Comments in Support of Petition for Adjusted Need Determination: 1 OR in Pitt/Hyde/Greene/Tyrell OR Service Area and 1 OR in Craven/Jones/Pamlico OR Service Area

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Good afternoon members of the Council. I'm Nathan Saucier, MD, an interventional nephrologist with Eastern Nephrology Associates in New Bern. I am here to speak in support of our petition for an adjusted need determination for one additional OR in the Pitt/Greene/Hyde/Tyrell OR service area, and one additional OR in the Craven/Jones/Pamlico OR service area, to provide vascular access procedures for dialysis patients in a single-specialty ambulatory surgery center.

Eastern Nephrology has focused on caring for chronic kidney disease (CKD) and end-stage renal disease (ESRD) patients since 1975. Currently we have over 1,300 ESRD patients who rely on dialysis to preserve and prolong their lives. Many of you already know that ESRD patients require a disproportionately expensive amount of medical treatment. Collectively, they are less than 1% of Medicare beneficiaries but they represent more than 7% of total Medicare spending. People with ESRD are medically complex with lots of co-morbidities, and their survival requires hemodialysis three times per week.

Eastern Nephrology is on the cutting edge of caring for this vulnerable population. We participate an ESRD Seamless Care Organization or "ESCO," which is an Accountable Care Organization specifically focused on ESRD patients. ESCOs are accountable for clinical quality outcomes *and financial* outcomes for ESRD patients, including all Medicare spending for those patients. CMS recognizes the importance of coordination and quality of care, and ENA partners with other nephrologists and dialysis facilities through the ESCO to provide the best quality care while reducing expenditures for the Medicare program.

One critical factor in caring for a dialysis patient is their vascular access (usually an arteriovenous fistula or graft, and sometimes a catheter), through which the patient's blood is filtered using a dialysis machine. Dialysis accesses are prone to dysfunction, infection, stenosis and thrombosis that frequently need interventions to maintain their patency and function. The need for an intervention is usually unexpected, and interventions must happen very quickly, or the patient deteriorates rapidly since they are unable to dialyze.

ESRD patients benefit enormously from a specialized, coordinated team providing care in a dedicated ambulatory setting, as opposed to receiving their dialysis access care in a hospital. Our community hospitals provide incredible care every day to all types of patients, but when it comes to the dialysis population, numerous studies have shown that patients have better outcomes, better patient satisfaction, and fewer hospitalizations, at lower cost to the healthcare system, if their care can be provided outside the hospital.

We currently provide *interventions* to correct vascular access dysfunction in the office setting, but CMS does not allow dialysis access *creation* procedures in office setting. Those procedures are currently done in hospitals but having them placed in an ASC can greatly decrease the cost to the healthcare system. Also, CMS reimbursement cuts of 30%-40% threaten our ability to do vascular access procedures in the office at all. These cuts have resulted in a negative profit margin for certain vital procedures, which has drastically affected our ability to practice medicine in this office setting. DHHS even noted in an Agency report earlier this year that a national survey indicated about 20% of vascular access centers have already closed.

The reimbursement changes were certainly intended to control cost, but the cuts will ultimately have the opposite effect, as centers must close or cut back on vascular access services, and dialysis patients are forced back to hospitals for care. That will result in much higher costs and worse outcomes, with more complications and hospitalizations, which will hurt outcomes and drive up costs even further. This will hurt the ESCOs' ability to save money for the healthcare system for dialysis patients.

Ambulatory surgery centers are the logical choice to perform creation and maintenance of dialysis access. ASC's can perform dialysis access creation procedures, and ASC reimbursement costs the healthcare system far less than doing the same procedures in a hospital.

But we are here today because we cannot provide care to our patients in the ASC setting without help from the Council. There are no ASCs near New Bern, and the only one in Greenville is already highly utilized, and does not accept vascular access procedures. Also, under the proposed State Medical Facilities Plan as it is written now, Eastern Nephrology cannot be approved to develop an ASC itself - Although there are ORs in next year's proposed plan, there is no need determination for any new ORs anywhere near our locations and the patients we serve.

If nothing is done, dialysis patients (who are predominantly minority and lower socioeconomic status in our region) will be forced back into hospitals for episodic care, resulting in worse outcomes. This will also increase the hospital admissions of very sick dialysis patients, and dramatically increase the cost to Medicare and the healthcare system.

We support the OR need methodology in general, but for these reasons, the needs of the dialysis patient population and the available capacity in our area of Eastern North Carolina justify an adjusted need determination. So we urge the Council to approve the adjusted need determination for these two OR service areas. Thank you for your time, and I am happy to answer any questions you may have.