

**Acute Care Services Committee
Agency Report
Exemption to Methodology for Vascular Access Operating Rooms
Proposed 2019 State Medical Facilities Plan**

Petitioners:

The Practices and Azura:

American Access Care of NC, PLLC
Eastern Nephrology Associated, PLLC
Metrolina Nephrology Associates, PA
North Carolina Nephrology, PA
Fresenius Vascular Care, Inc., d/b/a Azura Vascular Care

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Request:

The Practices and Azura (Petitioners) propose a change in the operating room (OR) need methodology such that “dedicated vascular access operating rooms located in single-specialty ambulatory surgical facilities be excluded from the [State Medical Facilities Plan] SMFP’s annual operating room inventory” (page 1). The Petitioners note that applicants would still be required to “demonstrate need and comply with the [certificate of need] CON standards applicable to operating rooms” (page 1).

The Petitioners alternatively propose an adjusted need determination for a demonstration project to develop a total of 12 ORs, two in each of the six Health Service Areas (HSA). The ORs would be located “in single-specialty vascular access ambulatory surgical facilities, to provide a full range of vascular access services necessary for [end-stage renal disease] ESRD patients...” (page 1). The criteria in the discussion of the demonstration project indicate the proposal to serve patients with chronic kidney disease (CKD) as well.

Background Information:

Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Healthcare Planning receives petitions twice during the course of plan development. Early in the planning year, petitioners may request changes that have the potential for statewide impact, defined as “the addition, deletion, and revision of policies or projection methodologies” (p.7, 2018 SMFP).

A functioning vascular access (VA) is essential for patients who receive dialysis. The three types of VA for ESRD patients are central venous catheter, arteriovenous (AV) graft, and AV fistula. The Petitioners report that 61% of their patients in North Carolina have an AV fistula, 19% have a central venous catheter, and 20% have an AV graft. The National Kidney Foundation recommends the use of AV fistulas whenever feasible because they are associated with the lowest rate of complications.¹ Vascular access centers (VAC) provide the surgical creation, management, and maintenance of VAs for ESRD patients. Some centers may also provide other vascular procedures for other types of conditions (e.g., peripheral arterial disease).

Fresenius owns and/or operates approximately 52% of the dialysis facilities in the state. Other major providers are DaVita with 36% of facilities and Health Systems Management with 8%. Various providers account for the remaining 4% of facilities. Fresenius also operates VACs, but DaVita and Health Systems Management do not.² Although no official information is available on the number of VACs in the state, one comment received by the Agency reported that there are approximately 12.

Persons with ESRD are eligible for Medicare regardless of age. The impetus for the petition is that the Centers for Medicare and Medicaid Services (CMS) instituted bundled payments for VA procedures on January 1, 2017. Specifically, procedures performed together more than 75% of the time must be bundled for payment. The Society for Vascular Surgery claims that a fee-for-service system produces an inherent incentive for physicians to treat immediate problems only. Rather, the purpose of bundling is to “target the highest quality vascular access method for a given patient” and then to “set up a bundled/global payment that incorporates placement of the vascular access as well a maintenance of this access over some defined period of time.”³ Note that the payment system applies to all types of VA reimbursement, not only those for ESRD patients. The Petitioners contend that many VACs will close because of the financial burdens of this change. They further state that closures would force ESRD patients into hospitals, thus incurring higher costs and poorer patient outcomes.

The Agency does not have systematic data on where VA procedures currently take place in North Carolina. VACs are not licensed, and the Agency collects no data on their procedures. The Agency’s annual License Renewal Applications (LRA) do not identify vascular surgical procedures in sufficient detail to ascertain the type of procedure or patient. However, LRAs from ASCs indicate that only about 0.2% of the total surgical procedures performed were vascular. Hospital outpatient departments (HOPD) also report that about 0.2% of the total procedures were vascular. Note that the HOPD figures do not include ambulatory procedures performed in shared

¹ http://kidneyfoundation.cachefly.net/professionals/KDOQI/guideline_upHD_PD_VA/va_guide1.htm

² DaVita owns Lifeline VACs in other states; the closest center to NC is in Norfolk, Virginia.

³ <https://vascular.org/news-advocacy/svs-medicare-physician-payment-plan-2013>

ORs in a hospital. Based on these statistics, it appears that most VA procedures are probably performed in VACs.

The Practices and Azura submitted a petition in the summer of 2017 requesting a demonstration project, almost identical to the one requested in the current petition. The Agency recommended denial, and the Acute Care Committee and SHCC concurred. The rationale for the denial was twofold. First, a number of questions remained that were not addressed in the petition. Second, sufficient time did not exist for proper consideration of the proposed demonstration project. The SHCC normally takes one full cycle to consider a demonstration project. For example, before approving the Single Specialty Ambulatory Surgical Facility Demonstration Project, the SHCC established a workgroup that began consideration of the demonstration in November of 2008. The project was approved for implementation in the 2010 SMFP. More recently, consideration of the Dental Ambulatory Surgical Facility Demonstration Project began in March 2016, with implementation in the 2017 SMFP.

Analysis/Implications:

Estimated Need for ORs for Vascular Access Procedures

NC had 17,789 dialysis patients as of 6/30/2017.⁴ This population grows by approximately 3.5% annually. Based on Azura's national experience, about 70% of ESRD patients need VA interventions. Patients in this 70% need about 2 interventions per year, with an estimated 60 minutes per procedure. It is unknown whether Azura's estimates include turnaround time.⁵

The following calculations use the Petitioners' figures presented in Exhibit B and the current OR methodology:

- $17,789 \times 70\% = 12,453$ patients
- 2 procedures per patient = 24,906 procedures
- 60 minutes per procedure = 24,906 surgical hours
- 1312.5 surgical hours = full utilization of an OR in an ASC
- $24,906 \div 1312.5 = 18.98 \rightarrow 19$ ORs

Based on these calculations, VA procedures for ESRD patients may currently require 19 ORs. This estimate uses the full utilization assumption for ASCs. The full utilization assumptions for hospitals are higher, and are based on the total number of surgical hours for the facility. Therefore, using the ASC full utilization percentage provides an estimate of the minimum number of ORs. Although the above estimates indicate that approximately 19 ORs may be required to serve the VA needs of ESRD patients, this estimate does not imply the need for 19 additional ORs. The estimate also does not imply that all ORs should be in ASCs, even though this illustration uses the ASC utilization threshold.

⁴ North Carolina Semi-Annual Dialysis Report, January 2018.

⁵ Other internet-based sources report 30-45 minute case times, but it is unclear exactly which procedures were included in the estimates.

Two potential groups of patients mentioned in the Petition were not included in the above calculations. First, the Petitioners propose to serve patients with CKD, but provide no estimate of the potential number and type of procedures expected. Second, the Petition also points out that initial VA placement in ASCs would be suitable for approximately 75% of new ESRD patients. Based on the estimated 3.5% annual growth in the ESRD population, the state would see approximately 623 new cases in 2018. If 75% can have initial VA placement in an ASC, this would increase the estimated number of patients by 467. Since no information on the length of these procedures was available, they were not included in the above estimates of the number of patients who may need interventions after initial access placement.

Impact of Recent CMS Regulations on Vascular Access Centers

The stated goal of the bundled payment structure for VA procedures is to have a zero percent impact on nephrology reimbursement overall.⁶ Several sources have estimated that the new regulations will decrease revenue by an average of 30-40% for VA procedures for ESRD patients, when performed in a physician's office.⁷ Moving VA procedures from a procedure room in a medical practice to a hospital outpatient setting will incur significant additional costs to Medicare. To the extent that patients shift to inpatient settings, they may also be at greater risk of health care-associated infection. Therefore, developing freestanding ASCs is one solution being sought across the nation.⁸ See Attachment A for a more detailed discussion of the issues.

After the 2017 rates went into effect, industry groups and professional associations engaged with CMS to address the consequences of the new payment structure and to seek changes. New CMS payment rates went into effect January 1, 2018. According to one group of attorneys who represent physicians and VACs, “[t]he 2018 reimbursement rates continue to place significant financial pressure on physicians who provide dialysis vascular access services in a Place of Service-11 (POS-11), vascular access center (VAC) or office-based laboratory (OBL) setting, while at the same time significantly decreasing any site-specific financial benefit of providing such services in a Medicare-certified ambulatory surgery center (ASC).”⁹ Some individuals in the industry have reported that CMS plans further changes to the rate structure in 2019, but this information cannot be verified.¹⁰

⁶ Riley, James B. & Greis, Jason S. (2016). Practical Considerations for Medical Practices Considering Converting their Vascular Access Centers into Medicare-Certified Ambulatory Surgery Centers. Chicago: McGuireWoods LLP.

⁷ Neumann, Mark E. (2016, September 29). *Nephrology: News & Issues*. Proposed bundling in Medicare Fee Schedule could cut interventional access revenue up to 40%.

⁸ Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

⁹ Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

¹⁰ Litchfield, Terry & McKittrick, Jason. (2017, November 7). Webinar: Analysis of 2018 Medicare Reimbursement Rates for Vascular Procedures. Retrieved from: <https://www.mcguirewoods.com/Events/Firm-Events/2017/12/Analysis-2018-Medicare-Reimbursement-Rates-Vascular-Procedures.aspx>

National data on the effects of the new CMS regulations is not yet available. Anecdotally, in 2017, the American Society of Diagnostic and Interventional Nephrology (ASDIN) reported that 20% of 71 VACs surveyed by the organization have closed as a result of the new regulations, and another 20% are likely to close.¹¹ It is unknown where patients of these closed VACs continue to receive services.

Issues Concerning Development of Dedicated Vascular Access ASCs

The Petitioners present a case for the development of new ambulatory ORs that specialize in serving the VA needs of patients with CKD and ESRD. If greater OR capacity is needed to serve these patients, three methods exist:

1. Convert unlicensed procedure rooms in VACs to licensed ORs.
2. Develop (build) new ORs in ASCs or hospitals.
3. Prioritize ESRD patients in ORs in existing ASCs or hospitals.

The first two options require a CON and a need determination in the SFMP, while the third does not. Moreover, the lead time for the first two options could easily be two years to completion. The third option is likely to require less time.

In general, the first option may best fit the business model of VACs, especially those with procedure rooms built to OR standards. However, having a licensed OR transforms the VAC from a physician's office into an ASC, which has different accreditation and regulatory requirements. This model would not be preferred in areas of the state that lack VACs with procedure rooms. Reportedly, dialysis patients in the western part of the state typically receive VA services in hospitals, rather than VACs.

In terms of the second option, the 2018 SMFP includes need determinations for 29 new ORs.¹² Past experience shows that new ASCs with fewer than two ORs tend not to be financially viable. However, CON applications have been approved for a single OR in an existing facility; in some cases, applicants have proposed to convert a procedure room into an OR. This option is open to VACs, as it is to all other CON applicants. While the CON review process may appear to give preference to multispecialty ASCs, it is possible for applicants to make a compelling case for single specialty facilities. Also, the summer petition process allows anyone to apply for an adjusted need determination if they believe that the methodology does not meet the needs of patients in a particular service area or region.

The third option would likely require a formal partnership with an existing ASC or hospital. The Petitioners point out that ASC scheduling does not allow for the often emergent need for VA procedures. They also note that not all ASCs accept ESRD patients, especially those who have

¹¹ Litchfield, Terry & McKitrick, Jason. (2017, November 7). Webinar: Analysis of 2018 Medicare Reimbursement Rates for Vascular Procedures. Retrieved from: <https://www.mcguirewoods.com/Events/Firm-Events/2017/12/Analysis-2018-Medicare-Reimbursement-Rates-Vascular-Procedures.aspx> (The original source for the survey is not available, thus it is not possible to know when it was conducted. It is only known that the survey does not cover the full 2017 calendar year. In addition, this survey probably does not have comprehensive coverage, because it is likely that ASDIN's national membership includes physicians from far more than 71 VACs.)

¹² One additional need determination exists for training of surgical residents in inpatient and outpatient procedures, and thus is not available to all types of applicants.

missed a dialysis treatment. In addition, ASCs may not have all of the equipment required for VA procedures (e.g., C-arm). The Petition does not discuss formal partnerships, but it is a reasonable option that may be advantageous to both the VA providers and the existing facility.

The Petition expresses a clear preference for the development of dedicated VA ORs in free-standing ASCs versus ambulatory ORs in a hospital. Given that one goal of the planning process is to avoid unnecessary duplication of services, the Agency undertook an examination of potential surplus capacity in ASCs and the distribution of 2018 SMFP OR needs. Figure 1 shows the number and location of surplus ORs in ASCs in North Carolina, as reported in the 2018 SMFP. This figure includes only multispecialty licensed ASCs with at least 1.5 surplus ORs; by definition, it excludes GI endoscopy facilities, demonstration sites, single specialty ASCs, and HOPDs. The calculated number of surplus ORs is 32.45. With the understanding that not all surplus ORs sit idle, the Agency conservatively estimates that the state has about 20 surplus ORs. The western part of the state is not well represented in Figure 1, but most other areas are. Figure 1 also shows the service areas that have OR needs in the 2018 SMFP. Here, the western part of the state is better represented.

Demonstration Project Alternative

The Petitioners also proposed a demonstration project as an alternative to the methodology change. The purpose of this type of demonstration appears to be to show that a certain model of service provision is successful, but the Petition offers no discussion what would constitute “success.” In this case, it does not seem necessary to demonstrate that an ASC can operate under the criteria proposed in the Petition.

Agency Recommendation:

Analysis of the available data led to two conclusions: (1) the CMS payment system is in a period of uncertainty such that no single solution is optimal; and (2) several viable alternatives to the Petitioners’ request exist in the current SMFP methodology.

Persons knowledgeable of the payment system and CMS have noted that the changes from 2017 to 2018 complicated the issues surrounding converting VACs into ASCs. In 2017, conversion to ASCs may have been a more clear option for VACs, all other things being equal. However, the 2018 changes may have made that preference somewhat less clear.¹³

Even if VACs have procedure rooms built to OR standards, conversion does not occur immediately. It is likely take at least a year from now to accomplish, depending on the CON review cycle. Further, development of new ORs pursuant to a permanent change to the methodology would take approximately two years to implement fully. The existing inventory of ORs in ASCs indicates that the state likely has sufficient capacity to accommodate most of the need. While operators of VACs may not prefer the third option discussed above, it is nevertheless an option that the SHCC has proposed to petitioners in the past. Moreover, it normally can be completed more quickly than conversion of procedure rooms or development of new ORs.

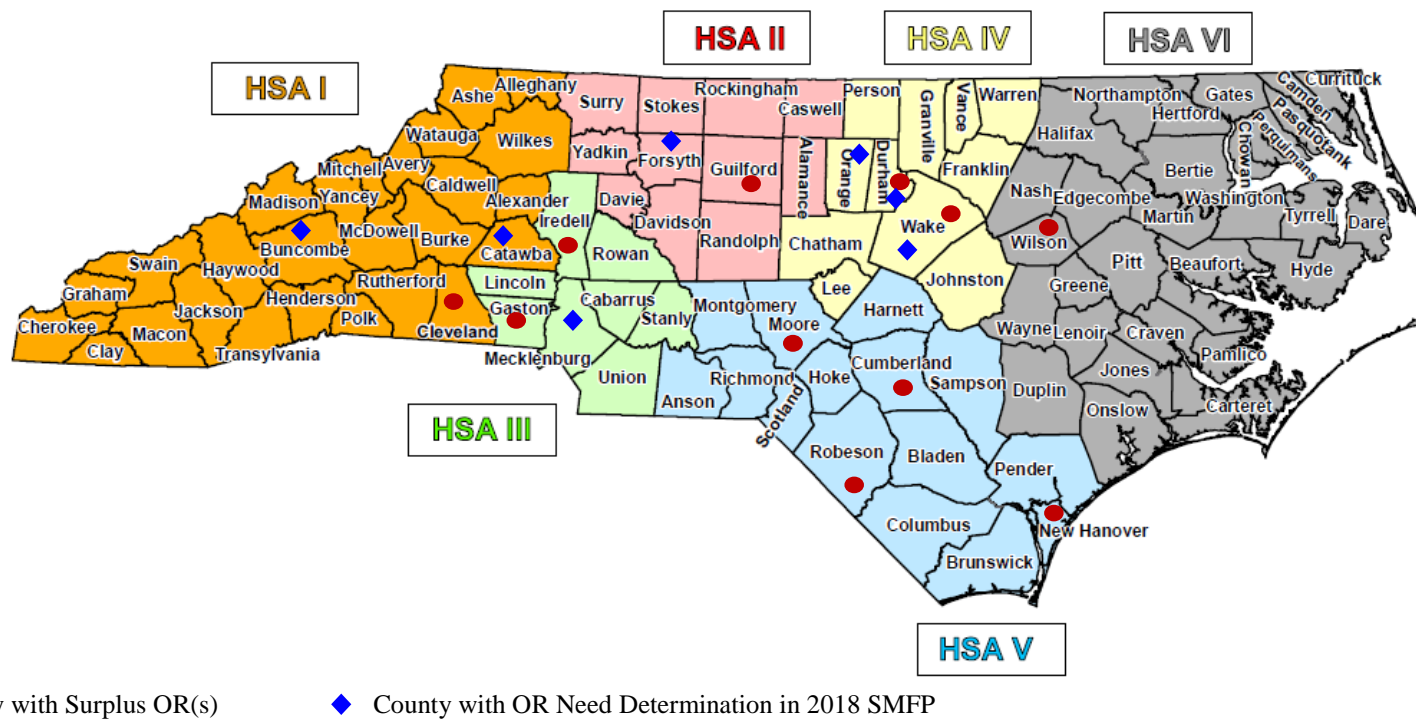
¹³ Greis, Jason S. & Cilek, Jake A. (2017). 2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL into an ASC Even More Challenging. Chicago: McGuireWoods LLP.

The OR methodology underwent substantial revision in 2017. The SHCC has typically been reluctant to make changes in a methodology so soon after its implementation. Altering the new methodology before it has an opportunity to function seems short-sighted. In lieu of partnering with existing ASCs that have surplus ORs, providers of VA services to ESRD patients can partner with an applicant for one of the ORs in the 2018 SMFP. As noted above, surpluses do not exist in all areas of the state. If a practice believes that patients are not being served well in a particular area of the state, submission of an adjusted need determination petition in the summer is always an option.

The Agency also considered the demonstration project alternative, but determined that the proposed demonstration would not be informative.

The Agency supports the current OR need determination methodology. Given available information and comments submitted by the deadline, and in consideration of factors discussed above, the agency recommends denial of the petition.

Figure 1. Multispecialty Ambulatory Surgical Centers with Surplus Operating Rooms, 2018 SMFP



HSA I	HSA II	HSA III
Cleveland: Cleveland Ambulatory Surgery Center - 4*	Guilford: High Point Surgery Center – 2.70 Guilford: Surgical Center of Greensboro – 1.58	Gaston: CaroMont Specialty Surgery – 4.12 Iredell: Iredell Surgical Center – 3**
HSA IV	HSA V	HSA VI
Durham: James A. Davis Amb. Surgical Center – 3.63 Wake: Blue Ridge Surgery Center- 2.76 Wake: Capital City Surgery Center – 2.26	Cumberland: Fayetteville Amb. Surgical Center – 2.46 Moore: Surgery Center of Pinehurst – 1.55 Robeson: Surg. Ctr. at SE Health Park – 2.36	New Hanover: Wilmington SurgCare – 1.66 Wilson: Eastern Regional Surgical Center – 3.37

* Chronically underutilized facility with 6 ORs. Current utilization is slightly over 1 OR (based on 1,312.5 hours).

** Chronically underutilized facility with 4 ORs. Current utilization is less than 1 OR (based on 1,312.5 hours).

Note: The need determination shown in Buncombe County covers the Buncombe/Madison/Yancey multicounty service area. The map does not include the need determination in Cumberland County because the ORs are restricted to the training of surgical residents.

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2018 Medicare Reimbursement Rates Make Deciding Whether to Convert a VAC or OBL Into an ASC Even More Challenging

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Earlier this month the Centers for Medicare and Medicaid Services (CMS) issued the 2018 Medicare Physician Fee Schedule (MPFS) and Ambulatory Surgical Center Fee Schedule (ASCS), which included updates to payment policies, payment rates and quality provisions for services furnished during the 2018 calendar year. The 2018 reimbursement rates continue to place significant financial pressure on physicians who provide dialysis vascular access services in a Place of Service-11 (POS-11) vascular access center (VAC) or office-based laboratory (OBL) setting, while at the same time significantly decreasing any site-specific financial benefit of providing such services in a Medicare-certified ambulatory surgery center (ASC).

Significant changes in reimbursement for dialysis vascular access care were first implemented in 2017 by CMS as a result of a new payment policy requiring services billed together more than 75 percent of the time to be bundled. The following interventional CPT code bundles were developed, which resulted in significant Medicare reimbursement reductions for a variety of commonly performed interventional services:

Procedure	2016 CPT Codes	2016 FFS Reimbursement	2017 Bundled CPT Code	2017 MPFS (POS-11) Reimbursement	% Change (2016-2017)
Angiogram of access	36147	\$855	36901	\$581	-32%
Angiogram with angioplasty	36147 35476 75978	\$2,052	36902	\$1,235	-40%
Angiogram with stent	36147 37238	\$4,712	36903	\$5,663	17%
Thrombectomy	36147 36148 36870	\$2,567	36904	\$1,801	-30%
Thrombectomy with angioplasty	36147 36148 36870 35476 75978	\$3,222	36905	\$2,304	-20%
Thrombectomy with stent	36147 36148 36870 37238	\$5,701	36906	\$6,868	17%

These dramatic reimbursement cuts made it financially difficult for many physicians to continue providing dialysis vascular access care in a POS-11 setting and, as a result, a significant number of VACs and OBLs closed in 2017 and additional centers are slated to close in 2018. It is

widely believed that a significant number of VACs and OBLs that exclusively provided dialysis vascular access care (and which do not perform peripheral arterial disease (PAD) services) experienced a net financial loss of between — 10 percent and 0 percent in 2017 in providing these services, depending upon a center’s patient volume, case mix and payor mix.

A number of trade groups and organizations, including the Renal Physicians Association (RPA), the Dialysis Vascular Access Coalition (DVAC) and the American Society of Diagnostic and Interventional Nephrology (ASDIN), actively engaged with CMS to advise the agency of the consequences of its reimbursement changes, including decreased availability of quality office-based care for this at-risk patient population, and increased cost to the Medicare program resulting from patients receiving dialysis access-related services in more expensive hospital outpatient departments. In an attempt to address the medical needs of this critically vulnerable patient population, some providers have considered the financial, operational and legal viability of converting their VAC or OBL into a Medicare-certified ASC and/or expanding their service offering to include PAD and other interventional procedures consistent with a physician’s relevant training and experience. The table below highlights the difference in 2017 Medicare reimbursement for certain dialysis vascular access services performed in an office-based VAC or OBL, as compared to the same services performed in an ASC setting:

Procedure	Bundled CPT Code	2017 MPFS Final Rate	2017 ASC Final Rate	\$ Differential
Angiogram of access	36901	\$581	\$520	\$61
Angiogram with angioplasty	36902	\$1,235	\$3344	\$2109
Angiogram with stent	36903	\$5,663	\$6,334	\$671
Thrombectomy	36904	\$1,801	\$3,474	\$1673
Thrombectomy with angioplasty	36905	\$2,304	\$6471	\$4167
Thrombectomy with stent	36906	\$6,868	\$9,861	\$2993

Based upon the 2018 MPFS rates it appears that these organizations’ concerns have been addressed in a limited manner. CMS has made modest increases in Medicare reimbursement for services performed in an ASC or OBL in 2018 as demonstrated in the following table:

Procedure	Bundled CPT Code	2018 MPFS Final Rate	2016 MPFS Final Rate	2017 MPFS Final Rate	\$ Change (2016-2018)	\$ Change (2017-2018)
Angiogram of access	36901	\$611	\$855	\$581	-\$244	\$30
Angiogram with angioplasty	36902	\$1,272	\$2,052	\$1,235	-\$780	\$37

Angiogram with stent	36903	\$5,725	\$4,712	\$5,663	\$1,013	\$62
Thrombectomy	36904	\$1,849	\$2,567	\$1,801	-\$718	\$48
Thrombectomy with angioplasty	36905	\$2,344	\$3,222	\$2,304	-\$878	\$40
Thrombectomy with stent	36906	\$6,949	\$5,701	\$6,868	\$1,248	\$81

The financial impact of the 2018 MPFS rates presents a “mixed bag” of news. When compared against the 2017 MPFS reimbursement rates, CMS made minor positive reimbursement changes to the entire crosswalk of dialysis vascular access codes, including to the industry’s most commonly billed CPT code (36902), which will experience a 3 percent reimbursement increase versus the 0.8 percent decrease that was originally proposed in the 2018 Proposed Rule. However, when the 2018 MPFS reimbursement rates are compared against the 2016 MPFS reimbursement rates one can see that 2018 Medicare reimbursement for a significant number of the most commonly used dialysis vascular access codes still falls far below 2016 reimbursement rates.

CMS also unexpectedly made significant reimbursement cuts to codes for dialysis vascular access services performed in an ASC setting in 2018 when it released the 2018 Final ASCS, which changes had not been previously discussed in the 2018 Proposed ASCS earlier this year. Industry groups continue reaching out to CMS to voice their concern about these reimbursement cuts, which may continue to enhance the problem of patients seeking out dialysis vascular access care in a more expensive hospital outpatient department setting. According to Jan Dees, President of American Vascular Access, a national provider of VAC and OBL services, “it is estimated there are 30 million patients in the United States in need of procedures impacted by these and other similar CPT codes. It is therefore critically important for patients to have easy access to VAC and OBL sites of service that can continue to provide conveniently located, high quality, timely and lower cost services.”

Yet, despite this decrease in Medicare reimbursement for dialysis vascular access care provided in an ASC setting, there continues to be a significant reimbursement differential between dialysis vascular access care provided in an OBL or VAC as compared against care provided in an ASC:

Procedure	Bundled CPT Code	2018 MPFS Final Rate	2018 ASC Final Rate	\$ Differential
Angiogram of access	36901	\$611	\$495	\$116
Angiogram with angioplasty	36902	\$1,272	\$2,776	\$1504
Angiogram with stent	36903	\$5,725	\$4,414	\$861
Thrombectomy	36904	\$1,849	\$2,913	\$1064
Thrombectomy with angioplasty	36905	\$2,344	\$4,947	\$2603

Thrombectomy with stent	36906	\$6,949	\$7464	\$515
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These Medicare reimbursement changes come at a time when many providers are considering converting their VACs and OBLs into Medicare-certified ambulatory centers as we discussed in a recent Whitepaper entitled [Practical Considerations for Medical Practices Considering Converting Their Vascular Access Centers Into Medicare-Certified Ambulatory Surgery Centers](#). These reimbursement changes and the possible eventual elimination of site-of-service payment reimbursement differentials by CMS across outpatient care settings as CMS moves to site-neutral payments, will only make conversion decisions more challenging.

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