Comments in Support of Petition for Change to OR Need Methodology
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Mr. Chairman, and committee members. My name is George Hart. I have been a practicing nephrologist in North Carolina for 25 years. Today I am here in support of the petition for a change in need methodology for the 2019 state medical facilities plan or, in the alternative, an adjusted need determination for a demonstration project, for vascular access ambulatory surgery centers for ESRD patients. I represent American Access Care of North Carolina located in Cary, Eastern Nephrology Associates located in Greenville, Metrolina Nephrology located in Charlotte, North Carolina Nephrology Associates located here in Raleigh, and Azura Vascular Care.

For more than 10 years we have operated multiple unlicensed outpatient dialysis vascular access centers across the state. These centers provide specialized care in the management and maintenance of arteriovenous vascular accesses, which are necessary for life-saving hemodialysis therapy. These vascular access centers have enabled individuals with End Stage Renal Disease (ESRD) to receive safe, prompt care, and avoid costly emergency room department visits and prolonged hospitalizations.

Unfortunately, Medicare reimbursement changed in January 2017 to establish 9 new bundled codes and resulting in 30%-40% cuts in reimbursement in the physician office setting, making it no longer financially feasible for many vascular access centers to continue operation. The methodology behind this bundling was seriously flawed as evidenced by the fact that the most common codes for office based vascular access services now pays a rate less than 25% of what is paid in the hospital outpatient setting.

As a result office-based services for vascular access preservation are now severely underfunded by Medicare and Medicaid, which funds more than 80% of all encounters. This is leading to the demise of the office as a viable site of service. Across the nation some centers have already closed. We worry that we will be forced to stop offering this care to our patients unless we find a way to convert these existing unlicensed vascular access centers into licensed, single specialty ambulatory surgical centers (ASC). Though ASC reimbursement codes were not so drastically impacted, they remain a less costly alternative to the hospital.

In order to preserve patients' access to care, we propose a change in the need methodology for operating rooms. Specifically, we request that dedicated dialysis vascular access operating rooms located in single specialty ambulatory surgical settings be excluded from the SMFP's annual operating room inventory. This will allow applicants to submit a CON application at any time, regardless of SMFP's determined operating room inventory. These dedicated vascular access operating rooms could then be treated similarly to dedicated C-section operating rooms, which are outside the OR inventory, but still require CON approval.

I want to stress that we recognize the importance of the existing need methodology for ORs generally, and do not wish to undermine it. Our focus is caring for our patients suffering with kidney disease who need access to specialized care, and therefore we propose that these vascular access ORs be limited in scope to only creating or maintaining dialysis accesses for advanced chronic kidney disease patients and ESRD patients undergoing dialysis. We will gladly provide any data requested by the committee. Our centers are already open to appropriately credentialed interventional nephrologists and radiologists as well as vascular surgeons. This will not change.

Across the USA, dialysis patients make up 1% of the covered Medicare population yet account for 7% of the total Medicare spend. Annually, the federal government spends more than $33 billion caring for these patients. Annual cost per patient per year exceeds $85,000. Here in North Carolina we are fortunate in that our costs per patient are approximately 20% below the national average yet they still exceed $70,000 annually. Applying these numbers to our approximately 17,800 ESRD patients living in North Carolina the cost of care for this population exceeds $1.3 billion annually. North Carolina's population has a higher percentage of patients affected with kidney disease versus other states. Our ESRD population grows at a rate of more than 3.5% annually. Our total costs are rising. We must embrace strategies which are proven to lower costs and improve outcomes.

The life of a dialysis patient is difficult. Most patients have diabetes and hypertension. Many suffer with peripheral vascular disease resulting in amputations. Blindness is common. Black Americans are disproportionately affected as are the poor and those over age 65. Most of our population is covered by Medicare or Medicaid. There can be huge socioeconomic challenges. Frequently plagued with substance abuse and depression most of these patients are disabled and unemployed and just getting back and forth to dialysis is a challenge. They require treatment three times a week for four hours at a time but only after a large needle is inserted through the skin into their vascular access. These accesses can take the form of a surgically created connection between an artery and a vein (arterial venous fistula or AVF), a connection requiring synthetic material (AV graft), or a plastic catheter inserted into a large vein in the neck, chest or leg, then partially tunneled under the skin. With blood flows as high as 1 liter per minute, prone to infections, these accesses are the lifeline for all dialysis patients. Their upkeep is paramount to maintaining their health. As any dialysis patient will attest, an access which works well is a most valued commodity.

This is why access to vascular access care is so important. Prior to 2005, access care was disjointed and dysfunctional, with little coordination of care between nephrologist, surgeon, or interventional radiologist who was frequently tasked with trying to intervene upon a dysfunctional access. There were frequent infections and all too frequently patients would burn through all of their possible options for an access in a short period of time. There were frequent ER visits and hospitalizations. Care was incredibly expensive with poor results. Dialysis treatments were constantly shortened or missed entirely. Attempts to direct care to ASCs were unsuccessful as our patients' multiple medical problems and comorbidities exceeded the

capabilities of the centers, and because ASC schedules frequently could not accommodate the last minute urgent needs. Accesses would be lost simply because we could not get the necessary care arranged in time.

Starting around 2005 nephrologists stepped into the role of providing comprehensive access care. Unlicensed vascular access programs rolled out in the larger practices nationwide and in North Carolina. Data from the US Renal Data System shows that from 2005-2014 there was a 20% reduction in hospitalization rates. There was a 71% reduction in vascular access infections and a 61% reduction in hospitalizations related to vascular access care. Re-hospitalization rates dropped. Patient survival improved as evidenced by a 2017 study showing a 15% reduction in mortality for ESRD patients receiving access care in free standing facilities vs a hospital setting. Costs have also been reduced as a result of fewer emergency room visits and hospitalized care.

We propose a change in the OR need methodology so that we do not return to 2005. Specifically we request that dedicated dialysis vascular access operating rooms located in single specialty ambulatory surgical settings be excluded from the SMFP's annual OR inventory, or in the alternative, a demonstration project for the development of vascular access ASCs in each Health Service Area. The conversion of unlicensed vascular access centers to single specialty vascular access ambulatory surgical centers will improve provider accountability by moving vascular access procedures from the office environment to the more highly regulated ambulatory surgical center environment, and to improve coordination of care by expand our outpatient care to include access creation, which is usually done in hospitals now. In my conversations with local hospital administrators I have stressed that shifting appropriate patients to the outpatient setting will free up space in hospital ORs for patients who truly need that level of service.

This is a win for patients, providers, hospitals and even taxpayers. Failure to address this crisis may result in our inability to continue to offer outpatient vascular access care. The more than 5,000 ESRD patients our centers treated last year (resulting in 11,887 procedures) will return to the emergency rooms and hospitals which have limited capacity to provide timely care. As we care for only 1/3 of the NC's ESRD population the actual impact will be far greater and widespread across the state. This deluge of patients will only further burden hospitals with avoidable hospitalizations involving poorly reimbursed procedures. Avoiding this is in the best interest of all stakeholders.

To that end I respectfully request that the state grant the petition for a change in need methodology for the 2019 plan to remove dedicated dialysis vascular access operating rooms located in single specialty ASCs be excluded from OR inventory or, in the alternative, an adjusted need determination for a demonstration project for vascular access ambulatory surgery centers for ESRD patients.