Petition for Adjusted Need Determination for 2019 State Medical Facilities Plan
One Additional OR in Pitt/Greene/Hyde/Tyrell OR Service Area
and One Additional OR in Craven/Jones/Pamlico County
for Vascular Access Procedures in a Single-Specialty Ambulatory Surgery Center

July 25, 2018

This Petition for Adjusted Need Determination is submitted by Eastern Nephrology Associates, PLLC ("ENA") and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care ("Azura"), which currently operate two physician office-based outpatient vascular access centers, in Greenville and New Bern, specializing in the management and maintenance of end stage renal disease (ESRD) patients' vascular accesses, which are necessary for life-sustaining hemodialysis treatments.

ENA and Azura propose an adjusted need determination for one additional operating room in the Pitt/Greene/Hyde/Tyrell OR Service Area and one additional operating room in the Craven/Jones/Pamlico OR Service area for the purpose of providing vascular access procedures for dialysis patients, including the surgical creation, management and maintenance of patients' vascular accesses, to be located in a single-specialty ambulatory surgical facility. These ASC facilities will ensure timely access to life-sustaining high-quality vascular access care for ESRD patients, and improve patient care and clinical outcomes by allowing the same interventional care team to create, follow, repair and maintain each ESRD patient's vascular access in one specialized, regulated outpatient setting.

Azura and several physician practices, including ENA, previously submitted two petitions seeking to enable the development of vascular access ASCs statewide, which were denied. This petition focuses on the particular needs of ESRD patients in a specific geographic area, and provides specific data and other information identified as lacking in previous petitions.[1] The clinical and patient care benefits of dedicated vascular access ORs to serve dialysis patients in single specialty ASCs are similar to the prior petitions; and the economic pressures that have made physician office-based vascular access centers unsustainable are largely unchanged from the prior petitions. However, this petition seeks only two additional ORs, and is limited to only two OR service areas in the State. For the reasons stated below, the need to develop vascular access ASCs in these two OR service areas is especially acute because of a lack of other options to provide the same level of care cost effectively. Moreover, an adjusted need determination is the only viable option for the development of vascular access ASCs in these two OR service areas, because there is no need determination for additional ORs in either county in the 2018 State Medical Facilities Plan or the proposed 2019 SMFP, and it is unlikely there will be a need determination in either OR service area in the near future.

If the existing physician office-based vascular access centers ("VACs") cannot become licensed as ASCs, vascular access maintenance procedures for dialysis patients will be forced into hospitals, resulting in unnecessary hospital admissions and increased costs to patients and the health care system, unnecessary delays in a patient's ability to dialyze, exposure to infection risk

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[1] https://www2.ncdhhs.gov/dhsr/mfp/pdf/2018/acs/0327_amsu_agencyrep.pdf, Acute Care Services Committee Agency Report, p. 6, suggesting potential petition(s) for adjusted need determination.

associated with an inpatient setting, and fragmentation of care. Consequently, providing these services in hospitals will result in much greater expense, and worse patient outcomes.

1. Name, address, email address and phone number of petitioners:

Eastern Nephrology Associates, PLLC
Eastern Nephrology Associates is an eighteen-physician nephrology practice headquartered in Greenville and New Bern, serving eastern North Carolina since 1975. ENA participates in CMS's Comprehensive ESRD Care Model through its participation in an ESRD Seamless Care Organization ("ESCO"). The Comprehensive ESRD Care Model[2] is built on CMS's experience with Accountable Care Organizations ("ACOs") and the Medicare Shared Savings Program to test ACOs for ESRD beneficiaries. 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.

Fresenius Vascular Care, Inc.
Azura Vascular Care is the trade name of Fresenius Vascular Care, Inc., a national network of outpatient vascular care and ambulatory surgery centers that specialize in minimally invasive techniques to treat and manage vascular conditions. Azura operates six vascular access centers in North Carolina, including those in Greenville and New Bern.

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2. Statement of requested adjustment, citing provision in proposed SMFP for which adjustment is proposed.

ENA and Azura request an adjusted need determination for one (1) additional operating room in the Pitt/Greene/Hyde/Tyrell OR Service Area and one (1) additional operating room in the Craven/Jones/Pamlico OR Service Area for the purpose of providing vascular access procedures for dialysis patients, including the surgical creation, management and maintenance of patients' vascular accesses, each to be located in a single-specialty ambulatory surgical facility. This change would constitute a change to Chapter 6 of the 2019 SMFP, and would read as follows:

[2] See https://innovation.cms.gov/initiatives/comprehensive-esrd-care/.

Table 6C: Operating Room Need Determination

(for Certificate of Need Review Commencing in 2019)

Operating Room Service Area	Operating Room Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Craven/Jones/Pamlico	**1*** **		
Mecklenburg	**11**		
New Hanover	**6**		
Orange	**3**		
Pitt/Greene/Hyde/Tyrell	**1*** **		
Wake	**2**		
It is determined that there is no need for additional operating rooms anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).
** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).
*** Operating rooms for the purpose of providing vascular access procedures for dialysis patients, to be located in a single-specialty ambulatory surgical facility.

3. Reasons for the Proposed Adjustment:

An adjusted need determination should be included in the 2019 SMFP in order to preserve dialysis patients' access to life-saving, high-quality care historically provided by physician office-based vascular access centers. Allowing for existing vascular access centers to become licensed ASCs will enable the Practices and other providers to continue serving the vulnerable ESRD patient population, and will also improve coordination of care and reduce costs for dialysis creation procedures, which could be done in ASCs but are now typically done in hospitals. Therefore, allowing this petition will improve access to and quality of care, reduce the cost of care, and critically, keep this vulnerable patient population's episodic vascular access care out of the hospital setting.

Clinical Background:

Kidney disease statistics for the United States indicate that 8-10% of adults have some level of chronic kidney disease.[3] End-stage renal disease (or "ESRD"), commonly known as kidney failure, currently affects about 661,000 Americans according to the National Institute of Diabetes and Digestive and Kidney Diseases.[4]

Individuals with ESRD must have either dialysis or a kidney transplant to survive. As of December 31, 2017, 18,038 North Carolina residents were undergoing dialysis for ESRD, and

[3] World Kidney Day: Chronic Kidney Disease. http://www.worldkidneyday.org/faqs/chronic-kidney-disease/.
[4] See https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

that total is growing at 3.7% per year.[5] These patients must undergo routine, ongoing hemodialysis, in which their blood is filtered through a machine that removes waste products from the blood, and which requires vascular access. Vascular access, including an arteriovenous ("AV") fistula or graft, enables a dialysis machine to access a patient's blood and facilitate the removal and filtration of the blood before it is returned to the patient. While indispensable to hemodialysis treatment, vascular accesses have high dysfunction rates, with patients being susceptible to clotting, infection, and venous injury. Therefore, dialysis access management and treatment of vascular access complications is critical to an ESRD patient's plan of care. Absent a functioning vascular access, ESRD patients cannot receive dialysis and are at risk of hospitalization, serious complications, and death.

Many ESRD patients also suffer from underlying disease complications and multiple co-morbidities, resulting in poor health outcomes, high rates of hospital admission and readmission, and higher mortality rates. ESRD is predominantly caused by high blood pressure and/or diabetes and disproportionately affects minorities and lower socioeconomic classes. Compared to Caucasians, ESRD prevalence is significantly greater in African Americans, Native Americans, and Asian Americans.[6]

An ESRD patient has two options for survival: kidney transplantation or dialysis treatment. The predominant dialysis modality is hemodialysis, which patients typically receive in outpatient dialysis clinics three times a week for four hours at a time. At each hemodialysis treatment, a dialysis machine removes a large volume of blood from the patient's body, filters the blood through a dialyzer to mimic the function of the kidneys, and returns the filtered blood to the patient. A necessary component of hemodialysis treatment is the patient's vascular access, a shunt that accesses the patient's body blood.

Vascular accesses are surgically created vein and artery blood shunts that fall into three categories: central venous catheters ("CVCs"), arteriovenous grafts ("AVGs"), or arteriovenous fistulas ("AVFs"). See **Exhibit A**. CVCs and AVGs are synthetic shunts, whereas AVFs are constructed from the patient's own veins and arteries. CVCs are typically the first access a dialysis patient will receive because catheters allow immediate access, whereas AVGs and AVFs require anywhere from 3 to 6 months post-surgery to mature into functioning accesses. Despite the maturation period, AVGs and AVFs are preferable to CVCs because CVCs have the highest infection rates among available accesses. CVCs have approximately a 20% infection rate, AVGs a 10% infection rate, and AVFs less than a 0.5% infection rate.[7]

All vascular accesses, however, are susceptible to high dysfunction rates due to blockages, blood clots, and infection. The average dialysis patient experiences 1.6-2.7 access interventions per year in order to maintain a well-functioning access.[8] These figures are for average ESRD

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[5] July 2018 N.C. Semiannual Dialysis Report, Table D. Growth rate of 3.7% calculated based on statewide total dialysis patients for 2013-2017 (5-year average annual change rate).

[6] See https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

[7] Al-Jaishi A, Liu A, Complications of the Arteriovenous Fistula: A Systematic Review, *J Am Soc Nephrol,* 28: ____-____, 2016. doi: 10.1681/ASN.2016040412.

[8] A 2004 study found averages of 2.77 intervention procedures per year for AVG patients and 1.6 procedures per year for AVF patients, with a RR of 3.13 for secondary interventions. *See* Perera GB, Mueller MP, Kubaska SM, Wilson SE, Lawrence PF, Fujitani RM. Superiority of Autogenous Arteriovenous Hemodialysis Access:

patients, including those who *do not* require interventions. Azura conservatively estimates an average ESRD patient will have 2.0 vascular access procedures per year, which include diagnostic procedures (e.g. fistulogram) that are not considered interventions. Petitioners' own experience is consistent. Collectively, the ENA/Azura centers in Greenville and New Bern performed 2.4 vascular access procedures per ESRD patient in 2017.[9] Without a functioning vascular access, patients cannot receive hemodialysis and are at risk of serious complications and death within 1-2 days.

Historically, dialysis access creation and maintenance required inpatient surgery, and the creation of vascular accesses is still performed primarily in a hospital setting. But since the early 2000s, dedicated, physician office-based vascular access centers have provided much-improved access to care for the maintenance and management of existing accesses, allowing patients with a dysfunctional access to receive interventional treatment and return to receive dialysis within hours. Vascular access maintenance procedures are minimally invasive and use x-ray fluoroscopy to guide wires and catheters through blood vessels. Vascular access procedures for ESRD patients include angioplasty (to unblock clogged vessels at the access site), dialysis catheter management, thrombectomy, and stent placement. Azura-affiliated facilities' policy is to accommodate patients on a same-day basis, and in any event no later than the following day.

While vascular access centers are a demonstrated superior care model, reimbursement cuts by CMS beginning in 2017 have made the operation of vascular access centers in the physician office setting unsustainable, as detailed below. Therefore, licensed vascular access ambulatory surgery centers ("vascular ASC") are necessary to preserve access to timely, cost effective care. Moreover, providing care in a licensed ASC would allow vascular ASCs to create vascular accesses, which are currently done in hospitals, in a less-expensive ambulatory setting and continue to keep overall health care spending on ESRD patients down by avoiding needless hospital admissions.

Dedicated Vascular Access ASCs Achieve Better Outcomes

Purpose-built vascular access centers like those operated by ENA and Azura in Greenville and New Bern have a proven track record of improved clinical outcomes as a result of specialization and better coordination of care.

- A 2017 study examined 214,796 clinically and demographically similar Medicare patients for whom data was available through the United States Renal Data System (80,831 patients who received dialysis vascular access care primarily in freestanding office-based centers, and 133,965 patients who received dialysis vascular access care primarily in hospital outpatient departments). Across all outcome measures, patients treated in freestanding centers had better outcomes than those treated in Hospitals. The annual mortality rate for freestanding center patients was 15.1% lower than hospital patients, and the overall mortality across the entire study period was 10.9% lower in freestanding center patients. *See* El-Gamil AM, Dobson A, Manolov N, et al. What is

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Maintenance of Function with Fewer Secondary Interventions. *Ann Vasc Surg.* 2004;18(1):66-73. doi:10.1007/s10016-003-0094-y.

[9] See **Exhibit B** (data regarding vascular access procedures performed at ENA/Azura centers in Greenville and New Bern).

the best setting for receiving dialysis vascular access repair and maintenance services? *J Vasc Access*. 2017;(18):e89-e118.

- A 2016 study comparing ESRD patients of Fresenius dialysis facilities who received vascular access care at a Fresenius Vascular Care affiliated access center to those who did not found that the hemodialysis patients who received care at an access center exhibited 33% lower 6-month mortality. *See* Han H, Chaudhuri S, Usvyat L, et al. Associations between coordinated vascular care visits and decreased rates of hospitalizations and mortality in hemodialysis patients. *J Vasc Access*. 2016;(17):e37-e64. Notably, these observations of improvements in outcomes are similar to previous findings reported by other institutions regarding the benefits of freestanding vascular access centers. *See, e.g.* Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial*. 2013;26(5):624-632. doi:10.1111/sdi.12120.

- A 2006 study examining the implementation of a vascular access center offering both vascular access creation and maintenance services in Phoenix, AZ, with a dialysis patient population of nearly 6,000, documented a demonstrated improvement in clinical outcomes, with approximately 0.6 fewer hospital days per patient year and decreased missed dialysis treatments of approximately 0.3 per patient year as compared to a national sample. *See* Mishler R, Sands JJ, Ofsthun NJ, Teng M, Schon D, Lazarus JM. Dedicated outpatient vascular access center decreases hospitalization and missed outpatient dialysis treatments. *Kidney Int*. 2006;69(2):393-398. http://www.ncbi.nlm.nih.gov/pubmed/16408132.

ENA and Azura have operated a vascular access center in Greenville since 2006 and in New Bern since 2009, and the proposal here will further improve upon this model. Moving vascular access procedures to a licensed ASC will increase an already high standard of provider accountability since ASCs are licensed and regulated.

Creation of Dialysis Accesses in ASCs Would Improve Care and Lower Costs

Conversion to an ASC will also enhance coordination of care and reduce costs for the creation of dialysis accesses. Currently, vascular accesses are surgically created at hospitals – not because the services require a hospital setting or inpatient-level care, but because vascular access creation procedures are generally not reimbursed in the office setting. However, hospitals are twice as expensive as ASCs for access creation procedures: the Medicare facility fee is approximately $1,100-$2,000 higher per procedure in hospitals compared to ASCs.[10] Petitioners are not aware of statewide or national volume data regarding dialysis creation procedures, and Petitioners do not have internal volume data regarding dialysis access creation procedures since those procedures are not currently done at ENA/Azura centers. But based on ENA's experience, approximately 70% of new ESRD patients would be suitable to have initial access creation performed at an ASC.

[10] See **Exhibit C**, comparison of HOPPS and ASC reimbursement for dialysis access creation procedures.

Performing access creation procedures in a specialized ASC would not only greatly reduce the cost of those procedures, but would also improve care for dialysis patients by permitting the same interventional care team to create, follow, repair and maintain the ESRD patient's vascular access in one specialized, regulated outpatient setting. Thus, the project will enhance the collaboration between dedicated ESRD providers, resulting in improved clinical outcomes and increased patient satisfaction. ESRD patients can have multiple co-morbidities that further complicate an already complex disease and require visits to multiple providers prescribing multiple care plans. As such, coordination of ESRD patients' care plans is essential. In addition, the hospital environment also exposes these patients to increased risk of infection and other complications and can have adverse implications for post-surgical recovery, potentially resulting in the need for extended and additional services.[11]

Allowing for vascular ASCs to provide dialysis patients with the full-spectrum of vascular access care provided by one integrated team of access specialists will optimize care and clinical outcomes for a fragile and complicated patient population.

Licensure of Vascular Access Centers as Ambulatory Surgical Facilities is Necessary to Preserve Access to Care

The ENA/Azura centers in Greenville and New Bern served 1,524 ESRD patients during 2017, and performed 3,660 vascular access procedures. Of the 1,524 total patients, more than 99% were North Carolina residents. Patients of these centers received an average of 2.4 dialysis access procedures each during 2017.[12] By law, Medicare is the designated ESRD insurance program. As a result, ESRD patients of any age qualify for Medicare if they are eligible for Social Security disability, and Medicare remains the primary insurer for most ESRD patients.[13] Accordingly, 84.5% of the Greenville Center's patients and 80.5% of the New Bern center's patients were Medicare or Medicaid beneficiaries. Data regarding the composition of the procedures performed and the duration of these office-based surgical procedures is included in **Exhibit B**.

Considering only the volume of dialysis access procedures performed in the ENA/Azura center in Pitt County in 2017, the resulting surgical hours would justify a need for 1.7 ORs based on a threshold utilization of 1,312.5 hours per OR. *See* **Exhibit B**. The volume of dialysis access procedures performed in the ENA/Azura center in Craven County in 2017 would justify a need for 1.0 OR, and procedure volumes at both locations continued to increase in the first two quarters of 2018.

But despite the proven track record of purpose-built ESRD vascular access centers, this care model is threatened as a result of severe cuts to CMS's physician fee schedule reimbursement for

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[11] See Dobson A, El-Gamil AM, Shimer MT, et al. Clinical and economic value of performing dialysis vascular access procedures in a freestanding office-based center as compared with the hospital outpatient department among Medicare ESRD beneficiaries. *Semin Dial.* 2013;26(5):624-632. doi:10.1111/sdi.12120. *See also* El-Gamil A, Dobson A, Manolov N, et al. What is the best setting for receiving dialysis vascular access repair and maintenance services? *J Vasc Access.* 2017;(18):e89-e118.

[12] The procedure totals include only procedures performed at the ENA/Azura centers, and do not include dialysis access creation procedures, or other procedures performed in hospitals or at any other location.

[13] Social Security Administration Program Operations Manual System, § DI 45001.001, "End Stage Renal Disease (ESRD) Entitlement Provisions," *available at* http://policy.ssa.gov/poms.nsf/lnx/0445001001

ESRD vascular access procedures. Reimbursement for these procedures was cut approximately 30% to 40% in the physician office setting effective January 2017.[14] While Medicare reimbursement slightly increased for some of the vascular access CPT codes in 2018, overall the 2018 rates remain well below 2016 numbers.[15] While ASC rates for vascular procedures have also been cut, the differential between physician office rates and ASC rates remains significant.[16] Office-based vascular access centers are staffed and operate very much like a single-specialty ASC, including high levels of specialized staffing, and the drastic reimbursement cuts make it impossible for office-based vascular access centers to maintain sufficient staffing to provide the quality of care that ESRD patients need and to keep those patients out of the more costly hospital outpatient and emergency settings.

Consequently, it is no longer viable for physicians to develop or operate office-based vascular access centers to serve dialysis patients, and existing office-based centers will reduce access to vascular access procedures, cease providing these procedures altogether, or even close, leaving dialysis patients no alternative but to receive surgical interventions in hospitals. This will lead to additional demand on valuable hospital resources, which will of course come with increased costs for patients and the health system overall. As noted by the Spring 2018 Agency Report to the Acute Care Services Committee recommending denial of the prior petition, a survey of 71 vascular access centers indicated that 20% have already closed and another 20% are likely to close.[17] The same presentation cited by the Agency report also notes that "The recent cuts in reimbursement have places a significant burden on patients as centers close and they are forced back to hospitals."[18]

Hospitals are a less efficient, less effective environment for these services because hospitals are not designed to respond to the unplanned, though non-emergent nature of hemodialysis access procedures, given the broad scope of care they provide. In a hospital environment, ESRD patients in need of vascular access maintenance do not typically present as emergent cases, which can result in long delays in which they cannot dialyze and their condition deteriorates while waiting to receive necessary maintenance procedures. Further, hospital interventional radiology departments often temporize an urgent or emergent clotted fistula or graft merely by placing a catheter until the schedule allows enough time for a thrombectomy procedure. This can further prolong the hospitalization and the deleterious sequelae of using a catheter for dialysis. Not only can this put the patient's health at risk, it also compounds the already vast investment of time the ESRD patient must commit to life-sustaining dialysis.

Existing ASCs are also not a viable option for the dialysis population in the Pitt/Greene/Hyde/Tyrell and Craven/Jones/Pamlico OR Service Areas.[19] First, there are no

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[14] See **Exhibit D**, American Society of Diagnostic and Interventional Nephrology (ASDIN) Letter to Andrew Slavitt, August 22, 2016 (commenting on proposed CMS reimbursement cuts to dialysis circuit CPT codes 39601-39609); *see also* 81 Fed. Reg. 80170, 80290-96 (Finalizing 2017 Physician Fee Schedule reimbursement cuts to dialysis circuit CPT code RVUs as proposed).

[15] 2018 Medicare Physician Fee Schedule Final Rule, 82 Fed. Reg. 52976 (November 15, 2017)

[16] See **Exhibit C**.

[17] See https://www2.ncdhhs.gov/dhsr/mfp/pdf/2018/acs/0327_amsu_agencyrep.pdf, Acute Care Services Committee Agency Report, p. 5.

[18] See http://media.mcguirewoods.com/events/2017/Analysis-2018-Medicare-Reimbursement-Rates-Vascular-Procedures.pdf.

[19] For purposes of this petition, discussion of "ASCs" does not include ASCs including only GI-endoscopy rooms.

ASCs in Craven County or the Craven/Jones/Pamlico OR Service Area,[20] and only one ASC in the Pitt/Greene/Hyde/Tyrell OR Service Area, Vidant Surgicenter in Greenville. Vidant Surgicenter does not accept dialysis access procedures, and is already sufficiently occupied to show a deficit of ORs in Chapter 6 of the proposed 2019 SFMP. In fact many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. ESRD patients typically suffer from 10-14 comorbidities and are classified as ASA Physical Status III (indicating severe systemic disease).[21] Traditional ASCs also schedule cases well in advance and cannot accommodate the urgent presentation of dialysis vascular access cases.

Integrating the full spectrum of vascular access services (from surgical access creation through full vascular maintenance) in a more regulated and convenient, Medicare-certified ESRD-focused ASC will preserve access to care in a more cost effective outpatient setting and improve coordination across the continuum of the ESRD patient's care while improving the hemodialysis patient's quality of life.

Vascular Ambulatory Surgery Centers Will Reduce the Cost of ESRD Care

As part of an ESCO under the CMS Comprehensive ESRD Care Model, ENA seeks to optimize the coordination and quality of care, while simultaneously reducing Medicare expenditures for the ESRD population. According to the United States Renal Data System, ESRD beneficiaries comprised less than 1% of the Medicare population in 2015 but accounted for an estimated 7.1% of all Medicare fee for service spend, totaling over $33.9 billion.[22] Because most ESRD patients have complex health needs, multiple co-morbidities, and are heavy users of prescription drugs, they often must engage multiple providers, resulting in significantly higher per-patient costs of care across the health care system. Indeed, a typical ESRD patient costs the health care system nearly ten times more than the average Medicare patient.

In the past, office-based vascular access centers could improve accessibility and quality while lowering overall costs. For example, the 2013 Dobson study discussed above determined that the cost of care per patient per month for patients who received services at freestanding vascular access centers was, on average, $584 lower than for other patients.[23]

Now, performing these procedures in unlicensed settings is no longer financially viable. Efficient and proactive access care – essential to reduce expense to the health care system – requires ESRD-focused ASCs, without which vascular access procedures will shift to hospitals, where costs far exceed that those in ASCs. See **Exhibit C** (comparison of HOPPS and ASC reimbursement for dialysis maintenance procedures). Based on the volume and payor mix of procedures done in the Greenville and New Bern vascular access centers so far during 2018, annualized, doing those procedures in an ASC would save approximately **$6.6M** in Medicare and Medicaid reimbursement, compared with doing the same procedures in a hospital. See

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[20] The only outpatient surgical facility in Craven County is CarolinaEast Surgery Center, which is not licensed as an ambulatory surgical facility and is instead part of a hospital outpatient department (HOPD). *See* 2018 Hospital Licensure Renewal Application, CarolinaEast Health System.

[21] See http://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system.

[22] United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017 (https://www.usrds.org/2017/view/v2_09.aspx).

[23] See p. 6, above.

Exhibit E (comparison of 2018 procedures, annualized, if billed under CMS Hospital Outpatient Prospective Payment System and ASC Payment System). Based on historical growth, Azura expects the ESRD patient population to increase approximately 3.7% annually,[24] so these savings would show a corresponding increase over time.

Further, keeping vascular access procedures out of hospitals also reduces costs by reducing hospitalizations. Studies confirm that access to appropriate outpatient and low-acuity resources can reduce hospital admissions and readmissions and improve patient outcomes, thereby reducing health care expenditures for the patients and the health care system overall.[25] On the other hand, unnecessary reliance on hospital care represents inefficient use of expensive resources and can unnecessarily fragment care and lead to increased potential for hospital readmissions, further driving up costs.

3.a. Adverse effects on population of the requested area likely to ensue if the adjustment is not made:

As noted above, without the requested adjusted need determination, vascular access care for patients in Pitt, Craven and the surrounding counties will be forced into hospitals, at a greater cost to the healthcare system and without the specialization or coordination of care that a vascular ASC can provide. Patients needing urgent dialysis procedures (e.g., declotting) who currently have access to office-based vascular access centers will lose access to timely care and will likely end up in hospital EDs and be admitted while waiting for care (further increasing expense, and increasing the chance of worse outcomes).

3.b. Alternatives to the proposed adjustment that were considered and found not feasible:

1. Status Quo: The status quo is not feasible. As a result of CMS's 30%+ reimbursement cut, office-based vascular access centers are no longer a sustainable setting for dialysis access procedures, and despite numerous closures of vascular access centers since early 2017, there is no indication that CMS will significantly increase reimbursement for vascular access procedures under the Physician Fee Schedule. The existing vascular access centers in Greenville and New Bern are owned by ENA, which has limited resources and cannot fund the provision of vascular access procedures at a loss indefinitely. Further, the status quo will not permit the improvement in care that could be achieved by allowing dialysis creation procedures, and therefore allowing the same interventional care team to create, follow, repair and maintain the ESRD patient's vascular access, in the more specialized and less expensive ASC setting.

2. Development of ASCs under existing OR need methodology. The development of an ASC by the Petitioners in Pitt or Craven County under the existing OR need methodology is not an option. By statute, an ambulatory surgical facility in North Carolina must have at least one licensed OR,[26] and all of the existing ORs in Pitt and Craven Counties belong to the hospitals in those counties. There are no need determinations for additional ORs in the Pitt/Greene/Hyde/Tyrell or the Craven/Jones/Pamlico OR Service area, or any nearby county in

[24] See Footnote 5, above.
[25] See pp. 5-6, above.
[26] See N.C. Gen. Stat. § 131E-176(1b).

the 2018 SMFP or the proposed 2019 SMFP; nor are there likely to be need determinations in those counties in the near future.

3. Prioritize Dialysis patients in ORs in Existing ASCs or Hospitals. In the Agency report recommending denial of the March 2018 Petition by Azura and several physician practices, DHHS suggested the potential of a formal partnership with a hospital or ASC to prioritize dialysis patients in existing hospital or ASC ORs.[27] However, that is not a viable option for ENA's patient population. As noted above, even if existing hospital ORs could accommodate and prioritize the necessary volume of vascular access procedures, the hospital setting costs the healthcare system far more than the same procedure performed in an ASC,[28] and studies indicate that performing vascular access procedures in hospitals results in more complications and inferior outcomes.[29]

Partnering with existing ASCs is also not a viable option since the only ASC in the Pitt/Greene/Hyde/Tyrell County OR Service Area (Vidant Surgicenter) is already highly utilized (shows a slight deficit of ORs in Table 6B of the Prosed 2019 SMFP) and does not accept vascular access procedures, and there are no ASCs in Craven/Jones/Pamlico County OR Service Area.[30] The Agency report also noted surplus ORs in North Carolina ASCs, primarily in the Western part of the State, but ENA's locations are in the East, in HSA VI.[31] Only one such ASC is located in Health Service Area VI, in Wilson, which is almost 40 miles from the existing VAC in Greenville and almost 80 miles from the existing VAC in New Bern. Less than 0.7% of the current patients of the two ENA/Azura centers reside in Wilson County.

4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.

The proposed adjusted need determination would not result in unnecessary duplication because there are currently no ESRD-focused or vascular ASCs in the relevant OR Service Areas, or anywhere in North Carolina. Moreover, the development of two ORs in single-specialty vascular ASCs would not unnecessarily duplicate hospital surgical capacity because, as noted above in detail:

1. Vascular access maintenance procedures do not require a hospital setting, and are mostly performed in physician offices now. Consequently, shifting maintenance procedures to licensed ASCs will not adversely affect hospital surgical utilization.
2. Dialysis access creation procedures are currently performed as an incidental part of hospitals' broader surgical services, but are not a significant part of hospitals' surgical volume. DHHS previously recognized that *all* vascular procedures comprise only about 0.2% of hospital outpatient department surgical procedures. Therefore, outpatient vascular access creation procedures for dialysis patients would make up even less. Shifting a small number of dialysis access creation procedures to licensed vascular ASCs

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[27] See https://www2.ncdhhs.gov/dhsr/mfp/pdf/2018/acs/0327_amsu_agencyrep.pdf, Acute Care Services Committee Agency Report, pp. 5-6.
[28] See **Exhibit C**, comparison of ASC rates with HOPPS rates.
[29] See Footnote 11, above.
[30] See Footnote 20, above.
[31] See https://www2.ncdhhs.gov/dhsr/mfp/pdf/2018/acs/0327_amsu_agencyrep.pdf, Acute Care Services Committee Agency Report, p. 8, Fig. 1.

would not significantly harm hospitals, but would improve patient care and outcomes, and greatly reduce the cost to the healthcare system.

Further, the proposed adjusted need determination would not unnecessarily duplicate existing ambulatory surgical facilities because:

1. The only existing ASC in the Pitt/Greene/Hyde/Tyrell OR Service Area is already highly utilized, and does not accept dialysis access cases.
2. The only outpatient surgical center in the Craven/Jones/Pamlico OR Service Area is part of a hospital outpatient department and bills at hospital outpatient department rates. Consequently, it cannot provide the cost advantage of a single-specialty ASC.
3. Existing ASCs generally cannot accommodate ESRD patients, who are chronically ill, generally with multiple co-morbidities, and who have frequently missed scheduled dialysis treatments;
4. Existing ASCs' scheduling processes generally cannot accommodate vascular access maintenance procedures as they usually present urgently;
5. Non-ESRD focused ASCs lack the specialized clinical staff to provide care with the efficiency and expertise that can be achieved in a vascular ASC.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value.

Safety and Quality: The proposed adjusted need determination would improve provider accountability by moving vascular access procedures from the office environment to the licensed, more highly-regulated ASC environment. Moreover, the status quo will result in drive ESRD patients to hospitals, which often cannot provide timely care and where the risk of complications and infections is much higher.

Access: As noted above, if vascular ASCs cannot be developed, vascular access procedures will ultimately lose access the fast, effective, and high-quality care those facilities currently provide. Instead, care will be driven to the hospital setting, where patients usually cannot be seen on an urgent basis. Further, the creation of licensed vascular ASCs would also improve access to high-quality vascular access creation procedures with better care coordination, better clinical outcomes and lower cost than the hospital setting in which they are currently provided.

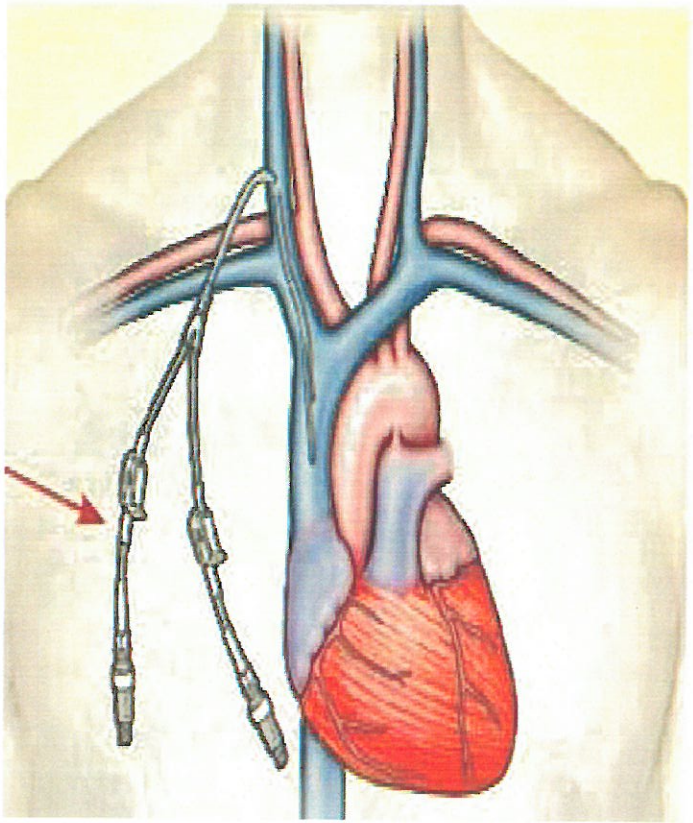
Value: If the status quo persists, care will be driven to the more expensive hospital setting. Also, the inability of hospitals to accommodate urgent vascular access maintenance issues as quickly as ASCs will result in patient complications, hospital admissions and expensive care that would be unnecessary if ESRD patients had urgent access to licensed vascular ASCs. As noted above, CMS reimburses ASCs hundreds or thousands of dollars per procedure less than in the hospital setting, which would save Medicare and Medicaid over $6M per year in reimbursement in North Carolina based the procedures done at the two ENA/Azura VACs alone so far in 2018 (not including vascular access creation procedures). [32] Accordingly, licensed vascular access ASCs would save the healthcare system millions of dollars per year.

[32] See **Exhibit E.**

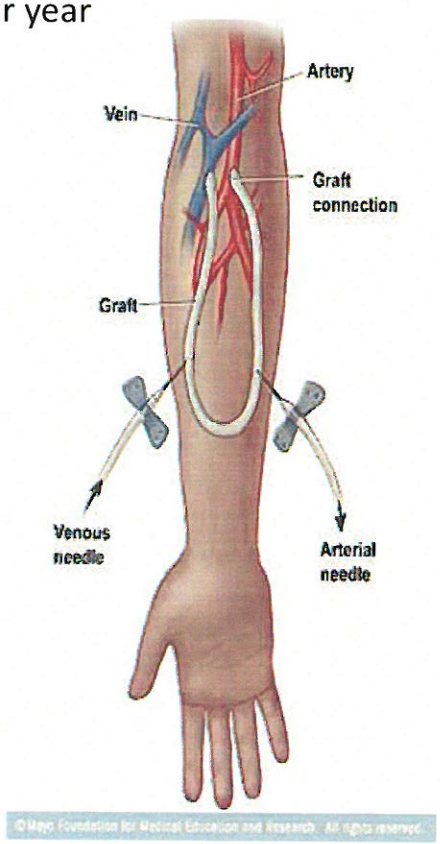
EXHIBIT A

3 types of Vascular Access

Catheter: Most problematic
High frequency of bloodstream infections



Graft: Moderately problematic.
Synthetic material gets infected at 10% per year



Fistula: Least problematic. Natural vein gets infected at 0.5% per year

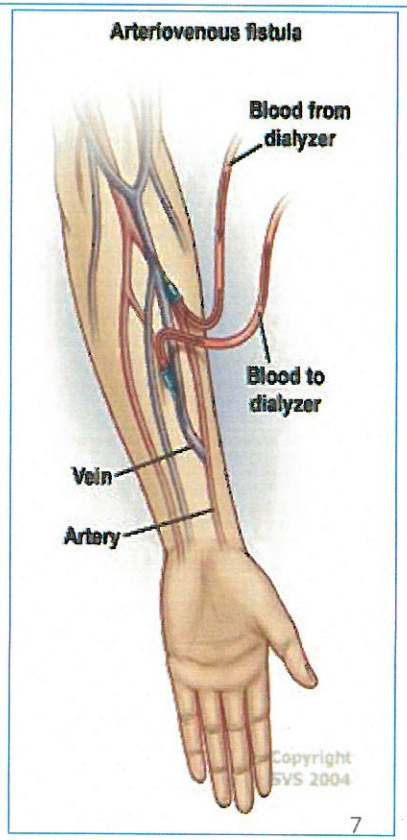


EXHIBIT B

Data Regarding Eastern Nephrology Associates/Azura Vascular Care Greenville and New Bern Locations

PROCEDURE VOLUME AND CASE TIMES – COMBINED

CASE TIME SPREADSHEET - COMBINED									
		2016		2017		2018 Q1		2018 Q2	
Procedure Type	Total Case Time	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours
PTA - ESRD	60	1,749	1,749	2,079	2,079	550	550	586	586
Catheter Change - ESRD	60	203	203	181	181	45	45	69	69
Catheter Removal - ESRD	60	291	291	250	250	70	70	59	59
Catheter Insertion - ESRD	60	144	144	127	127	42	42	49	49
Catheter Other - ESRD	60	6	6	5	5	1	1	3	3
Fistulogram - ESRD	50	320	267	351	293	131	109	116	97
ESRD Other	60	12	12	22	22	-	-	-	-
ESRD Coil Embolization	75	5	6	50	62	29	36	27	33
Stents - ESRD	45	99	74	326	245	96	72	87	65
Thrombectomy - ESRD	75	278	348	269	336	61	76	70	88
Total		3,107	3,100	3,660	3,599	1,025	1,001	1,066	1,049
Average Hours per Case			0.998		0.984		0.977		0.984
Avg. Case Time in Minutes			60		59		59		59
Surgical Hours (Cases x Avg. Time/60)			3,100		3,599		1,001		1,049
Surgical Hours Per Year Per OR			1,312.50		1,312.50		328.13		328.13
OR Need			**2.4**		**2.7**		**3.1**		**3.2**
							1 Quarter		1 Quarter

PROCEDURE VOLUME AND CASE TIMES – GREENVILLE

CASE TIME SPREADSHEET - GREENVILLE

		2016		2017		2018 Q1		2018 Q2	
Procedure Type	Total Case Time	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours
PTA - ESRD	60	1,027	1,027	1,264	1,264	341	341	375	375
Catheter Change - ESRD	60	144	144	129	129	32	32	59	59
Catheter Removal - ESRD	60	212	212	183	183	52	52	40	40
Catheter Insertion - ESRD	60	87	87	82	82	21	21	33	33
Catheter Other - ESRD	60	6	6	5	5	1	1	2	2
Fistulogram - ESRD	50	251	209	245	204	97	81	74	62
ESRD Other	60	12	12	19	19	-	-	-	-
ESRD Coil Embolization	75	4	4	15	19	7	8	13	16
Stents - ESRD	45	67	50	180	135	50	38	54	41
Thrombectomy - ESRD	75	189	236	194	243	49	61	46	58
Total		1,999	1,988	2,316	2,282	650	635	696	684
Average Hours per Case			0.995		0.985		0.977		0.984
Avg. Case Time in Minutes			60		59		59		59
Surgical Hours (Cases x Avg. Time/60)			1,988		2,282		635		684
Surgical Hours Per Year Per OR			1,312.50		1,312.50		328.13		328.13
OR Need			**1.5**		**1.7**		**1.9**		**2.1**
							1 Quarter		1 Quarter

PROCEDURE VOLUME AND CASE TIMES – NEW BERN

CASE TIME SPREADSHEET - NEW BERN									
		2016		2017		2018 Q1		2018 Q2	
Procedure Type	Total Case Time	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours	Total Cases	Total Case Hours
PTA - ESRD	60	722	722	815	815	209	209	211	211
Catheter Change - ESRD	60	59	59	52	52	13	13	10	10
Catheter Removal - ESRD	60	79	79	67	67	18	18	19	19
Catheter Insertion - ESRD	60	57	57	45	45	21	21	16	16
Catheter Other - ESRD	60	-	-	-	-	-	-	1	1
Fistulogram - ESRD	50	69	58	106	88	34	28	42	35
ESRD Other	60	-	-	3	3	-	-	-	-
ESRD Coil Embolization	75	2	2	35	43	22	28	14	18
Stents - ESRD	45	32	24	146	110	46	35	33	25
Thrombectomy - ESRD	75	89	111	75	94	12	15	24	30
Total		1,109	1,112	1,344	1,317	375	366	370	364
Average Hours per Case			1.003		0.980		0.977		0.984
Avg. Case Time in Minutes			60		59		59		59
Surgical Hours (Cases x Avg. Time/60)			1,112		1,317		366		364
Surgical Hours Per Year Per OR			1,312.50		1,312.50		328.13		328.13
OR Need			**0.8**		**1.0**		**1.1**		**1.1**
							1 Quarter		1 Quarter

ENA/AZURA GREENVILLE AND NEW BERN FACILITIES – PATIENT COUNTY OF ORIGIN BY %

	2016		2016 Total	2017		2017 Total	2018		2018 Total	Grand Total
County	GE	NB		GE	NB		GE	NB		
Pitt	35.39%	2.35%	24.35%	34.57%	2.99%	23.20%	30.89%	1.33%	19.81%	22.98%
Craven	0.72%	30.28%	10.60%	0.35%	29.39%	10.81%	0.18%	35.05%	13.25%	11.20%
Lenoir	3.97%	14.80%	7.59%	5.61%	12.19%	7.98%	5.74%	11.78%	8.00%	7.83%
Beaufort	11.23%	2.52%	8.32%	10.51%	2.86%	7.75%	8.83%	2.06%	6.29%	7.68%
Onslow	0.13%	16.57%	5.62%	0.20%	21.31%	7.80%	0.18%	22.39%	8.50%	7.11%
Martin	11.15%	1.26%	7.84%	9.37%	1.46%	6.52%	8.74%	0.88%	5.79%	6.88%
Carteret	0.00%	11.02%	3.68%	0.04%	15.32%	5.54%	0.00%	15.02%	5.63%	4.85%
Hertford	6.33%	1.09%	4.58%	6.66%	0.14%	4.31%	9.80%	0.00%	6.13%	4.77%
Bertie	5.45%	1.26%	4.05%	5.21%	0.21%	3.41%	7.06%	0.15%	4.47%	3.86%
Edgecombe	5.74%	0.50%	3.99%	4.78%	0.14%	3.11%	5.91%	0.15%	3.75%	3.57%
Washington	4.90%	1.18%	3.65%	4.43%	0.63%	3.06%	4.06%	0.29%	2.65%	3.21%
Jones	0.00%	9.50%	3.18%	0.04%	7.45%	2.71%	0.00%	6.92%	2.59%	2.86%
Halifax	2.41%	0.42%	1.74%	4.90%	0.07%	3.16%	4.06%	0.00%	2.54%	2.50%
Northampton	2.83%	0.08%	1.91%	4.19%	0.00%	2.68%	3.27%	0.00%	2.04%	2.27%
Pamlico	0.00%	3.78%	1.27%	0.00%	4.04%	1.45%	0.00%	2.80%	1.05%	1.30%
Nash	1.31%	0.00%	0.87%	1.33%	0.00%	0.85%	3.62%	0.00%	2.26%	1.13%
Wilson	2.49%	0.08%	1.69%	1.14%	0.07%	0.75%	1.06%	0.00%	0.66%	1.09%
Greene	1.44%	0.25%	1.04%	1.06%	0.28%	0.78%	1.15%	0.00%	0.72%	0.87%
Chowan	1.27%	0.08%	0.87%	1.06%	0.07%	0.70%	1.41%	0.00%	0.88%	0.80%
Clay	0.04%	0.08%	0.06%	1.57%	0.35%	1.13%	1.06%	0.44%	0.83%	0.66%
Duplin	0.25%	1.18%	0.56%	0.67%	0.14%	0.48%	1.15%	0.44%	0.88%	0.59%
Hyde	1.35%	0.00%	0.90%	0.59%	0.00%	0.38%	0.26%	0.00%	0.17%	0.53%
Wayne	0.30%	1.09%	0.56%	0.24%	0.42%	0.30%	0.26%	0.00%	0.17%	0.37%
Tyrrell	0.59%	0.00%	0.39%	0.47%	0.00%	0.30%	0.26%	0.00%	0.17%	0.31%
Gates	0.25%	0.00%	0.17%	0.27%	0.00%	0.18%	0.26%	0.00%	0.17%	0.17%
#N/A	0.17%	0.17%	0.17%	0.27%	0.07%	0.20%	0.00%	0.00%	0.00%	0.15%
Perquimans	0.21%	0.00%	0.14%	0.12%	0.00%	0.08%	0.35%	0.00%	0.22%	0.13%
Pender	0.00%	0.42%	0.14%	0.00%	0.14%	0.05%	0.00%	0.00%	0.00%	0.07%
Sampson	0.00%	0.00%	0.00%	0.04%	0.21%	0.10%	0.00%	0.29%	0.11%	0.06%
Warren	0.00%	0.00%	0.00%	0.12%	0.00%	0.08%	0.18%	0.00%	0.11%	0.05%
Dare	0.00%	0.00%	0.00%	0.08%	0.00%	0.05%	0.09%	0.00%	0.06%	0.03%
Wake	0.00%	0.00%	0.00%	0.08%	0.00%	0.05%	0.00%	0.00%	0.00%	0.02%
Pasquotank	0.04%	0.00%	0.03%	0.00%	0.00%	0.00%	0.09%	0.00%	0.06%	0.02%
Franklin	0.00%	0.00%	0.00%	0.04%	0.00%	0.03%	0.00%	0.00%	0.00%	0.01%
Cumberland	0.00%	0.00%	0.00%	0.00%	0.07%	0.03%	0.00%	0.00%	0.00%	0.01%
Johnston	0.04%	0.00%	0.03%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%
Robeson	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.09%	0.00%	0.06%	0.01%
Grand Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%

ENA/Azura Facilities – Total ESRD Patients	
Facility	**Calendar Year 2017**
Greenville	1,045
New Bern	479
Total	1,524

EXHIBIT C

Local Medicare Allowable amounts for Greenville/New Bern, NC Market

2018 CTP Descriptor: Fistula Creation Procedures		2018 Physician Fee		2018 Facility Fee			2018 Total Reimbursement		
		ASC	HOPPS	ASC	HOPPS	ASC Facility Fee Lower than HOPPS	ASC	HOPP	ASC Total Lower than HOPPS
36818	Cephalic Transposition	$ 672.85	$ 672.85	$ 2,030.85	$ 4,103.89	-50.5%	$ 2,703.70	$ 4,776.74	-43.4%
36819	Basilic Transposition	$ 708.77	$ 708.77	$ 2,030.85	$ 4,103.89	-50.5%	$ 2,739.62	$ 4,812.66	-43.1%
36820	Forearm Transposition	$ 711.44	$ 711.44	$ 2,030.85	$ 4,103.89	-50.5%	$ 2,742.29	$ 4,815.33	-43.1%
36821	Any End-to-End Anastomosis	$ 643.60	$ 643.60	$ 1,186.97	$ 2,398.60	-50.5%	$ 1,830.57	$ 3,042.20	-39.8%
36830	Graft Creation	$ 645.98	$ 645.98	$ 2,030.85	$ 4,103.89	-50.5%	$ 2,676.83	$ 4,749.87	-43.6%

2018 CTP Descriptor: Vascular Access Maintenance Procedures		2018 Physician Fee		2018 Facility Fee			2018 Total Reimbursement		
		ASC	HOPPS	ASC	HOPPS	ASC Facility Fee Lower than HOPPS	ASC	HOPP	ASC Total Lower than HOPPS
36901	Fistulogram	$ 165.47	$ 165.47	$ 291.69	$ 589.44	-50.5%	$ 457.16	$ 754.91	-39.4%
36902	Peripheral Angioplasty	$ 235.90	$ 235.90	$ 2,307.67	$ 4,663.28	-50.5%	$ 2,543.57	$ 4,899.18	-48.1%
36903	Peripheral Stent	$ 311.73	$ 311.73	$ 4,095.21	$ 8,275.50	-50.5%	$ 4,406.94	$ 8,587.23	-48.7%
36904	Thrombectomy Only	$ 364.34	$ 364.34	$ 2,307.67	$ 4,663.28	-50.5%	$ 2,672.01	$ 5,027.62	-46.9%
36905	Thrombectomy + Peripheral Angioplasty	$ 437.16	$ 437.16	$ 4,095.21	$ 8,275.50	-50.5%	$ 4,532.37	$ 8,712.66	-48.0%
36906	Peripheral Stent + Thrombectomy	$ 505.16	$ 505.16	$ 6,329.66	$ 12,790.83	-50.5%	$ 6,834.82	$ 13,295.99	-48.6%

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August 22, 2016

Andrew M. Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1654-P
P O Box 8013
Baltimore, Maryland 21244-8013

RE: File Code-CMS-1654-P; Payment Policies under the Physician Fee Schedule & Other Revisions to Part B For CY 2017; Proposed Rule; (July 15, 2016)

Dear Acting Administrator Slavitt:

The American Society of Diagnostic and Interventional Nephrology (ASDIN) appreciates the opportunity to comment on the 2017 Proposed Physician Fee Schedule. **We specifically wish to address the CMS proposals related to the Dialysis circuit family of CPT codes 369x1, 369x2, 369x3, 369x4, 369x5, 369x6 and 369x7.** CMS did not accept the RUC recommendation regarding the valuation of both physician work and practice expense portions of the codes. We believe that the proposed RVUs are incorrect, and if not adjusted will have severe ramifications for the care of ESRD patients moving forward.

Background

ASDIN is a national medical society with approximately six hundred physician members and one hundred and twenty-five associate members whose focus is the provision of dialysis access care for patients with end-stage renal disease. Our members practice in both hospital and non-hospital settings, performing dialysis access procedures such as angiography, angioplasty, and thrombectomy which assist in the creation, maintenance, and repair of dialysis access. Because of service, quality, and cost considerations, these procedures are often done by our members in specialized vascular centers which are part of the physician office (site of service 11). These highly

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Journal of Vascular Access is the official journal of the
American Society of Diagnostic and Interventional Nephrology

EXHIBIT D

focused office-based centers have been demonstrated to provide tremendous value by increasing access to timely procedures, performing continual patient education, coordinating with patients' nephrologist and dialysis facility, and ensuring excellent outcomes. This allows patients to remain on dialysis without disruption due to vascular access complications. Studies have shown that the care patients receive in these centers is of high quality, and has reduced both overall hospitalization and costs to Medicare.

- *Dobson, A. et al Clinical and Economic value of Performing Dialysis Access Procedures in a Freestanding Office-based center as compared with the Hospital Outpatient Department among ESRD beneficiaries. Seminars in Dialysis. 2013.*

We are concerned that the dramatic reductions (see appendix A) in valuation for CPT codes 369x1 through 369x7 in the Physician Fee Schedule (PFS) proposed rule for 2017 would, if finalized, severely threaten the viability of these vascular access centers and lead to both increased costs and disruption of a system of care that has been very positive for patients with kidney disease. Ultimately, this disruption will lead to reduced patient access to timely care and overall reduction in the quality of care received.

Physician Work RVUs

A number of our members participated in the RUC survey of the Dialysis circuit family of codes through their membership in the Renal Physicians Association (RPA). We agree with the RPA comments to the 2017 proposed rule related to the Dialysis Circuit family of codes (369x1 – 369x9). During the survey process, our members recognized a significant problem with the survey that we believe is unique to the Dialysis circuit codes. This survey issue is particularly important because CMS has based its rejection of the RUC recommended physician work RVUs particularly for code 369x1 (the base code in this family) on concern about maintaining appropriate relativity with the Open and Percutaneous Transluminal angioplasty family of codes 372x1 – 372x4. We wish to point out a significant difference between these code families that we believe impacts the work intensity of the Dialysis circuit codes – and makes it appropriate for the dialysis circuit codes to have higher IWPUT as was in the RUC recommended RVUs.

According to CPT, the Dialysis access circuit is defined as originating in the artery adjacent to the arterial anastomosis and including all venous outflow (whether single or multiple veins) to the axillary-subclavian vein junction. We agree with this definition of the dialysis access because each component is integral to having a functional fistula or graft. While several different arteries and veins may be included in this definition, from a functional perspective it is a single "vessel." Hence, it is appropriate to treat the dialysis access as a single vessel for coding purposes and that is how the bundled Dialysis circuit codes (369x1 – 369x6) are built – they include all imaging and intervention within the dialysis access. The dialysis access as defined has a greater propensity for multiple lesions than native vessels in part because of the arteriovenous physiology and in part because it is cannulated with needles on a regular basis. Because of this greater propensity for multiple lesions, it is appropriate to define the access vessel as CPT has done and allow reporting of only a single angioplasty or stent in that entire conduit. This means that there is no code to recognize the work of "additional vessel" angioplasty or stent placement. There is also no code to recognize the additional work of arterial versus venous angioplasty. This is very different than the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). Add-on codes 372x2 and 372x4 describe arterial or venous

angioplasty (respectively) in each additional named vessel. This allows the building of a survey tool with a "typical" vignette with one angioplasty procedure, but appropriately allow reporting the additional work of intervention in a second or third lesion in separate vessels.

However, the survey built on the "typical patient" (51% of the cases) in the Dialysis circuit code family 369x1 – 369x6 is unable to recognize the additional work of additional angioplasty or stent – even though multiple or arterial lesions occur with significant frequency. The higher intensity (IWPUT) of these codes compared to the Open and Percutaneous Angioplasty codes 372x1 and 372x3 reflects the work of treating these additional lesions within the dialysis circuit.

We believe that taking these differences into consideration, the RUC recommended work RVUs for codes 369x1 – 369x6 maintain appropriate relativity between the Dialysis circuit code family (369x1 – 369x6) and the Open and Percutaneous Transluminal Angioplasty family of codes (CPT codes 372x1 – 372x4). We ask that CMS accept the RUC recommended RVUs for codes 369x1, 369x2, 369x3, 369x4, 369x5, and 369x6.

Additionally, since the CMS proposed lower work RVU for 369x7 is based upon comparison to these codes, **we ask that CMS accept the RUC recommended RVUs for 369x7.**

Practice Expense

We believe that the RUC recommended PE inputs for the nine CPT codes in the Dialysis circuit family (369x1 – 369x9) should be accepted and disagree with the refinements proposed by CMS. These are discussed individually in the following paragraphs.

Additional preservice clinical labor time for CPT codes 369x4 – 369x6 (Thrombectomy codes)
These codes describe procedures performed on an urgent basis in a patient with a thrombosed dialysis access. This is different than codes 369x1 – 369x3 which describe procedures performed electively on patients with a dysfunctional dialysis access. The elective procedures are scheduled and planned well in advance of the procedure and performed on days that do not conflict with the patient's dialysis schedule. However, the urgent procedures (369x4 – 369x6) are typically done when a patient presents to their dialysis treatment with a thrombosed access. They are unable to receive dialysis and an urgent call is placed by the dialysis facility to request thrombectomy. These procedures are typically done the same day so that the patient can receive dialysis within 12-24 hours and avoid hospitalization. The urgent nature of the procedure, need for additional preoperative testing because of missed dialysis, and need for arranging unscheduled dialysis treatment requires additional preservice time of the procedural staff. Arranging for an off schedule dialysis treatment is typically the responsibility of the procedural staff after the patient has been assessed in the preoperative area and the plan to restore or obtain dialysis access has been determined.

L037D Clinical labor to prepare and position patient
The RUC proposed additional 3 minutes are reasonable because these cases are done on the upper extremity using portable c-arm fluoroscopy. The additional time includes prepping and positioning the arm, applying appropriate shielding to the patient's torso, positioning the c-arm unit, and then positioning other radiation shielding devices. Prepping the arm can be done in a number of fashions but

typically requires 2 staff members. One staff member dons sterile gloves and holds the patient's arm extended to the side and up off the arm board (many ESRD patients cannot hold their arm in this position for the time required to fully prep). Another staff member then preps the arm and hand including fingers with Chloraprep applicators, applies a sterile glove or towel to cover the hand, and then the patient's arm is lowered into position on the arm board where it can be further draped for the procedure. Each of these activities require more time in the arm case than procedures done in the long plane of the body including the torso and legs. Three minutes is a more accurate reflection of the additional time than CMS's proposed one minute.

Thrombectomy device (Treretola)

A mechanical thrombectomy device (Arrow Trerotola device is most typical, SA015) and a Fogarty thrombectomy balloon (SD032) are both used in a dialysis access thrombectomy because they serve different purposes. The typical thrombosed fistula has an irregular vessel diameter that is filled with thrombus. A thrombectomy device is used to macerate this thrombus so that it can be aspirated or lysed. A pharmacologic agent may also be given to aid in thrombus lysis. This must be done prior to establishing inflow by removing the fibrin plug that forms at the arterial anastomosis. Once thrombus lysis through the body of the access is completed, it is safe to re-establish inflow by passing a Fogarty balloon catheter across the arterial anastomosis, inflating the balloon, and dragging it back into the access through the anastomosis. This maneuver dislodges the fibrin plug, allowing flow into the access. The Fogarty balloon is small and highly compliant allowing it to be pulled through the artery and into the access without damaging the vessels. The thrombectomy device cannot be used safely for this function. This device is larger so risks pushing the fibrin plug into the artery if passed across the arterial anastomosis from the access – risking distal arterial embolization. The device is also much more rigid being made from metal and with irregular shape that risks damaging the endothelium of the artery causing arterial injury. The Arrow Trerotola device packaging specifically warns against using it within the native artery. The Fogarty balloon also is not effective as a thrombus maceration device because of its small size. Both a thrombectomy device and Fogarty balloon are required in the typical fistula thrombectomy case.

Covered stent (Gore Viabahn SD254)

Covered stents are the only stent devices that are FDA approved and supported by evidence from randomized controlled trials for use in dialysis access procedures. They are typically used in recurrent or elastic stenoses in dialysis access – and have become the standard of care for these interventions. They are also used to repair venous rupture caused by balloon angioplasty. This is the reason that a covered stent is included in 369x3 and 369x6. Bare metal stents are still used in central venous angioplasty because of concern that covered stents will occlude the internal jugular vein. That is the reason that the Cordis bare metal stent is included in 369x8.

- *Haskal ZJ, Trerotola S, Dolmatch B, Schuman E, Altman S, Mietling S, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. N Engl J Med. 2010;362(6):494-503.*
- *Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. J Vasc Surg. 2016.*

Hemostatic patch

Two hemostatic patches are required in thrombectomy procedures (369x4 – 369x6) because these procedures require two separate cannulations and sheaths. Opposing sheaths are placed in the access to allow clearing of thrombus in both the arterial and venous portions of the access. The two sheaths also allow imaging and interventions on the entire access. At the end of the case, both sheath sites are removed and covered with a hemostatic patch which aids in preventing bleeding and maintaining sterility.

Chloraprep applicator 26ml

Skin antisepsis prior to percutaneous and open interventions is critical to infection prophylaxis. This is especially important for ESRD patients who have a higher risk of Staphylococcal infections. In the past, povidone iodine has been the most widely used antiseptic for skin cleansing prior to catheter insertion (1). However, studies have shown that preparation of central venous sites with a 2% aqueous chlorhexidine gluconate (in 70% alcohol) is superior for skin site preparation to either 10% povidone-iodine or 70% alcohol alone (2-6). In 2002, the CDC recommended that 2% chlorhexidine be used for skin antisepsis prior to catheter insertion (7). Although not specifically recommended for other interventional procedures, Chloraprep (2% Chlorhexidine gluconate in isopropyl alcohol) has become the typical solution used to prepare the arm and access site for these procedures (369x1 – 369x9). It has demonstrated superiority in preventing procedure related infections due to better antimicrobial properties and more prolonged effect on the skin. Chloraprep is different than Hibiclense solution which is 4% Chlorhexidine (no alcohol). The combination of Chlorhexidine and isopropyl alcohol has greatest efficacy as preoperative skin prep in dialysis catheter and endovascular procedures. Because of this greatest efficacy and CDC recommendations (for catheters), Chloraprep has become standard of care for the Dialysis circuit family of procedures.

1. *Clemence MA, et al. Central venous catheter practices: results of a survey. Am J Infect Control 1995;23:5.*
2. *National Kidney Foundation. Clinical Practice Guidelines for vascular access. Am J Kidney Dis 2006;48(Suppl 1):S176-273.*
3. *O'Grady NP, et al. Guidelines for the prevention of intravascular catheter-related infections. Am J Infec Control. 2011;39(4 Supple 1):S1-34.*
4. *Maki DG, et al. Prospective randomized trial of povodine-iodine, alcohol, and chlorhexidine for prevention of infection associated with central venous and arterial catheters. Lancet. 1991;338(8763):339-43.*
5. *Chaiyakunapruk N, et al. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site are: a meta-analysis. Ann Intern Med. 2002;136(11):792-801.*
6. *Mimoz O, et al. Prospective randomized trial of two antiseptic solutions for prevention of central venous or arterial catheter colonization and infection in intensive care unit patients. Crit Care Med. 1996;24(11):1818-23.*
7. *O'Grady NP, et al. Guidelines for prevention of intravascular catheter related infections. Atlanta, GA, Centers for Disease Control and Prevention. 2002:1.*

Wires

369x1 – 369x3 would typically utilize a micropuncture introducer kit that includes a 0.018" wire, a starter Bentson type 0.035" wire, and a hydrophilic 0.035" wire. Thrombectomy cases (369x4 – 369x6) require an additional 0.035" wire to cross the arterial anastomosis for imaging of the arterial inflow and interventions (commonly occurring) on the arterial side of the access. Once flow is established in the access by means of thrombectomy, a wire and catheter are passed through the access and across the arterial anastomosis so that contrast can be injected directly into the feeding artery. This allows one to

image the peri-arterial dialysis access safely without risking embolization of retained thrombus if an occlusive retrograde contrast injection technique were to be used. Central venous angioplasty cases (369x7 – 369x8) require an additional 260cm wire in order to have adequate length to park the tip in the inferior vena cava. Placing the wire tip in this location is an important safety maneuver to ensure that the wire remains fully across the angioplasty site (in case of rupture) and does not extend into or through the right ventricle causing arrhythmia or bleeding into the pericardium.

Conclusion

Finally, we wish to point out that the cumulative impact of reimbursement reductions for the Dialysis circuit family of codes 369x1 – 369x9, both in terms of physician work and practice expense RVUs, is quite dramatic (see appendix A). If the 2017 proposed work and PE RVUs are implemented many outpatient access centers that focus on providing care for ESRD patients may no longer be able to operate. Having dedicated centers with ability to respond rapidly to immature, dysfunctional, and thrombosed accesses has been critical in improved outcomes seen in the past few years including increased prevalent native arteriovenous fistulas, decreased catheter use, and lower inpatient hospitalization for vascular access complications (USRDS data). Migration of the Dialysis circuit family of codes 369x1 – 369x7 back to the hospital setting will greatly increase cost to the Medicare Program. **We strongly urge CMS to avoid the drastic reimbursement changes that would interrupt the progress made to date and create such challenges for our patients.**

We want to thank CMS for the opportunity to comment on the 2017 Physician Fee Schedule Proposed Rule. We look forward to working with you to ensure the best outcomes for Medicare beneficiaries with ESRD.

Sincerely,

Kenneth Abreo, MD
President
ASDIN

Addendum A

	2016 codes	2017 codes	2016 Total NF RVU	2017 Total NF RVU	Change
Angiogram of access	36147	369x1	23.80	16.03	-32.65%
Angiogram with angioplasty	36147, 35476	369x2	52.47	34.18	-34.86%
Angiogram with stent	36147, 37238	369x3	131.10	90.73	-30.79%
Thrombectomy	36147, 36148, 36870	369x4	67.33	37.12	-44.87%
Thrombectomy with angioplasty	36147, 36148, 36870, 35476	369x5	61.56	51.12	-16.96%
Thrombectomy with stent	36147, 36148, 36870, 37238	369x6	160.48	110.06	-31.42%

EXHIBIT E

Comparison of ENA/Azura Centers' 2018 Vascular Access Procedure Volumes (annualized) at 2018 Hospital OPD Rates and 2018 ASC Rates

Projected 2018 Impact	Medicare	Medicaid	Medicare & Medicaid
ASC	$ 8,227,035.03	$ 65,150.10	$ 8,292,185.13
OPPS	$ 14,761,580.27	$ 115,428.02	$ 14,877,008.29
Additional Cost of OPPS	$ 6,534,545.24	$ 50,277.92	$ 6,584,823.16