- The petitioner is pursuing a pathway for an ambulatory surgery center to provide vascular access creation procedures that are now performed in hospitals and vascular access maintenance procedures that are now performed in physician office settings. The petition reports that 3,660 vascular access procedures were performed in 2017 but does not discuss how many of those are access creation procedures performed in hospitals or the less complicated access maintenance procedures. Therefore, neither the impact on area hospitals nor the need for a higher level of care for maintenance procedures has been supported, and the petitioner has not demonstrated that the adjustment would not duplicate existing health resources.

- The petition argues that quality in Vascular Access Centers is superior to alternatives but does not explain why those centers must be licensed and certified as ambulatory surgery centers, other than for reimbursement purposes. Approval of the petition would establish an adjustment to the need methodology allowing for the development of more costly settings, which is not consistent with the Basic Principles of the State Medical Facilities Plan; Safety/Quality, Access and Value.

- Similarly, approval of this petition could set a troubling precedent, signaling that a provider performing office-based, minimally invasive procedures could seek dedicated ASC operating rooms if the reimbursement levels were to drop. This could impact other specialties, including orthopedics, dermatology, pain management, wound care, radiology, ophthalmology, etc., which perform some level of office based minimally invasive procedures as part of their practice.

- The Centers for Medicare and Medicaid Services (CMS) *Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems*, found in the July 31 Federal Register, includes two of the petitioner's listed vascular procedures, diagnostic angiography of the dialysis circuit (36902) and thrombectomy of the dialysis circuit with diagnostic angiography (36905). Both procedures are proposed by CMS to be designated permanently as office-based procedures for 2019 (See page 37155-6). According to the CMS analysis, "these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices." CMS' proposal, if adopted, would significantly change reimbursement rates for these procedures (from those proposed in Exhibit C of the petition) and likely remove any financial benefit to organizing vascular access centers as ambulatory surgery centers.

- The Proposed 2019 SMFP Table 6B indicates a surplus of operating rooms in both the Pitt/Greene/ Hyde/Tyrell (-9.36) and Craven/Jones/Pamlico (-5.11) service areas.

- This petition is closely linked to the needs of an extremely frail population in urban and rural parts of North Carolina. Yet the petition lacks documentation of efforts to collaborate with rural and other hospitals, especially those where dialysis access creation procedures are now performed, to better coordinate vascular services in local communities.

- For these reasons we believe the Azura petition fails to meet the Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value, and should not be approved.

Thank you for your consideration of our comments. Please contact Mike Vicario (mvicario@ncha.org) or myself if you have questions or concerns.

Sincerely,

Stephen J. Lawler
President
North Carolina Healthcare Association

Cc: Christopher Ullrich M.D., SHCC Chair