

**Petition for Adjusted Need Determination for 2018 State Medical Facilities Plan
Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients**
July 26, 2017

This Petition for Adjusted Need Determination is jointly submitted by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology, PA (the “Practices”), and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (“Azura”), which operate several outpatient vascular access centers in North Carolina specializing in the management and maintenance of End Stage Renal Disease patients’ vascular accesses, which are necessary for life-sustaining hemodialysis treatments.

The Practices and Azura propose an adjusted need determination for a demonstration project to develop two (2) operating rooms in each of the six (6) Health Service Areas statewide, to be located in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for ESRD patients, including the surgical creation, management and maintenance of patients’ vascular accesses. These facilities will improve access to life-sustaining dialysis care, the quality of vascular access care for ESRD patients, and clinical outcomes for these patients.

In addition, because of recent regulatory and reimbursement changes, existing, physician office-based vascular access centers will no longer be sustainable if they cannot become licensed ambulatory surgical facilities and will close, forcing ESRD patients into hospitals. Providing vascular access services in the hospital setting will result in unnecessary use of inpatient resources, 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 associated with an inpatient setting, and fragmentation of care. Consequently, providing vascular access services in hospitals will result in much greater expense, and with worse patient outcomes.

Kidney disease statistics for the United States indicate that 1 in 10 adults have some level of chronic kidney disease¹, and individuals with complete kidney failure – i.e., End Stage Renal Disease (“ESRD”) – must have either dialysis or a kidney transplant to survive. As of December 31, 2016, 17,387 North Carolina residents were undergoing dialysis for ESRD.² 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 very 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.

¹ World Kidney Day: Chronic Kidney Disease. <http://www.worldkidneyday.org/faqs/chronic-kidney-disease/>.

² July 2017 N.C. Semiannual Dialysis Report, Table A.

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

American Access Care of NC, PLLC

American Access Care of NC is an interventional radiology and vascular surgery practice located in Cary.

Eastern Nephrology Associates, PLLC

Eastern Nephrology Associates is a 20-physician nephrology practice headquartered in Greenville and New Bern, serving eastern North Carolina since 1975.

Metrolina Nephrology Associates, PA

Metrolina Nephrology Associates is a 34-physician nephrology practice with offices in Charlotte, Concord, Gastonia, Huntersville, Monroe, Mooresville, and Salisbury, serving the Metrolina area for over 40 years.

North Carolina Nephrology, PA

North Carolina Nephrology (formerly Capital Nephrology Associates and Wake Nephrology Associates) is a 20-physician nephrology practice with offices in Raleigh, Cary, Fuquay-Varina, Zebulon, Smithfield, Louisburg, and Dunn, serving Raleigh and the surrounding counties.

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-affiliated vascular access centers currently operate in Raleigh, Cary, Greenville, New Bern, Charlotte, Concord and Lenoir, NC.

Address/Email Address/Phone Number of Petitioners:

Azura Vascular Care

Attn: Murat Sor, MD

Chief Medical Officer

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

The Practices and Azura request an adjusted need determination for the development of two (2) operating rooms in each Health Service Area in the State, exclusively to provide vascular access procedures for end stage renal disease (ESRD) patients in separately licensed ambulatory surgical facilities. This change would constitute a change to Chapter 6 of the SMFP, and would read as follows:

Table 6___: Renal Single Specialty Ambulatory Surgical Facility Demonstration Project

Operating Room Service Area	Operating Room Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
HSA I	2*		
HSA II	2*		
HSA III	2*		
HSA IV	2*		
HSA V	2*		
HSA VI	2*		

* Need determination is pursuant to the Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project.

Vascular Access Single Specialty Ambulatory Surgical Facility Demonstration Project

In response to a petition from several physician practices and Azura Vascular Care, an adjusted need determination for Vascular Access Single Specialty Ambulatory Surgical Demonstration Projects (Project) was approved by the State Health Coordinating Council. Locating the facilities in different regions of the state serves the access and value Basic Principles by avoiding a concentration of Vascular Access Ambulatory Surgical Centers in one geographic area. There is a need determination for up to two operating rooms in each of the six Health Service Areas statewide, which operating rooms must be located in separately licensed vascular access single specialty ambulatory surgical facilities.

Applicant(s) shall demonstrate in the certificate of need application that the proposal will meet each criterion set forth below.

	Criterion	Basic Principle and Rationale
1	The application shall contain a description of the percentage ownership interest in the facility by each vascular surgeon and nephrologist.	Value – Implementing the innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation’s impact.
2	The proposed facility shall provide open access to non-owner and non-employee nephrologists and vascular surgeons.	Access – Services will be accessible to a greater number of ESRD patients if the facility has an open access policy for nephrologists and vascular surgeons.
3	The operating rooms shall provide only vascular access creation and management procedures for ESRD patients.	Value – Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation’s impact.
4	The proposed facility shall be certified by the Centers for Medicare and Medicaid Services (CMS), and shall commit to continued compliance with CMS conditions of participation.	Access – Requiring services to low income and medically underserved patients promotes equitable access to the services provided by the demonstration project facilities.
5	The proposed operating rooms shall provide care to underserved ESRD patients. At least 60% of the total number of patients served	Access – Requiring Service to Medicare patients promotes equitable access to the services provided by the demonstration project

	each year shall be Medicare or Medicaid recipients. ³	facilities.
6	The proposed facility shall obtain accreditation after licensure by the Accreditation Association for Ambulatory Health Care (AAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), or the Joint Commission (TJC), and shall commit to continued compliance with their respective standards.	Quality – Adherence to certification processes ensures that the facility is committed to meeting the generally accepted industry standards for quality and safety for their patients.
7	Health care professionals affiliated with the proposed facility, if so permitted by North Carolina law and hospital bylaws, are required to establish or maintain hospital staff privileges with at least one hospital with which the proposed facility has a transfer agreement in place.	Quality - Encouraging health care professionals to establish or maintain hospital staff privileges and to begin or continue meeting Emergency Department coverage responsibilities helps ensure the continued viability of community based hospital resources.
8	The proposed operating rooms shall meet all reporting, monitoring and evaluation requirements of the demonstration project set forth by the Agency.	Safety and Quality, Access, Value - Timely monitoring enables the Agency to determine whether proposed projects are meeting criteria and to take corrective action if approved applicants fail to meet criteria.
9	For each of the first three full federal fiscal years of operation, the applicant(s) shall provide the projected number of procedures in each proposed operating room for the following payor types: (i) charity care/self-pay; (ii) Medicare; (iii) Medicaid; (iv) TRICARE; (v) private insurance; and (vi) payment from other sources.	Access - Requiring service to a wide range of patients promotes equitable access to the services provided by the demonstration project facilities.
10	The performance standards in 10A NCAC 14C.2103 would apply.	Value - Performing at least a minimum number of outpatient procedures helps assure that patients receive the maximum healthcare benefit per dollar expended.

To ensure that the demonstration project facilities meet all three Basic Principles, each selected site shall be required to provide annual reports to the Agency showing compliance with the criteria in Table ___ of the 2018 State Medical Facilities Plan. The Agency shall specify the report components and format. The Agency will produce an annual summary of each facility’s annual report, and will evaluate the demonstration project after it has been in operation for three full federal fiscal years. Depending on the results as presented by the Agency, the State Health Coordinating Council shall consider whether to permit expansion beyond the original demonstration project sites.

³ 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. See 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>.

3. Reasons for the Proposed Adjustment:

An adjusted need determination should be included in the 2018 SMFP in order to preserve access to life-saving, high-quality care historically provided by physician office-based vascular access centers that provide dialysis access maintenance services. 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. The demonstration project would also enable the development of new centers in areas not yet served. 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:

ESRD, commonly known as kidney failure, currently affects about 650,000 Americans and is growing nationally at 5% per year. Many ESRD patients 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. 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 a 20% infection rate, AVGs a 10% infection rate, and AVFs a 0.5% infection rate. All vascular accesses, however, are susceptible to high dysfunction rates due to blockages, blood clots, and infection. The average dialysis patient experiences 2.2 to 2.5 access interventions per year in order to maintain a well-functioning access. For ESRD patients on hemodialysis, vascular access is a lifeline – but also an Achilles' heel. 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, new reimbursement rules 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 Will Achieve Better Outcomes

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

- 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>.
- A recent 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 the 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.

Azura-affiliated vascular access centers have offered this successful care model in North Carolina since approximately 2008, 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. Conversion to an ASC will also enhance coordination of care. Currently, Petitioners' patients' 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.

A vascular access-focused ASC will allow providers to also perform access-creation procedures, resulting in integrated, coordinated 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, 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 the ESRD patient's care plans is essential.

Because the proposed operating rooms would exclusively serve ESRD patients, the vascular ASC's providers will offer increased specialization and expertise in episodic vascular access procedures that hospitals cannot match. Forcing these patients into the hospital environment also exposes them 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.⁴ Allowing for vascular ASCs to provide dialysis patients with the full-spectrum of vascular access care under the auspices of 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

Azura-affiliated centers in North Carolina had 13,660 Patient visits and performed 11,050 interventional procedures during 2016. The 5,823 patients treated represented 79 of 100 counties, and over a third of North Carolina's total dialysis patient population of 17,387.⁵ 74.4% of these patients were Medicare or Medicaid beneficiaries.

But despite the proven track record of purpose-built ESRD vascular access centers, this care model faces extinction as a result of severe cuts to CMS's physician fee schedule reimbursement for ESRD vascular access procedures. Reimbursement for these procedures was cut approximately 30% in the physician office setting effective January 2017.⁶ 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.

⁴ 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.

⁵ See July 2017 N.C. Semiannual Dialysis Report, Table A.

⁶ See **Exhibit B**, 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).

Consequently, it is no longer viable for physicians to develop or operate office-based vascular access centers, and existing office-based centers will ultimately close. In fact, numerous office-based vascular access centers nationwide have already shut down or are scheduled to close or be sold, less than a year after the cuts took effect, including eleven vascular access centers across the Southern United States, four in California, and three in Ohio and Pennsylvania.

Additionally, numerous office-based vascular access centers that were previously profitable now operate at a loss as a result of the reimbursement cuts. In North Carolina alone, the Practices anticipate substantial capital calls at several centers operated by the Practices and Azura merely to be able to continue operations until the centers can become licensed as or develop ASCs.

If they cannot, the centers cannot continue to operate at a loss indefinitely and will be forced to 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. In addition, the hospital is 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. Specifically, in the experience of Azura-affiliated physicians, ESRD patients in the hospital environment often are not seen “urgently” due to competing priorities of the hospital Interventional Radiology (IR) department – the service typically tasked with treating these issues. Urgent ESRD cases are classically placed to the end of the day in hospital IR departments as inpatients so that critically ill patients from the Emergency Department (ED) and Intensive Care Units (ICUs) can be accommodated first, along with previously scheduled IR outpatients. Further delaying care for this population is that many hospital IR departments also require a potassium level be drawn. Furthermore, owing to their competing responsibilities, hospital IR departments often only 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.

Further, traditional non-ESRD focused ASCs suffer from many of the drawbacks of hospitals, and are therefore not a viable alternative for providing vascular access care. Non-vascular ASCs are less accessible to ESRD patients (which are approximately 80% Medicare and/or Medicaid) because ASCs typically rely on a high percentage of higher-reimbursing commercially insured patients and frequently have treatment criteria that rule out this patient population. For example, many ASCs do not accept chronically ill patients (ASA III) or those who have missed dialysis treatments. Critically, 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

According to the United States Renal Data System, ESRD beneficiaries comprised less than 1% of the Medicare population in 2014 but accounted for an estimated 7.2% of all Medicare fee for service spend, totaling over \$32.8 billion.⁷ 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, providers were able to improve accessibility and quality while lowering overall costs by moving vascular access maintenance procedures from hospital settings to purpose-built physician office settings that functioned much like ASCs. 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.⁸

Now these unlicensed settings are no longer financially viable. Therefore efficient and proactive vascular access treatment— essential to reduce the expense to the health care system generally – requires ESRD focused ASCs. Lacking an ASC environment, vascular access procedures will shift to hospitals, where cost of care and reimbursement far exceed that those in ASCs. See **Exhibit C** (comparison of OPPI and ASC reimbursement for dialysis maintenance procedures). Based on the volume and payor mix of procedures done in Azura-affiliated vascular access centers in North Carolina during 2017 (annualized), doing those procedures in an ASC would save approximately \$16.5M in Medicare and Medicaid reimbursement, compared with doing the same procedures in a hospital. See **Exhibit D** (impact analysis of 2017 procedures, annualized, if billed under CMS Hospital Outpatient Prospective Payment System or ASC Payment System). Based on historical growth, Azura expects the ESRD patient population to increase approximately 5% annually, so these savings would show a corresponding increase over time.

By matching specialized resources to ESRD patients' medical needs and eliminating the unnecessary use of inpatient resources, ESRD-focused ASCs would generate additional cost savings – to the patient and the health care system. 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

⁷ United States Renal Data System. 2016 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, 2016 (https://www.usrds.org/2016/view/v2_11.aspx).

⁸ See Footnote 3, above.

health care system overall.⁹ 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, ESRD patients' vascular access care will be forced into hospitals, at a greater cost to the healthcare system but without the specialization or coordination of care that a vascular ASC can provide. Moreover, it would unnecessarily consume limited hospital capacity and resources. Patients needing urgent dialysis procedures (e.g., declotting) who currently have access to office-based vascular access centers will lose access to timely care as those facilities close, and will likely end up in hospital EDs and be admitted while waiting for care (at greater expense, yet increasing the chance of worse outcomes).

Moreover, vascular access creation procedures would remain in the hospital setting, foregoing the advantages in care coordination, improved outcomes and lower cost that a vascular ASC can provide.

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 the remaining office-based vascular access centers are no longer sustainable, and despite numerous closures of vascular access centers in 2017, there is no indication that CMS will increase reimbursement for vascular access procedures under the Physician Fee Schedule. The existing vascular access centers in North Carolina are owned by physician practices with limited resources, which cannot fund the operation of the vascular access centers at a loss indefinitely.

2. Apply to develop an ASC under existing OR need methodology. By statute, an ambulatory surgical facility in North Carolina must have at least one licensed OR,¹⁰ and in 2017, there were no need determinations for additional ORs in any of the counties in which any of the Azura-affiliated vascular access centers currently operate (Mecklenburg, Cabarrus, Caldwell, Wake, Pitt and Craven Counties). Therefore, none of the existing vascular access centers could have been approved to become or to develop a licensed ASC. The proposed 2018 SMFP currently includes need determinations for additional ORs in only two of those counties (Mecklenburg and Wake). Therefore, four existing vascular access centers (in Caldwell, Cabarrus, Craven and Pitt Counties) cannot be approved for a vascular ASC CON in the foreseeable future under the current need methodology. Moreover, there will likely be numerous competitive application in 2018 for the ORs in Mecklenburg and Wake Counties, by hospitals and other surgical providers, and the number of approvable applications may well exceed the number of OR CONs that can be awarded, which could prevent the development of vascular ASCs despite the clear need.

⁹ See Footnote 4, above.

¹⁰ See N.C. Gen. Stat. § 131E-176(1b).

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 demonstration project would not result in unnecessary duplication because there are currently no ESRD-focused or vascular ASCs in North Carolina. Moreover, the development of several 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, and are secondary to more emergent and clinically intensive surgeries. Therefore, shifting some dialysis access creation procedures to licensed vascular ASCs would improve patient care and outcomes, and reduce the cost to the healthcare system by providing care in a less expensive outpatient setting.

Further, the demonstration project would not unnecessarily duplicate existing ambulatory surgical facilities because:

1. Existing ASCs generally cannot accommodate ESRD patients, who are chronically ill, generally with multiple co-morbidities, and who have frequently missed scheduled dialysis treatments;
2. Existing ASCs' scheduling processes generally cannot accommodate vascular access procedures as they usually present urgently;
3. 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 demonstration project would improve provider accountability by moving vascular access procedures from the office environment to the more highly-regulated ASC environment. Moreover, a lack of licensed vascular ASCs as office-based vascular access centers close will drive ESRD patients to hospitals, which often cannot provide timely care and where the risk of complications and infections is much higher. As noted above, there is extensive evidence that specialized vascular access centers result in better clinical outcomes than other settings.

Access: As noted above, if vascular ASCs cannot be developed, office-based vascular access centers will continue closing, and ESRD patients will 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.

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.

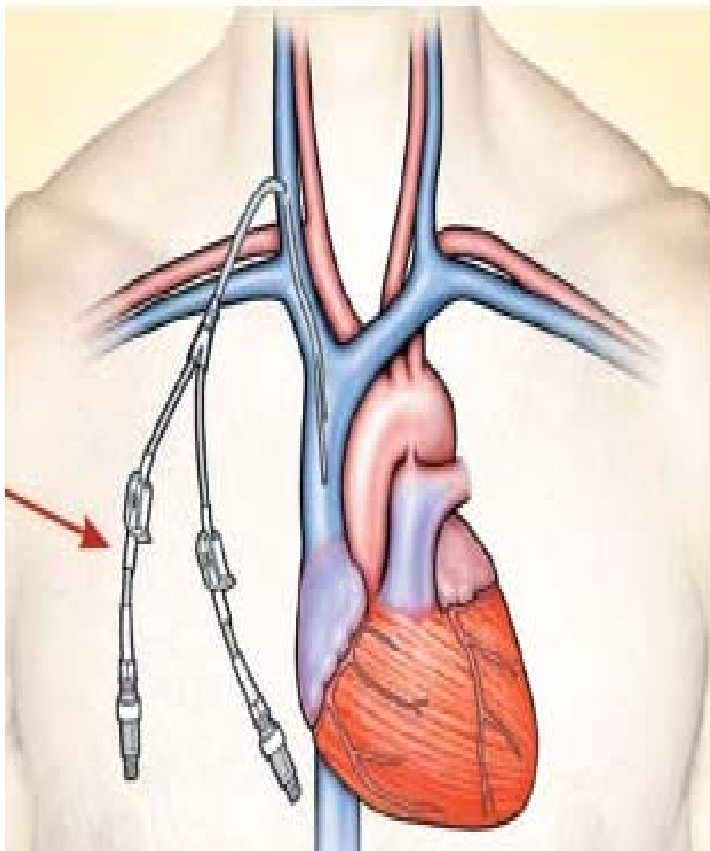
The proposed demonstration project would also promote geographic access by including a need determination for vascular ASCs in all six Health Service Areas statewide.

Value: If the status quo persists, existing vascular access centers will continue closing and care will be driven to the more expensive hospital setting, including numerous procedures for indigent patients that are currently provided by vascular access centers free of charge. Also, the inability of hospitals to see patients as quickly as vascular access centers for urgent vascular access maintenance issues will result in patient complications, hospital admissions and expensive care that would be unnecessary if ESRD patients had urgent access to licensed vascular ASCs.

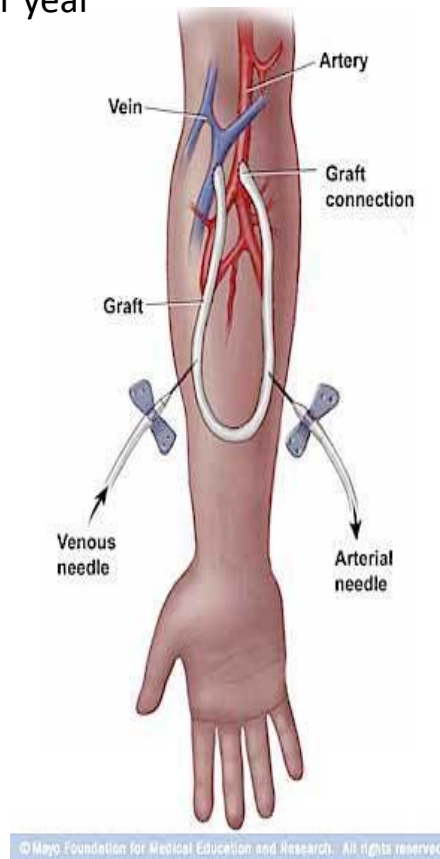
As noted above, CMS reimburses ASCs hundreds or thousands of dollars per procedure less than in the hospital setting, which would save Medicare and Medicaid over \$16M in reimbursement in North Carolina alone based on 2017 procedures. Accordingly, licensed vascular access ASCs would save North Carolina's healthcare system tens of millions per year.

3 types of Vascular Access

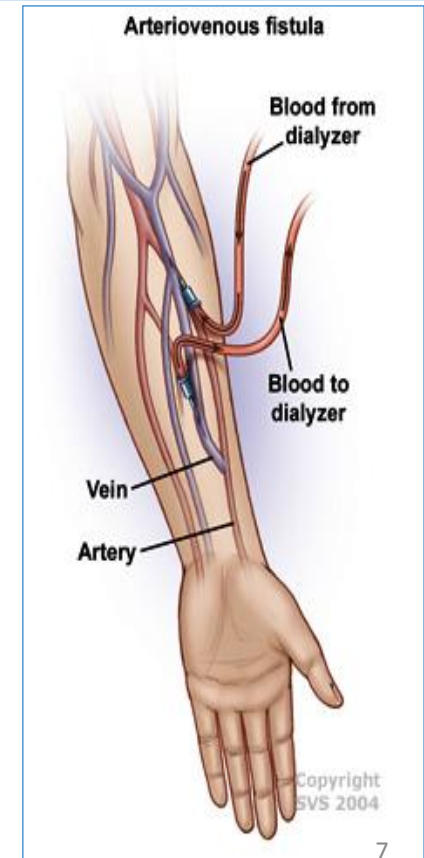
Catheter: Most problematic
High frequency of bloodstream infections



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



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





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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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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

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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

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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 (Trerotola)

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.

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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 Infect Control*. 2011;39(4 Suppl 1):S1-34.
4. Maki DG, et al. Prospective randomized trial of povidone-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 care: a meta-analysis. *Ann Intern Med*. 2002;136(11):792-801.
6. Mimos 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

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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%

2017 MEDICARE REIMBURSEMENT BY FACILITY SETTING: VASCULAR ACCESS MAINTENANCE

2017 CPT Descriptor: Vascular Access Maintenance Procedures		2017 Physician Fee		2017 Facility Fee			2017 Total Reimbursement		
		ASC	HOPPS	ASC	HOPPS	ASC Facility Fee Lower Than HOPPS	ASC	HOPPS	ASC Total Lower Than HOPPS
36901	Fistulogram	\$151.09	\$151.09	\$369.36	\$684.13	-46%	\$520.45	\$835.22	-38%
36902	Peripheral Angioplasty	\$225.02	\$225.02	\$3,119.32	\$4,825.20	-35%	\$3,344.34	\$5,050.22	-34%
36903	Peripheral Stent	\$307.93	\$307.93	\$6,025.55	\$9,752.43	-38%	\$6,333.48	\$10,060.36	-37%
36904	Thrombectomy Only	\$354.58	\$354.58	\$3,119.32	\$4,825.20	-35%	\$3,473.90	\$5,179.78	-33%
36905	Thrombectomy + Peripheral Angioplasty	\$445.02	\$445.02	\$6,025.55	\$9,752.43	-38%	\$6,470.57	\$10,197.45	-37%
36906	Peripheral Stent + Thrombectomy	\$519.31	\$519.31	\$9,341.78	\$14,782.14	-37%	\$9,861.09	\$15,301.45	-36%

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IMPACT ANALYSIS - 2017 PROCEDURE VOLUME (ANNUALIZED): COMPARISON OF OPPTS v. ASC

2017 ESRD Procedures for MCR/MCD Patients - Actual CPT/Insurance Mix Applied to ASC Facility			
Month	MEDICARE (MCR Allowable)	MEDICAID (13.75% of MCR Allowable)	MCR and MCD
JAN	\$ 1,743,441.05	\$ 20,151.93	\$ 1,763,592.98
FEB	\$ 1,830,385.61	\$ 21,281.00	\$ 1,851,666.61
MAR	\$ 2,038,574.42	\$ 19,837.15	\$ 2,058,411.57
APR	\$ 1,865,327.15	\$ 21,963.28	\$ 1,887,290.43
MAY	\$ 2,003,559.81	\$ 29,615.56	\$ 2,033,175.37
JUN	\$ 2,060,137.66	\$ 15,184.04	\$ 2,075,321.69
2017 YTD	\$ 11,541,425.69	\$ 128,032.96	\$ 11,669,458.65
Yearly	\$ 23,082,851.38	\$ 256,065.91	\$ 23,338,917.29

Yearly Impact	MCR	MCD	MCR & MCD
ASC	\$ 23,082,851.38	\$ 256,065.91	\$ 23,338,917.29
OPPS	\$ 39,318,483.70	\$ 446,094.69	\$ 39,764,578.39
Additional Cost of OPPTS	\$ 16,235,632.32	\$ 190,028.78	\$ 16,425,661.10

*based on NATIONAL asc and opps rates

**does not include Managed MCR/MCD plans

2017 ESRD Procedures for MCR/MCD Patients - Actual CPT/Insurance Mix Applied to OPPTS			
Month	MEDICARE (MCR Allowable)	MEDICAID (13.75% of MCR Allowable)	MCR and MCD
JAN	\$ 2,957,084.29	\$ 34,889.33	\$ 2,991,973.61
FEB	\$ 3,101,725.99	\$ 38,644.19	\$ 3,140,370.18
MAR	\$ 3,492,972.77	\$ 33,880.11	\$ 3,526,852.88
APR	\$ 3,153,785.12	\$ 37,954.74	\$ 3,191,739.86
MAY	\$ 3,431,354.39	\$ 50,485.74	\$ 3,481,840.13
JUN	\$ 3,522,319.30	\$ 27,193.23	\$ 3,549,512.53
2017 YTD	\$ 19,659,241.85	\$ 223,047.34	\$ 19,882,289.19
Yearly	\$ 39,318,483.70	\$ 446,094.69	\$ 39,764,578.39