State Health Coordinating Council Christopher Ullrich, MD, Chairman c/o Healthcare Planning and Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Petition for Change to Basic Methodology 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.

Dear Dr. Ullrich.

I am a partner of Eastern Nephrology Associates and medical director of our vascular access center, Azura Vascular Care of Greenville, NC. Eastern Nephrology Associates is a nephrology practice with 16 general nephrologists, 3 interventional nephrologists, and 1 interventional radiologist. We are writing to support the above-referenced petition to remove dedicated vascular access operating rooms from the operating room need methodology, or alternatively for a demonstration project to develop dedicated vascular access ORs in each health service area statewide.

Eastern Nephrology Associates currently has 1250 ESRD patients who must have a functioning dialysis access to receive hemodialysis to replace their lost kidney function. Eastern Nephrology Associates currently operates an unlicensed, office-based vascular access center in Greenville, NC. Since 2006, our office-based center has allowed us to manage the vascular access care not only for all of our dialysis patients, but also for patients managed by other nephrology practices in eastern, NC, from the South Carolina to Virginia border.

We support the petition and the development of licensed ambulatory surgery centers with special purpose ORs for vascular access procedures outside the general OR need methodology, similar to the way hospitals can apply to develop dedicated c-section ORs today. Dialysis patients have unique and complex needs that benefit greatly from the coordinated care that a vascular access center provides, and hospital surgical departments and traditional ASCs are not well suited to this population. Benefits of our vascular access center include prompt care, continuity of care, and quality care in a complex healthcare environment which is increasingly placing an emphasis on cost reduction.

It is our experience that the cost of performing dialysis access procedures in the office setting now exceeds Medicare reimbursement for those procedures. Physicians who perform dialysis access procedures cannot sustain the loss from these procedures indefinitely. We agree with the petition that unless vascular access centers can be licensed as ASCs, these procedures will ultimately be referred to hospitals, which are reimbursed at much higher rates than either physician offices or ASCs. Even worse, hospitals do not specialize in dialysis access care, and

frequently cannot accommodate urgent cases as quickly as a specialized dialysis access facility, which compromises patient outcomes and increases the chances of hospitalization.

As a result, the requested change to the OR need methodology would reduce the cost of care for dialysis patients by helping ensure timely interventions and preventing unnecessary hospitalizations, and also by allowing dialysis access procedures to be done in a less expensive ASC setting. It would also improve coordination of care and result in better patient outcomes for dialysis patients compared with providing this care in hospitals. In addition, because most dialysis access procedures have been provided in unlicensed physician offices in the past, allowing the petition will not adversely affect other ASCs or hospitals.

In conclusion, Eastern Nephrology Associates reiterates that the unique characteristics of dialysis patients justify a change to the SMFP that would exclude dedicated vascular access ORs from the general OR need methodology such that they could be developed without a prospective need determination. At a minimum, a demonstration project should be approved to allow development of dedicated vascular access ORs in ASCs in each Health Service Area statewide, to evaluate the effectiveness of this specialized care model.

Best regards,

Richard Blair, MD

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