March 22, 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: **Petition Regarding Methodology Exclusion for Vascular Access Ambulatory Surgical Facilities**

Dear Dr. Greene and members of the Committee:

NCHA represents 130 hospitals and health systems in North Carolina, and we thank you for the opportunity to comment on the Petition received by the State Health Coordinating Council on March 8 proposing an exclusion to the operating room need methodology.

The applicant, Azura, currently operates vascular access centers in several office locations in the state. Their petition indicates that recent CMS regulatory and reimbursement changes will impact its Medicare/Medicaid Vascular Access Center's financial viability. The proposal is to establish an exemption allowing those centers to become single specialty Ambulatory Surgery Centers exclusively for those procedures. This would permit those centers to become licensed and certified and to bill Medicare/Medicaid for facility and professional related fees.

NCHA does not support the petition for the following reasons:

1. The Single Specialty Ambulatory Surgery Facility Demonstration Project from the 2010 SMFP encourages the State Health Coordinating Council to consider whether expansion of single specialty ambulatory surgical facilities should occur beyond the original three demonstration sites. Over the past years the Council has been presented with numerous petitions requesting single specialty carve-outs for specific procedures. In addition to the initial project's three centers, current law/rule has provisions for gastrointestinal endoscopy and for Dental Single Specialty Ambulatory Surgical Facilities. NCHA believes that it is premature to establish another open Single Specialty Ambulatory Surgery category before the State Health Coordinating Council has reviewed the results of the original Demonstration Project and made its recommendations.
2. The 2018 SMFP includes need determinations for 30 new operating rooms in several counties where the applicant has vascular care centers. The petitioner should consider applying for a certificate of need under that process.
3. The petition states that a January 2017 lowered fee schedule (by 30% to 40% in physician offices) for vascular access procedures is largely behind the need to develop new surgery centers. However, cuts in ambulatory surgery center reimbursement are also reported. The petitioner acknowledges that the described vascular procedures can be safely provided in a physician office or clinic setting. Approval of the petition would establish an exemption that facilitates the development of more costly settings in licensed and certified ambulatory surgery centers. Therefore, the petitioner's request for an exemption is not consistent with the Basic Principles of the State Medical Facilities Plan; Safety/Quality, Access and Value.

4. The CMS Comprehensive ESRD Care (CEC) Model, which runs until December 20, 2020, is an Accountable Care model that includes Fresenius providers in North Carolina. The model includes shared savings payments and risk for certain ESRD providers, but also "will lead to better health outcomes for Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B," by "working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive." A review of the CEC program does not speak to the role of ambulatory surgery centers in providing care and it appears the petitioner's request for ambulatory surgery center development could undermine the expectations of the CEC program. Regardless, we believe that it should have been discussed in the petition's explanation of the payment changes and the coordination of ESRD services.
5. The petitioner has not demonstrated the impact it would have on existing facilities. While indicating that some of the patients discussed in the petition would continue to be served in hospitals, it is not clear how many patient procedures would be relocated from hospital settings. The March 7 SHCC meeting discussion focused on the potential for planning policies to harm vulnerable providers, which includes hospitals located in rural parts of North Carolina. This petition proposes a policy change that could enable new ambulatory surgery centers to begin providing serving patients now being served by these or any other hospitals, an unnecessary duplication of services.

   This petition is also closely linked to the needs of an extremely frail population in both 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. NCHA does not support this petition.
6. According to the most recent Semiannual Dialysis Report there are 17,789 ESRD patients in the state, and approximately 22% of them live in the counties where Azura VACs are currently located. The petition suggests as many as 35,578 ambulatory procedures could result, occupying 26 ORs in the state. However, a substantial ESRD population lives in areas where there are no current vascular access centers or population density for a proposed new ambulatory surgery center. The petition does not address the consequences for patients living in those areas if vascular access centers close.
7. The CON law and regulatory process has no mechanism for the audit of CON approved projects to ensure that they are providing only the services for which they are approved and serving the population and payer mix proposed in their certificate of need application.

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, SHCC Chair