DIALYSIS VASCULAR ACCESS COALITION

November 29, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1678–FC
7500 Security Boulevard
P.O. Box 8013
Baltimore, MD 21244-1850

**Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-FC)**

Dear Administrator Verma:

The Dialysis Vascular Access Coalition (DVAC) appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the final rule with comment for the CY 2018 Ambulatory Surgical Center Payment System (CMS-1678-FC).[1] DVAC is a consortium of medical specialty societies, physicians, and vascular centers that provides specialized vascular access services to individuals with advanced kidney disease and End-Stage Renal Disease (ESRD). The DVAC members are specialty societies, including the American Society of Diagnostic and Interventional Nephrology (ASDIN) and the Renal Physicians Association (RPA), as well as industry providers, including American Vascular, Azura Vascular Care and Lifeline Vascular Access. **DVAC represents well over 50% of the non-hospital sector providing vascular access services to patients with ESRD.**

DVAC appreciates this opportunity to comment on the final rule. This letter offers comments and recommendations on the following issues:

- Importance of Maintaining Non-Hospital Vascular Access
- Vascular Access Payment Reductions in the 2018 ASC Final Rule
- Incorrect Change in 2017 Status Indicators for 36901 – 36906 for 2018
- Future Office or OPPS-Based Designations for 36901 – 36906

[1] Federal Register, 82 FR 52356 (November 13, 2017)

## I. IMPORTANCE OF MAINTAINING NON-HOSPITAL VASCULAR ACCESS

The majority of Medicare beneficiaries with end-stage renal disease (ESRD) receive hemodialysis treatment, which removes fluid and toxins from the blood. In order to access the patient's bloodstream, different *vascular access* options include surgical creation of a fistula (surgical connection of an artery to a vein), a graft (connecting an artery to a vein with an implanted tube), or the insertion of a central line catheter (an external tube). Non-hospital vascular access centers (VACs) provide vascular access services for ESRD patients on dialysis, a population with severe health challenges. VACs and the practitioners who operate therein typically either (1) prepare permanent vascular access placement or (2) preserve vascular accesses by repairing clotted or compromised accesses. **Over the last two years, payment for vascular access preservation services in the non-hospital setting – under both the Ambulatory Surgical Center payment system and the Physician Fee Schedule – has been drastically cut and is jeopardizing the delivery of non-hospital vascular access services altogether.**

*Payment reductions in non-hospital setting are a significant setback for ESRD patients*

It is unnecessary and costly for dialysis vascular procedures to be performed in the hospital outpatient setting. When the CMS-led Fistula First Breakthrough Initiative began in 2003, significant delays in vascular access care for ESRD patients in the hospital outpatient setting were common. In addition, there was limited patient access to ESRD patient-focused, non-hospital vascular access centers to provide vascular access services. The majority of ESRD patients had no choice but to receive vascular access services in the hospital outpatient setting and were often relegated to haunt the hospital emergency department as they awaited needed vascular access services as provider capacity would allow. It is important to note that vascular access repair must be done within a short window of time or the vascular access is likely to fail irreparably. As a result, the inferior alternative, a central line catheter, must be inserted to perform dialysis. This situation was bad for ESRD patient quality and outcomes given higher mortality rates and higher use of grafts and catheters over fistulas (the gold standard option for vascular access with the lowest rate of infection).

As the importance of fistulas became more widely recognized (as well as the complications and costs associated with less preferred vascular access options), increasing demand for timely vascular access services was met by the development of non-hospital vascular access centers in the physician office and ASC settings. These non-hospital centers avoid the scheduling delays for vascular access services that were common in the early-to-mid 2000s and provide an ESRD patient-focused site-of-service for ESRD patients to receive vascular access services from practitioners who are highly specialized in the provision of such services. Fistula use has since increased significantly from around 30% in the mid-2000s to over 60% today. Total Medicare spending (inpatient, outpatient, physician office, and ambulatory surgical center) for these services also has decreased markedly since that time.

Medicare payment reductions to the ambulatory surgical center and physician office settings are already beginning to turn the clock back on vascular access services for ESRD patients. The DVAC provided comments to the CY 2018 Physician Fee Schedule (PFS) Proposed Rule regarding significant payment reductions to that site-of-service in the CY 2017 PFS Final Rule; those comments are included as an attachment to this letter. Survey data provided by the American Society of Diagnostic and Interventional Nephrology (ASDIN) makes clear that the payment reductions to the physician office setting are already causing significant physician office closures.

The payment reductions in the 2018 ASC Final Rule now threaten to make this site-of-service also not an option, which will drive patients back into the hospital for care.

The comments in this letter focus on the payment reductions for vascular access services in the ambulatory surgical center site-of-service that were contained in the CY 2018 ASC Final Rule. However, there is a larger policy question for CMS to consider. That question is whether it is CMS policy to have a viable non-hospital, patient-focused option for ESRD patients to receive vascular access services. Closures of non-hospital vascular access centers will force patients to receive these services in the non-specialized hospital setting and result in (1) higher costs, (2) demonstrated delays in fistula creation, (3) increased fistula failure, (4) increased catheter use, (5) longer drive times for dialysis access services, (6) marked increase in out-of-pocket costs to patients, and (7) lower quality of care.[2] **As a broader policy matter, the payment reductions in the 2017 PFS for the physician office setting and the 2018 ASC PPS for the ambulatory surgical center setting threaten non-hospital, patient-focused vascular access services as a viable site-of-service option.**

We are aware that the ASC, PFS, and OPPS fee schedules are separate and distinct payment methodologies with their own data inputs and their own policies. However, when it comes to the viability of non-hospital vascular access services, we urge CMS to look at its data and policies for these fee schedules on a holistic basis. Appropriate consideration of the data for vascular access services in the near-term will determine the viability of non-hospital vascular access services in the coming years.

## II. VASCULAR ACCESS PAYMENT REDUCTIONS IN 2018 ASC FINAL RULE

Effective January 1, 2017, CPT established nine new bundled codes to describe dialysis vascular access preservation services that were previously reported under separate codes. These are 36901 – 36906 plus three add-on codes (36907 – 36909) which have no separate payment in the ASC setting.

| Old Procedures | | New Code |
|---|---|---|
| 36147 | → | 36901 |
| 35475, 35476, 36147, 75962, 75978 | → | 36902 |
| 36147, 37238 | → | 36903 |
| 36147, 36148, 36870 | → | 36904 |
| 35475, 35476, 36147, 36148, 36870, 75962, 75978 | → | 36905 |
| 36147, 36148, 36870, 37238 | → | 36906 |

Since the 2017 ASC Final Rule, these codes have undergone several important changes to their status indicators which are largely responsible for the significant payment reductions between the 2017 and 2018 ASC payment rates. The changes to these codes have been as follows:

[2] El-Gamil, A. M., Dobson, A., Manolov, N., Davanzo, J. E., Beathard, G. A., Litchfield, T. F., & Cowin, B. (2017). What is the best setting for receiving dialysis vascular access repair and maintenance services? The Journal of Vascular Access, 0-0. doi:10.5301/jva.5000790

| Codes | 2017 ASC Final Rule | 2018 Proposed Rule | 2018 Final Rule Code | Percent Change 2017 to 2018 |
|---|---|---|---|---|
| 36901 | $370 (P2) | $316 (R2) | $319 (P2) | -13.72% |
| 36902 | $2,983 (J8) | $3,445 (J8) | $2,525 (G2) | -15.37% |
| 36903 | $5,653 (J8) | $6,058 (J8) | $4,481 (G2) | -20.74% |
| 36904 | $2,983 (J8) | $3,445 (J8) | $2,525 (G2) | -15.37% |
| 36905 | $5,653 (J8) | $6,058 (J8) | $4,481 (G2) | -20.74% |
| 36906 | $8,850 (J8) | $9,395 (J8) | $6,926 (G2) | -21.75% |

J8 = Device-intensive procedure; paid at adjusted rate.

G2 = Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.

P2 = Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight.

R2 = Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight.

## III. CMS SHOULD MAINTAIN 2017 STATUS INDICATORS FOR 36901 – 36906 FOR 2018

While the change to 36901 appears to have been data-driven and based on changes to the relative weight in the OPPS fee schedule between 2017 and 2018, the rest of the changes to these codes (36902 – 36906) have been driven in most part due to changes in the status indicators. **Importantly, however, in its discussion in the CY 2017 ASC Final Rule on the decision to assign 36901 with a temporarily office-based status indicator, CMS noted it had "no claims data" for 36901.** This acknowledgement is important given that 36901 is part of the same family of codes that was instituted in 2017 where this family of codes also includes codes 36902 – 36906. In other words, it follows that CMS had "no claims data" for any of the codes 36902 – 36906 when it made the determination – *without any opportunity for notice and comment* – to change the status indicator for those codes from J8 to G2.

**In fact, the DVAC's own analysis of Medicare claims data for 2017 using the new code set (36901 – 36906) found the device costs for 36903 and 36906 to be well over the 40% threshold required for the device-intensive designation criteria.**[3] In other words, the decision not to use claims data to change the status indicator for 36902 – 36906 is very likely to result in at least two of these codes reverting *back* to the device-intensive designation in 2019. Therefore, compounding the drastic payment reductions in the ASC Final Rule to these services will be a whip-saw reaction in 2019 for at least several of these same services. ESRD patients and the providers who serve them should not be subject to such volatility in payment rates.

As a broader policy matter, we believe CMS should not be making *any* status indicator changes in the ASC final rule without the opportunity to comment in the proposed rule. We note in the 2015 Physician Fee Schedule, after significant stakeholder concerns were raised regarding not "having an opportunity for public comment on specific CMS proposals to change rates prior to payments being based upon those rates," CMS revised its policy to only include RUC recommendations in proposed rules.[4] **In the case of the codes 36902 – 36906, given both the lack of notice and comment opportunity for the significant reductions to these critical vascular access services as well as**

[3] Braid-Forbes Health Research, *Device costs recorded with new dialysis access codes*, November 10, 2017

[4] 79 FR 67548 (November 13, 2014)

**the lack of data utilized to make such a decision, we strongly urge CMS to maintain the current status indicator designations for the family of codes 36902 – 36906 in 2018.**

**Recommendation: We strongly urge CMS to maintain the current (2017) status indicator designations for the family of codes 36902 – 36906 in 2018.**

## IV. CMS SHOULD DELAY FURTHER OFFICE-BASED DESIGNATIONS UNTIL THE NON-HOSPITAL SECTOR STABILIZES

While Section 603 of the Balanced Budget Act of 2015 discourages the inappropriate *acquisition* of physician practices and ambulatory surgical centers by hospitals, there currently is *no* CMS policy which will address the significant *migration* to the higher cost hospital outpatient department (HOPD) setting if the non-hospital vascular access sector is rendered nonviable. As non-hospital vascular access centers close and utilization migrates to the HOPD setting, this will mean significant increases in spending for vascular access services under the Medicare program as well as higher copayments for ESRD patients. As an example, the table below reflects how 36902, the highest utilized code for vascular access services, would be reimbursed in CY 2018 in the three sites of service. **Even with the use of the add-on code (36907) – which is only used 20% of the time – global payments for 36902 would still only be 53% of the HOPD in the ASC setting (and only 37% of the HOPD in the office-based setting).**

| CPT | Procedure | 2018 Final HOPD Rate | 2018 Final ASC Rate | 2018 Final Office Rate | **ASC as a % of HOPD** | **Office as a % of HOPD** |
|---|---|---|---|---|---|---|
| 36902 | Angio / angioplasty dialysis circuit | $5,336 | $2,776 | $1,272 | **52%** | **24%** |
| 36902 + 36907 | w/ central angioplasty | $154 | $154 | $770 | **53%** | **37%** |

These points are highly relevant to CMS policy for vascular access codes under the ASC fee schedule as they relate to any "office-based" designation, a CMS policy which provides that if 51% of services are provided in an office-based setting that the ASC fee schedule should be limited to the office-based payment rate. We note that when CMS originally instituted the office-based designation policy under the ASC fee schedule, the stated policy objective was to prevent the inappropriate migration of services from the physician office to the ASC.[5] **Given the cost, quality, and access issues previously mentioned, we submit that the migration of vascular access services from the non-hospital setting (to include physician office and ambulatory surgical center) to the hospital outpatient department is inappropriate.**

*ASCs Provide the Most Comprehensive Set of Services for Vascular Access Services*

Due to the comprehensive set of services available in the ambulatory surgical center setting, the ASC setting is, in fact, the *optimal* setting for vascular access services. This is due to the fact that

[5] 72 FR 42486 (August 2, 2007)

ASCs provide *both* the creation of fistulas (and other accesses) *as well as* the maintenance of these accesses. Although physician offices provide patient-focused fistula *maintenance* services, due to the surgical nature of fistula *creation* services (i.e. 36818, 36819, 36820, 36825, 36830, and 36832), these codes are not payable under Medicare in the physician office setting. At the same time, it is important to maintain the physician office setting for vascular access services given barriers to the establishment of ASCs as well as rural access concerns. For example, 35 states have certificate-of-need requirements for ASCs which often mean a physician office alternative is the only possible non-hospital vascular access option in many states.

As CMS considers the most appropriate time to implement the "office-based" designation policy, the DVAC urges CMS to recognize that the most pressing policy consideration at hand for CMS is the viability of the non-hospital vascular access sector overall. Reducing ASC rates to the PFS setting, particularly when DVAC data provided to CMS indicates that PFS rates continue to be undervalued, would be antithetical to that concept. On the other hand, by delaying further office-based designation for vascular access services in the ASC setting, CMS will have the opportunity to monitor for further non-hospital center closures and ensure the viability of the non-hospital vascular access sector in the years ahead.

**Recommendation: We respectfully request CMS delay office-based designations for 36902 – 36906 until the non-hospital sector stabilizes and, at a minimum, until a full year of 2018 data is available.**

**Conclusion**

DVAC's comments on the CY 2018 Ambulatory Surgical Center Fee Schedule Final Rule seek to ensure ongoing access to non-hospital vascular access services. Non-hospital vascular access centers are designed to meet the specialized vascular needs of patients with ESRD. Hospital outpatient departments, which may provide a wide range of services, are not designed to meet the vascular needs of complex dialysis patients either in terms of the timeliness of vascular care or in the quality of specialized vascular procedures. Non-hospital vascular access centers monitor the quality of care and utilization of services and are in frequent communication with the dialysis facilities and patients they serve. Processes are in place for rapid and expedited response to provide vascular access care to patients with compromised vessels, to preserve and prevent failure of fistulas, and to avoid missed dialysis treatments.

We look forward to continuing to work with CMS to (1) maintain and improve access to non-hospital vascular access services and (2) build on the important gains of the Fistula First Breakthrough Initiative. If you have additional questions regarding these matters and the views of the DVAC, please contact Jason McKitrick at (202) 465-8711.


AMERICAN
VASCULAR


ASDIN
AMERICAN SOCIETY OF DIAGNOSTIC AND INTERVENTIONAL NEPHROLOGY


azura
vascular care


Lifeline
Vascular Access SM


RPA
Renal Physicians Association

# ATTACHMENT –

# DVAC COMMENT TO THE

# 2018 PHYSICIAN FEE SCHEDULE

# PROPOSED RULE


September 11, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1676–P
7500 Security Boulevard
P.O. Box 8013
Baltimore, MD 21244-1850

**Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)**

Dear Administrator Verma:

The Dialysis Vascular Access Coalition (DVAC) is pleased to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule for the CY 2018 Physician Fee Schedule (CMS-1676-P).[1] DVAC is a consortium of medical specialty societies, physicians, and vascular centers that provide vascular access services to individuals with advanced kidney disease and End-Stage Renal Disease (ESRD). DVAC represents specialty societies, including the American Society of Diagnostic and Interventional Nephrology (ASDIN) and the Renal Physicians Association (RPA), as well as industry providers, including American Vascular, Azura Vascular Care and Lifeline Vascular Access. **DVAC represents well over 50% of the office-based sector.**

DVAC appreciates this opportunity to comment on the proposed regulations. This letter offers comments and recommendations on the following issues:

- Impact of the 2017 PFS Final Rule on Vascular Access
- "Typical Patient" Is a Source of Underlying Data Errors
- Need to Update the Fistula-Related Breakthrough Initiative
- PACS Workstation
- Patient Relationship Categories

[1] Federal Register, 82 FR 33950 (July 21, 2017)

## I. BACKGROUND

The majority of Medicare beneficiaries with end-stage renal disease (ESRD) receive hemodialysis treatment, which removes fluid and toxins from the blood. In order to access the patient's bloodstream, different access options include surgical creation of an arteriovenous fistula (AVF) (surgical connection of an artery to a vein), an arteriovenous graft (AVG) (connecting an artery to a vein with a tube), or the insertion of a central line catheter (a tube). Free-standing vascular access centers (VACs) provide vascular access services for ESRD patients on dialysis, a population with severe health challenges. VACs and the practitioners who operate therein provide a full array of procedures focused on (1) preparation for permanent vascular access placement and (2) routine or periodic repair of clotted or compromised vascular accesses. It is important to note that repair of a compromised fistula or graft must be done within a short window of time or the vascular access is likely to fail, and the inferior alternative, a central line catheter, must be inserted to perform hemodialysis. The comments in this letter focus on the importance of preservation and repair of vascular accesses after they have been created.

## II. IMPACT OF THE 2017 PFS FINAL RULE ON VASCULAR ACCESS

Effective January 1, 2017, CPT established nine new bundled codes (36901 - 36909) to describe dialysis vascular access preservation services that were previously reported under separate codes.

| Old Procedures | | New Code |
|---|---|---|
| 36147 | → | 36901 |
| 35475, 35476, 36147, 75962, 75978 | → | 36902 |
| 36147, 37238 | → | 36903 |
| 36147, 36148, 36870 | → | 36904 |
| 35475, 35476, 36147, 36148, 36870, 75962, 75978 | → | 36905 |
| 36147, 36148, 36870, 37238 | → | 36906 |
| 35476, 75978 | → | 36907 |
| 37238 | → | 36908 |
| 37241 | → | 36909 |

While we appreciate that CMS incorporated some of the comments of the dialysis vascular access community in its finalization of rates for these services in 2017, unfortunately, critical flaws remained in the final rates for these services. This is evidenced by the fact that the most common code (36902) was cut by 39% from 2016 to 2017 and is now paid at a rate of 25% of what is paid in the hospital outpatient department. The table below reflects how 36902 would be reimbursed in the CY 2018 PFS Proposed Rule. **Even with the use of the add-on code (36907) – which is only used 20% of the time – 36902 would still be reimbursed at only 37% of the HOPD rate.**

| CPT/HCPCS | Bundled Procedure | 2018 Proposed HOPD Rate | 2018 Proposed Office Rate | **Office as a % of HOPD** |
|---|---|---|---|---|
| 36902 | Angio / angioplasty dialysis circuit | $5,217 | $1,228 | **24%** |
| 36902+36907 | w/ central angioplasty | $5,342 | $1,962 | **37%** |

*A. Impact on Access*

The RVUs that CMS has finalized for dialysis preservation services are so inadequate that we are gravely concerned that a significant number of VACs might not be able to continue to provide these services. As a result, ESRD patients once served by the centers will be forced to drive farther to hospital outpatient departments and other sites-of-service where they will have to pay more for vital vascular access services. As evidence of this problem, the American Society of Diagnostic and Interventional Nephrology (ASDIN) surveyed its membership and found the following:

- More than 20 percent of 71 physician office centers surveyed ***already have closed*** due to the cuts contained in the CY 2017 Physician Fee Schedule Final Rule.
- More than 55 percent of respondents either have closed or intend to close their physician office center due to these cuts.
- Patients would be subjected to significant additional drive times:
    - Almost 60 percent of respondents indicated that their patients would have to drive more than 30 additional miles to receive vital vascular access services due to their center's closure.
    - 27 percent of patients would have to drive an hour or more.
    - Some respondents indicated additional drive times of up to 4 hours or a potential loss of access altogether to these services in rural areas.

The survey and additional comments by ASDIN respondents are included as "Addendum 1" to this letter.

*B. Impact on Cost*

Such significant payment disparities between sites-of-service for similar services are not just evidence of a payment flaw, they end up costing more in the long run. While relative site-neutrality between sites-of-service tends to optimize patient access as well as program and beneficiary spending, significant payment disparities tend to eliminate service lines and cost Medicare and its beneficiaries more. As the CY 2018 proposed reimbursement rates illustrate, the cost of performing the same procedures in the HOPD setting as compared with the physician office setting are almost 5 to 1 for the key vascular access preservation code (36902). As freestanding vascular access centers close and utilization migrates to the HOPD setting, this will mean significant increases in spending for vascular access services under the Medicare program as well as higher copayments for ESRD patients.

*C. Impact on Quality*

Studies have shown that dedicated access centers like those operated by DVAC members provide higher quality care to Medicare beneficiaries at a lower cost than hospital outpatient departments. The largest and most rigorous study[2] of vascular access care across sites found, by comparison to patients treated in hospital outpatient departments (HOPDs), patients treated in freestanding vascular access centers were found to have:

- Lower all-cause mortality
- Fewer infections
- Fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD.

Based on the evidence, ESRD patients forced to HOPDs to receive needed vascular access services as a result of the 2017 PFS cuts to freestanding vascular access centers will be subject to lower quality care. The study cited here, and reviewed by the American Society of Diagnostic and Interventional Radiology (ASDIN), is included in its entirety as "Addendum 2."

## III. TYPICAL PATIENT IS A SOURCE OF UNDERLYING DATA ERRORS

DVAC and other stakeholders raised significant concerns relating to CMS' use of the "typical patient" to develop vascular access service code valuations as part of the public comment process for the CY 2017 PFS rulemaking process. These concerns related to the use of a "typical patient" by CMS as a 45-year old patient, when in fact United States Renal Data System (USRDS) and other published data show the typical ESRD patient is >65 years old. Additionally, ESRD patients typically have multiple co-morbid medical problems, chronic debilitation, and are taking an average of 6-10 medications each day. Stakeholders provided such evidence in support of CMS using higher RUC recommended physician work RVUs for vascular access preservation services, rather than the CMS-modified values contained in the CY 2017 PFS Final Rule. Use of RUC-recommended work RVUs would be as follows:

- 36901: 3.36 work RVUs (instead of CMS-modified 2.82)
- 36902: 4.83 work RVUs (instead of CMS-modified 4.24)
- 36903: 6.39 work RVUs (instead of CMS-modified 5.85)
- 36904: 7.50 work RVUs (instead of CMS-modified 6.73)
- 36905: 9.00 work RVUs (instead of CMS-modified 8.46)
- 36906: 10.42 work RVUs (instead of CMS-modified 9.88)
- 36907: 3.00 work RVUs (instead of CMS-modified 2.48)
- 36908: 4.25 work RVUs (instead of CMS-modified 3.73)
- 36909: 4.12 work RVUs (instead of CMS-modified 3.48)

[2] El-Gamil, Audrey et al., *What is the best setting for receiving dialysis vascular access repair and maintenance services?*, September 2, 2017

In the CY 2017 PFS Final Rule, CMS noted it was "skeptical" of RUC-recommended values for the new codes, but would consider new compelling evidence to support the RUC-recommended values. Moreover, in the CY 2018 PFS Proposed Rule, CMS noted "Stakeholders have expressed concerns regarding the typical patient for these procedures as reflected in the information included in the RUC recommendations for CY 2017 and the importance of appropriate payment for ensuring access to care for Medicare beneficiaries." In that light, we provide further evidence relating to the current application of CMS crosswalks used to value vascular access preservation codes.

*American Society of Anesthesiologists (ASA) Scores Are Evidence of CMS Need to Reevaluate*

ASA scores are assessments of a patient's overall health that is based on five classes (I to V).[3] ESRD patients receiving dialysis access services are typically an ASA 3 (patient with severe systemic disease) or ASA 4 (patient with severe systemic disease that is a constant threat to life). Yet, ASA scores for services used by CMS to value the new dialysis access codes are typically ASA I (normal healthy patient) or ASA II (patient with mild systemic disease). The table below provides further evidence regarding these crosswalk errors for 36901 – 36906 (36907 – 36909 are add-on codes).

| New Code | ASA Score* | CMS Crosswalk | ASA Score** |
|---|---|---|---|
| 36901 | ASA 3 / 4 | 44388 | ASA 1 / 2 |
| 36902 | ASA 3 / 4 | 44408 | ASA 1 / 2 |
| 36903 | ASA 3 / 4 | 44403 | ASA 1 / 2 |
| 36904 | ASA 3 / 4 | 43264 | ASA 1 / 2 |
| 36905 | ASA 3 / 4 | Based on ratio to 36901 | ASA 1 / 2 |
| 36906 | ASA 3 / 4 | Based on ratio to 36901 | ASA 1 / 2 |
| * 93.9% of dialysis access patients are ASA 3/4 with majority of patients needing urgent care<br>** 74% - 84% of patients in CMS crosswalks are ASA 1/2 | | | |

Given the significant amount of compelling evidence that the CMS-modified work RVUs significantly undervalue the intensity of providing vascular access services to ESRD patients, at a minimum, we urge CMS to accept the RUC-recommended work RVUs for these services. Indeed, DVAC believes comparing new vascular access preservation codes (e.g. involving a high flow arterialized fistula) to a colonoscopy or other elective GI procedures is inappropriate, as evidenced by ASA scores, and seeks to work with the Agency to consider more appropriate crosswalks for the family of services represented by 36901 – 36909.

**Recommendation: We urge CMS, at a minimum, to accept the RUC-recommended work RVUs for dialysis access preservation services (36901 – 36909) as they reflect a higher intensity patient than the current CMS-modified work RVUs. However, we also ask CMS to work with stakeholders to consider more appropriate crosswalks for these services to better reflect the patient (i.e. a patient with a severe disease undergoing a non-elective procedure) as well as the service itself (i.e. involving a high flow artery rather than a GI procedure).**

*"Typical Patient" Concerns Affect other Inputs in Vascular Access Preservation Code Valuations*

DVAC's concerns with the "typical patient" used to develop code valuations for dialysis access preservation services go well beyond issues relating to the work RVUs. DVAC's analysis of supply and clinical labor inputs used in the CMS database reveals that CMS inputs are also well below

[3] More info on ASA scores available here: https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system

what the industry knows is the case for a typical patient based on auditable, verifiable data pulled from electronic patient records. Because this industry data represents more than 50% of the market, we know that the data collected by DVAC represents what is used in the case of a typical patient. Included as an addendum to this letter is average supply usage data by procedure type for procedures performed in DVAC centers from January – June 2017 for the family of codes 36901 – 36909. DVAC is also in the process of collecting clinical labor inputs which show, among other things, that the rate per minute used by CMS for the registered nurses who help with these procedures may be undervalued by as much as 40%.

**Recommendation: We urge CMS to use the industry supply data collected by the DVAC – which represents over 50% of the market – to correct current inputs in the CMS database. This data is included as "Addendum 3" to this letter. We also urge CMS to work with stakeholders to correct other flaws in the database, including those relating to clinical labor inputs.**

## IV. NEED TO UPDATE THE FISTULA-RELATED BREAKTHROUGH INITIATIVE

It has been well-established since at least the early 2000s that the AV fistula is the "gold standard" access choice for hemodialysis patients and offers the lowest rate of infection for patients. However, in 2003, fistulas made up only 32% of accesses. In 2005, CMS launched the Fistula First Breakthrough Initiative and, as a result, fistula use is now well over 60% in the prevalent population.[4] More recently, this initiative evolved into the Fistula First/Catheter Last initiative to focus on decreasing the use of catheters. However, an update to the Fistula First initiative is also needed to ensure proper preservation of fistulas as current data show as many as 50% of newly placed fistulas will not mature or function without timely and appropriate intervention (thereby driving use of central line catheters associated with costly complications).

The Fistula First initiative has promoted and focused primarily on increasing the number of AVFs and decreasing the number of catheters. However, little attention has been paid to the need for the maturation and preservation of AVFs after they are surgically created. As stated, up to 50% of AVFs fail to mature after initial surgical creation.[5] [6] Additionally, almost twice (1.9 X) as many AVFs will be open at 2 years when maintained as compared to those without secondary procedures.[7] **In view of these known statistics, and taking into account the rates of failed fistulae and need for catheter insertions and associated costs, we urge CMS to acknowledge the importance of timely vascular procedures to mature and preserve AVFs, and to update the Fistula First to include preservation as an equally important component of the Fistula First / Catheter last initiative.**

*CMS Cuts in 2017 PFS to Dialysis Access Services are a Setback to Fistula First Initiative*

When the Fistula First initiative began in 2003, significant delays in scheduling fistula placement in hospital outpatient settings were common. Additionally, patients with clotted fistulas were not necessarily given scheduling priority in the HOPD setting. To meet this demand, a number of freestanding dialysis access centers have opened in the past 10 years. Due to the national initiatives, and providers' responses to provide early and timely vascular care for patients with ESRD receiving

[4] http://fistulafirst.esrdncc.org/wp-content/uploads/2015/11/LLFL-Team-Approach-for-Achieving-Catheter-Freedom.pdf
[5] Miller PE, et al. Predictors of adequacy of arteriovenous fistulas in hemodialysis patients. Kidney Int. 1999;56(1):275-280
[6] Asif A, et al. Early arteriovenous fistula failure: a logical proposal for when and how to intervene. Clin J Am Soc Nephrol. 2006;1(2):332-339
[7] Ayez, N et al. Secondary interventions in patients with autologous arteriovenous fistulas strongly improve patency rates, Journal of Vascular Surgery, October 2011

hemodialysis, the Fistula First initiative has made great gains. However, the initiative also has not yet reached its goals and the achievements to date are vulnerable and may be reversed if ready access to high-quality, timely services is compromised.

An essential component of the Fistula First initiative should be patient access to dialysis access services where fistulas are not only *created*, but properly *preserved* to prevent failure. As noted above, cuts to these dialysis access preservation services (including for fistulas) through the CPT 36901 – 36909 series in the CY 2017 PFS are causing significant patient harm due to:

- Longer drive times for dialysis access services as freestanding providers close;
- Lower quality of care (e.g. lower mortality, higher infection rates and higher hospitalization rates) as patient move to the HOPD setting; and
- Higher patient expenditures and copays for care provided in the HOPD setting.

We believe the confluence of these patient harms will be a setback for the Fistula First initiative. Given this evidence, we ask that CMS update the Fistula First initiative to a **"Fistula First/Fistula Preservation"** goal that recognizes the importance not just of *creating* a fistula over other options, but *preserving* the fistula over time. We also ask that the Center for Clinical Standards and Quality work with the Hospital and Ambulatory Policy Group to correct the untenable site-of-service differentials which threaten the success the Fistula First initiative has made over the last decade.

**Recommendation: We ask that CMS update the Fistula First initiative to a "Fistula First/Fistula Preservation" goal that recognizes the importance not just of *creating* a fistula first over other options, but *preserving* the fistula over time.**

**V. PACS Workstation**

In the CY 2018 PFS Proposed Rule, CMS discusses the use of the professional picture archiving and communication systems (PACS) workstation in vascular ultrasound codes and seeks comments regarding whether or not the use of the professional PACS workstation would be typical in certain CPT and HCPCS codes, including the following (among others):

- *G0365 (vessel mapping of vessels for hemodialysis access).* Professional PACS workstation currently included.
- *93930 (Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study).* Professional PACS workstation not included.
- *93931 (Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study).* Professional PACS workstation not included
- *93970 (duplex scan of extremity veins; complete bilateral study).* Professional PACS workstation not included.
- *93971 (duplex scan of extremity veins; unilateral or limited study).* Professional PACS workstation not included.
- *93990 (Duplex scan of hemodialysis access).* Professional PACS workstation not included.

The aforementioned codes are either (1) used in the planning for dialysis in pre-surgical vessel mapping and are critical in access placement (in the case of G0365) or (2) used for vascular ultrasound of the extremity and/or access for diagnosis and treatment of dialysis access dysfunction.

Given the chronic nature of vascular access issues related to ESRD patients, preservation of these images in the professional PACS workstation is a vital part of coordination of care.

**Recommendation: We request that the professional PACS workstation be included in all of the aforementioned codes.**

**VI. Patient Relationship Categories**

We ask that CMS provide additional information regarding the use of vascular access codes in assigning costs to physicians in MACRA. We realize MACRA mandates the use of these codes, but there will be significant administrative burden in their use. Providers involved in the care of dialysis patients and their vascular access will report across multiple categories. In addition, the proposed codes are quite vague and do not specify chronic vs acute issues nor do the codes identify care coordination which can be quite complex in dialysis patients who have a serious chronic illness and multiple episodes of acute issues related to vascular access.

**Recommendation: We ask that CMS provide additional information regarding the use of patient relationship category codes in assigning costs to physicians under MACRA.**

**Conclusion**

DVAC's comments on the CY 2018 Physician Fee Schedule Proposed Rule seek to ensure ongoing access to vascular access services. We look forward to continuing to work with CMS to (1) maintain and improve access to vascular access services, including in the most high-quality and cost-effective settings, and (2) build on the important gains of the Fistula First Breakthrough Initiative. If you have additional questions regarding these matters and the views of the DVAC, please contact Jason McKitrick at (202) 465-8711.

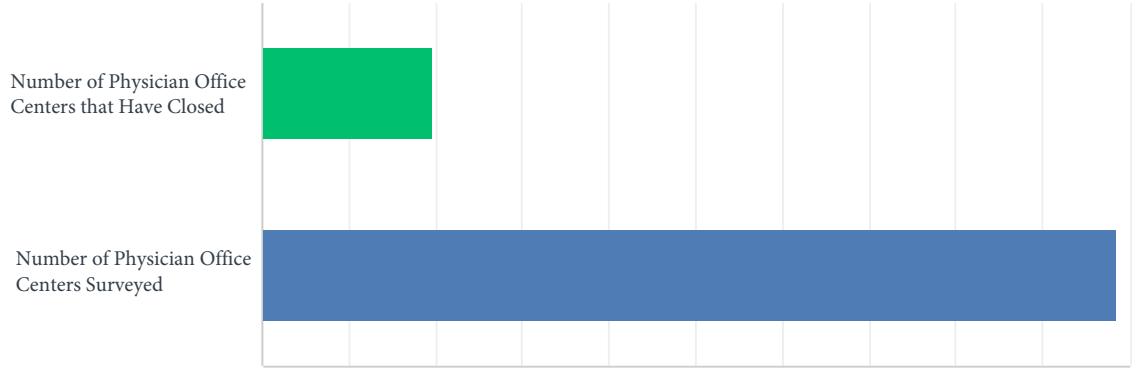




# ADDENDUM 1

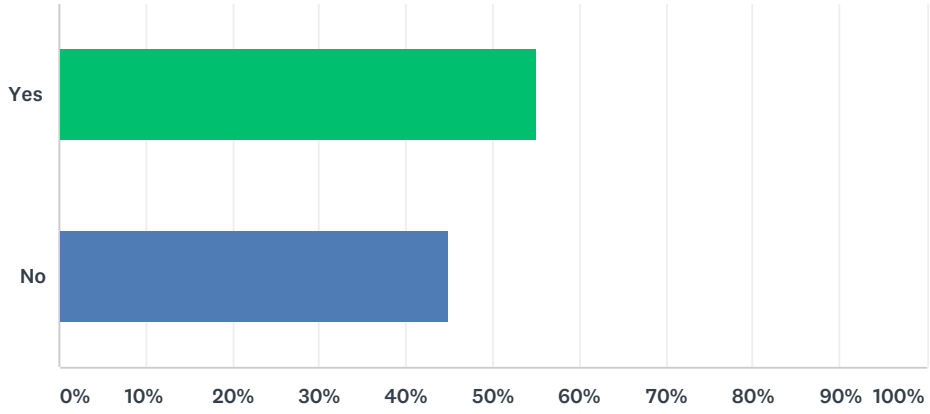
QUESTION 1

## How many of your physician office settings have closed as a result of the cuts contained in the CY 2017 Physician Fee Schedule? (please provide both number of physician office centers that have closed as well as how many you operated before the closures so we can understand the percentage of physician office centers that have closed thus far)?




| ANSWER CHOICES | Average # per physician | Total Number | |
|---|---|---|---|
| Number of physician office centers that have closed: | | 15 | |
| Number of physician office centers surveyed: | 2 | 71 | |
| | | | |

# Q1 Have you closed or do you anticipate closing your physician office center due to cuts under Medicare for vascular access services?




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 55.10% | 54 |
| No | 44.90% | 44 |
| TOTAL | | 98 |

QUESTION 3

# For Medicare patients that you believe will lose access to coverage at your center, what would you estimate would be the average increased drive time for these patients to receive vascular access coverage at another site-of-service?

| # | RESPONSES | DATE |
|---|---|---|
| 1 | 45 minutes | 9/7/2017 8:09 PM |
| 2 | 15 minutes | 9/1/2017 7:55 PM |
| 3 | Varies | 8/29/2017 8:22 PM |
| 4 | n/a | 8/29/2017 8:09 AM |
| 5 | 1 hour | 8/29/2017 8:01 AM |
| 6 | none | 8/28/2017 11:27 PM |
| 7 | 1-2 hours | 8/28/2017 9:55 PM |
| 8 | 20 miles | 8/28/2017 9:06 PM |
| 9 | 30-45 minutes | 8/28/2017 8:42 PM |
| 10 | 30 min | 8/28/2017 7:35 PM |
| 11 | it will double-triple | 8/28/2017 7:28 PM |
| 12 | 25 min | 8/28/2017 5:06 PM |
| 13 | 45 minutes | 8/28/2017 4:55 PM |
| 14 | 10 miles | 8/28/2017 4:55 PM |
| 15 | 1 hour | 8/28/2017 4:36 PM |
| 16 | 40 minutes | 8/28/2017 4:35 PM |
| 17 | 2 hrs | 8/28/2017 4:33 PM |
| 18 | 2 to 3 hours | 8/28/2017 3:50 PM |
| 19 | 20-30 minutes | 8/28/2017 12:23 PM |
| 20 | they will drive the same distance but to the hospital | 8/28/2017 8:59 AM |
| 21 | Not sure | 8/28/2017 8:27 AM |
| 22 | 1hr | 8/28/2017 8:26 AM |
| 23 | Na | 8/28/2017 7:20 AM |
| 24 | 0 | 8/27/2017 11:00 PM |
| 25 | n/a | 8/27/2017 10:19 PM |
| 26 | 30 minutes | 8/27/2017 12:15 PM |
| 27 | 25 miles | 8/27/2017 9:21 AM |
| 28 | 25 miles | 8/26/2017 10:41 PM |
| 29 | 30 min | 8/26/2017 8:34 PM |
| 30 | 1.5 hours | 8/26/2017 3:33 PM |
| 31 | NA - no other options except hospitalization | 8/26/2017 11:03 AM |
| 32 | 30 minutes | 8/26/2017 10:26 AM |

| | | |
|---|---|---|
| 33 | 30 min | 8/26/2017 7:53 AM |
| 34 | No Medicare patient will loose access to our center. | 8/26/2017 7:10 AM |
| 35 | 90 minutes | 8/26/2017 3:58 AM |
| 36 | 1 hour | 8/26/2017 1:32 AM |
| 37 | 30 minutes | 8/26/2017 1:26 AM |
| 38 | 1-2 Hours easily | 8/26/2017 12:04 AM |
| 39 | 30 minutes | 8/25/2017 10:30 PM |
| 40 | Similar | 8/25/2017 9:31 PM |
| 41 | 90 min | 8/25/2017 9:24 PM |
| 42 | 30min | 8/25/2017 8:25 PM |
| 43 | N/a | 8/25/2017 8:17 PM |
| 44 | 30 minutes | 8/25/2017 7:15 PM |
| 45 | 30-60 minutes if they go at all. Local hospitals particularly in rural AZ do not provide these services with any level of expertise | 8/25/2017 6:43 PM |
| 46 | up to 3 hours | 8/25/2017 6:37 PM |
| 47 | 2 hrs or more | 8/25/2017 6:33 PM |
| 48 | 2 to 4 hours | 8/25/2017 6:32 PM |
| 49 | 30 mins or go to hopspital | 8/25/2017 6:29 PM |
| 50 | 5 minutes | 8/25/2017 6:18 PM |
| 51 | 30 mins | 8/25/2017 6:13 PM |
| 52 | 1hr | 8/25/2017 5:57 PM |
| 53 | 10 minutes | 8/25/2017 5:55 PM |
| 54 | 2 hours | 8/25/2017 5:32 PM |
| 55 | 15 - 20 minutes in our Metropolitan area | 8/25/2017 5:22 PM |
| 56 | 30 minutes | 8/25/2017 5:19 PM |
| 57 | 5-7 miles | 8/25/2017 5:08 PM |
| 58 | 1 hour | 8/25/2017 5:02 PM |
| 59 | 15 minutes | 8/25/2017 4:59 PM |
| 60 | 30min | 8/25/2017 4:54 PM |
| 61 | 20 minutes | 8/25/2017 4:53 PM |
| 62 | 45 minutes | 8/25/2017 4:45 PM |
| 63 | 30 minutes | 8/25/2017 4:44 PM |

# Comments

| # | RESPONSES | DATE |
|---|---|---|
| 1 | I personally know of other vascular access centers in our city that are losing money and potentially closing. I know of more patients being routed to hospitals with dramatically increased costs. | 9/1/2017 7:55 PM |
| 2 | we have had to cut our staff which has increased procedure waiting times. this has also caused an increased wait to get an appointment. | 8/29/2017 11:06 AM |
| 3 | The patients can be admitted to the hospital for access care as they were 10 years ago. Higher costs and length of stay are expected, the treating physician will not be specialized in access care and I expect many patients will decline to go due to the burden. | 8/29/2017 8:01 AM |
| 4 | We are converting to an ASC. Hopefully our reimbursements will improve. | 8/29/2017 7:14 AM |
| 5 | We are not yet to the point of closing but further cuts will likely push us over the edge. At this point reasonable profitability is in question. If we close these patients will then go to the hospital and cost will increase severely... | 8/28/2017 11:27 PM |
| 6 | As a nephrologist for the past 20 years, I have had a greater sense of satisfaction and positive impact on dialysis patients in my role as interventional nephrologist than I have as a general nephrologist. With the provision of vascular access services, we have had tremendous success in improving our patients' quality of life (avoiding catheters and hospitalizations), improving fistula rates, and providing cost savings (POS 11 is much less costly than ASC or hospital based vascular access services). But it looks like CMS is planning to phase out POS11. Such a plan cannot be based on what would be best for dialysis patients or taxpayers. It is shameful that our delivery of sensible vascular access care in a medium-sized private practice setting cannot be supported. And this is while spending in the healthcare industry - insurance, pharmaceuticals, hospital, administrative, regulatory costs - continue to spiral out of control. | 8/28/2017 9:06 PM |
| 7 | CMS needs to target hospitals not professional fees. That is insane. | 8/28/2017 7:28 PM |
| 8 | I've been forced to undergo the process of converting to an ASC. It is the only way our current business can survive providing needed service to our patients. As it stands, we may have to close our practice if unsuccessful, so while I do not anticipate closing we all understand it is a strong possibility. | 8/28/2017 4:55 PM |
| 9 | We have had one vascular access center, here in Louisville, KY, close within the past four months. Although we do vein and arterial interventions at our center we have strongly considered closing our office. If our volume of vascular access patients decreases any more we will strongly consider closing our outpatient center. What was CMS thinking when they presented these ridiculously lower fees for the necessary care of our patients. Sending these patients to the ER is not an acceptable course of action. They will not be given the timely and appropriate care that they deserve. This patient group will have more catheters inserted because neither the vascular surgeons nor the interventional radiologists will have the immediate time to add them to their already full schedule; especially the clotted accesses which should be treated immediately so that they can continue with their dialysis schedule through their existing shunts or fistulas. We, as vascular access interventionalists, have made an impact on lowering the incidence of catheter usage. This last cut in fees will force the reintroduction of IJV TCC placements because there will not be the appropriate interventionalists available to perform these vascular access procedures. Placing a catheter takes considerably less time than performing either an open or percutaneous thrombectomy. What are we going to do when a patient presents to the ER with a clotted graft/fistula and an elevated Potassium and the procedure (thrombectomy) is to be performed in the OR. The anesthesialogists at our hospital, who demand to be present for any vascular access case performed in the OR, will not induce the patient for the thrombectomy. What are we going to do - perform the procedure in the hallway? There simply will not be the number of appropriate physicians, who perform these procedures adequately, available to treat the dialysis patient. | 8/28/2017 12:23 PM |
| 10 | We have a large number of illegal residents who receive hemodialysis under our care. We have previously provided their access care free of charge at our outpatient access center but now due to financial pressure caused by the 2017 fee schedule, refer these patients to the hospital. | 8/28/2017 8:59 AM |

| | | |
|---|---|---|
| 11 | We have a large nephrology practice, and had to make significant investments into converting to the ASC. Meanwhile, many patients had to get their service done in the hospital and/or increase wait time or drive longer distances (we have to centers and had to do reconstruction at both, so that some patients had to come to a center far away from them). We are still in the process of converting to ASC. If this does not happen, we would have to close both of our centers which would not only jeopardize patient's vascular access survival but will increase waiting time, driving time and cost to the system due to patients needing to have their services provided in the hospital setting. | 8/28/2017 8:27 AM |
| 12 | More than the drive time, i am more concerned about the overall quality of access care for our dialysis patients. Fistula rates are going to drop significantly and correspondingly catheter rates would increase. I am also concerned about significant increase in hospitalization risk and mortality in our patients. There might also be a major increase in health care spending due to excessive hospitalizations as a result of inadequate access care. | 8/28/2017 8:26 AM |
| 13 | There will be serious repercussions. Pts will lose permanent access due to these cuts (lack of access to care) . We will see the permacath rates rise. More pts will end up in hospital for access related issues bc they could not be effectively managed as an outpatient . | 8/28/2017 7:20 AM |
| 14 | Our center has been severely affected by the recent reimbursement cut leading to consolidation of services and deep cost cutting measures. If we are forced to close our center the result will be: - Increased missed dialysis sessions (as we currently provide same day service for all emergency cases such as thrombectomies and non-functional catheters having the patient back to dialysis the same day for emergency cases) - Increased hospitalization due to lack of above service as hospital IRs and emergency rooms will be unable to provide such service expediciously - Current detailed all round access care by dedicated access professionals at our center has led to some of the lowest prevalent dialysis catheter rates in the region. Loss of this center would lead to increased catheter rates, and result in a completely fractured access care by multiple hospitals and providers. The net effect is significant increase in patient morbidity and mortality and a large increase in cost for the payers due to hospitalizations. | 8/27/2017 11:00 PM |
| 15 | If reimbursement continues to decline, I could foresee a day when I decide to no longer perform vascular access services. That time hasn't arrived yet, but could certainly come within the next couple of years. | 8/27/2017 10:19 PM |
| 16 | We are in the process of converting our two centers to ASC status. It is quite a long and costly process. Without the conversion and payment changes, we would have to close both centers since the reimbursements based on our payer mix and patient case load made the two centers unable to make any money yet alone pay the physicians to staff the center. The physician payment reductions were in our case draconian and we are hoping that the ASC makes the centers profitable again | 8/27/2017 12:17 PM |
| 17 | Closing the access center will result in at least 40-50% increase in the patient's fee for access procedures in the hospital | 8/27/2017 9:21 AM |
| 18 | The cuts have been draconian. Please help us | 8/26/2017 8:34 PM |
| 19 | In our area no outpatient center had been able to establish itself. - One was supposed to open, and is now looking at conversion to ASC. - One multi-use interventional rooms is opening, unclear if it is going to be profitable. - Nearest outpatient centers are in Providence, RI, and Beverly, MA (access and varicose veins) | 8/26/2017 5:30 PM |
| 20 | We have mitigated our losses with careful management of staffing and patient management. If we cannot maintain this, we will be forced to close or attempt to convert to an ASC which is difficult in a CON state. Closing would be an unmitigated disaster for patients leading to an enormous overload of hospital admissions, dialysis access mismanagement, dramatic increases in costs to CMS, and most importantly decreased life expectancy for our patients -- there really is no other option outside of hospitalization in our region for these patients. | 8/26/2017 11:03 AM |
| 21 | services will still happen but at the regional hospital. Patient treatment delays, travel tie, cost to medicare and infection risks will all increase | 8/26/2017 10:26 AM |
| 22 | Our interventional nephrology service is hospital based | 8/26/2017 8:17 AM |

| | | |
|---|---|---|
| 23 | Our interventional nephrology practice almost went out of business due to the steep Medicare cuts in FY 2017. Based on the procedures done in 2016 we calculated a 32% decrease in expected revenue for 2017 when our profit margin in 2016 was 28%. Fortuitously, we had a couple of former transplant surgeons who also specialized in fistula and graft creation join our practice in late 2016. They brought a significant number of patients with them for whom they were providing the vascular access maintenance and interventional services. Due to this increase in volume and modifying our practice pattern due to recent literature favoring an increased use of covered stents, we have been able to stay afloat, but just barely. The Medicare cuts for FY 2017 were brutal and grossly unfair. We provide a valuable service to our dialysis patients and we should not have to struggle so hard just to break even or make a small profit. In 2018 some of these cuts should be reversed. In 2018 I believe there should be a 20% increase in the reimbursement for the performance of a fistulagram with angioplasty. This would still be a significant cut from the 2016 reimbursement level ( >10%) but it would give us some breathing room and make it easier for us to function as a viable Access Center providing a unique and indispensable service to the community and a very sick group of patients. By drastically cutting the reimbursement for outpatient Vascular Access Centers the net effect will be for more and more of the outpatient Vascular Access Centers to close. The closing of the outpatient centers will push patients to the hospital to have the same procedures done at more than three times the cost, especially when you take into account the increased rate of hospital admission this practice will lead to. How this will benefit Medicare is complete mystery to me and I believe the severe cuts in outpatient vascular access reimbursement were a wrongheaded decision that needs to be reversed quickly. | 8/26/2017 7:53 AM |
| 24 | The center in San Juan, Puerto Rico will continue servicing the Medicare population as it is our main source of payment. We are worry that the Medicare Advantage groups may stall indefenetely the contracts Once we switch to to a ASC. | 8/26/2017 7:10 AM |
| 25 | We have a smaller center in South Delaware that serves about 1/3 of our dialysis population. Due to the 2017 cuts, that center is barely viable financially and is at risk for closure. It is not suitable for conversion to ASC. We are looking at option to bring all those patients to our larger North DE center, which we used to do 5-10 years ago before opening the South center. That will result in 60-90 mile trips, delayed and/or deferred care. We have found that some patients were unable/unwilling to make this trip in the past, leading to more complicated access problems or failure. | 8/26/2017 3:58 AM |
| 26 | Perpetual cuts to vascular access reimbursement and the simultaneous demand for lower catheter rates by CMS is mutually exclusive. | 8/26/2017 1:32 AM |
| 27 | Medicare patients which would have been easily served at these free standing outpatient vascular centers will now have to be referred for in hospital based procedures that will definitely cost more to Medicare. It's a no brainer !!!! | 8/26/2017 12:04 AM |
| 28 | This will greatly impact the quality of care our patients get. they will be forced to go get their procedures in the hospital with longer wait times , and at a much higher cost to Medicare. Also they will have to work with physicians whom they don't know from dialysis. | 8/25/2017 10:30 PM |
| 29 | Our vascular access center is patient center where we take care of their vascular access problems immediately. If we discontinue our services they will have to go to a hospital where they have to go through scheduling and probably be evaluated in weeks and than schedule the vascular procedure for another few week. As an interventional nephrologist I always try to treat our patients regardless of their insurance status. It is getting extremely difficult and very stressful to continue with this kind of excellent care. Patients are really the only affected by all these cuts as being treated in a timely manner improve their morbidities and mortalities. | 8/25/2017 9:31 PM |
| 30 | Dialysis access maintenance is vital to the ESRD program, because without it the entire structure falls apart. Decreasing reimbursements for these procedures will undoubtedly have a negative impact on a patient's access to dialysis access care. Patients would then be forced to use inferior accesses which results in longer treatment times in order to meet clearance targets. More patients would then have to rely on tunneled catheters which have higher morbidity and mortality. Smaller vascular facilities will close, shunting patients to already-overbooked larger centers. These procedures are on the front lines of the United States ESRD Program maintenance. As in Chess, even the small pieces can have a substantial impact on the overall outcome. I subsequently urge the committee to reconsider their reimbursement cuts to these valuable services. | 8/25/2017 8:25 PM |
| 31 | Converting to ASC because of this; cannot share ASC with other specialties presents a problem. Kansas won't allow us to "share" our ASC space with another nephrology practice in town but Missouri will. Lots of illogical laws with this endeavor. Result will be increased cost for us and higher payout from the providers with NO CHANGE in quality. In Trump's words, "Sad!" | 8/25/2017 8:17 PM |

| | | |
|---|---|---|
| 32 | The proposed cuts will cause increased Medicare costs, through more hospitalizations for dialysis access - due to closures of outpatient centers focused on access care. Additionally, lack of specialized access care centers will lead to a greater prevalence of dialysis catheters- which lead to higher mortality rates, increased hospitalizations, and higher Medicare costs. | 8/25/2017 7:15 PM |
| 33 | We have 3 centers and do more than 5000 procedures annual and losing money under the current OBL fee schedule. We are in process of converting all centers to ASC otherwise would need to close our centers as we are over 85% govt payer | 8/25/2017 6:52 PM |
| 34 | patient services have been severely reduced in northern and western AZ Closed 3 VAC and likely a 4th. Moving some services to hospital setting that is MORE expensive for the medicare system AND more time consuming for patients and physicians and over all less efficient. The PROVEN advantages of outpatient vascular access centers have been lost. We are converting VAC to ASC where possible at substantial cost. The ASC conversion will provide no better care to patients. | 8/25/2017 6:43 PM |
| 35 | we have had to close multiple VACs due to the cuts in reimbursement, most of them in more rural locations without many other options. Not all patients can make the trip to a larger city, and those who can need to travel an additional 1-3 hours or more. this has significantly and adversely affected a large number of individuals, and we may end up seeing an increase in catheter percentage as a result as time goes on | 8/25/2017 6:37 PM |
| 36 | It's aweful for the patients | 8/25/2017 6:33 PM |
| 37 | It will not be necessarily an increase in driving time. It will be a significant increase in waiting time both to get the procedure done, and once they get there. Besides the cost for the procedure is significantly higher. The cuts make no sense. They derive patients form a much cheaper and agile facility, to a more cumbersome and expensive setting. | 8/25/2017 6:32 PM |
| 38 | We have closed 2 centers in rural areas. These patients now have significant additional travel time or must go to a hospital based treatment location which results in delays, missed dialysis or admission for more expensive inpatient therapy | 8/25/2017 6:32 PM |
| 39 | Cuts have been ridiculous. I am not asking to make a fortune but i would like medicare to pay for expenses and a reasonable gain without being gouged nor me loosing money | 8/25/2017 6:29 PM |
| 40 | If patient's could not be accomodated at our VAC, they would be referred to hospital IR. | 8/25/2017 6:18 PM |
| 41 | Decreasing payments to out pt access centers had definitely halted new growth in this field. At the same time the existing centers are undergoing extreme financial strain. Cutting staff time and staff. Pushing the dialysis patients to get the same care in the hospitals is likely to siginficantly delay life saving care, MUCH higher cost, increased hospitalizations and hence increased chances of nosocomial infections etc. This would a step in the backward direction in the field of ESRD care. | 8/25/2017 6:13 PM |
| 42 | It has been very difficult to take care of these patients. I have heard from colleagues they are being sent to hospitals and ASC where the cost is significantly higher. | 8/25/2017 5:57 PM |
| 43 | Trying to survive by incorporating PAD into my practice. This is unfortunate because I previously had dedicated my practice primarily to the creation and maintenance of dialysis access which I perform at a very high level. | 8/25/2017 5:44 PM |
| 44 | We are considering an ASC but the $$$ outlay is significant and not certain we can accomplish it. patients will have to wait for services with inpatient radiology at the nearest hospital facility. Dialysis patients are always put last on the list and have to wait. While drive times may not be as much - WAIT times and access to good, dedicated interventional care will definitely be impeded. | 8/25/2017 5:22 PM |
| 45 | The Medicare insured patients vascular assess needs are sent to the local hospitals which delays treatment, increases the out of pocket patient costs and interferes with the normal dialysis treatments. | 8/25/2017 5:22 PM |
| 46 | The cuts have been draconian. We will stay open only as long as possible because our patients desperately need our help. Directing the patients back to the hospital for access management will be a financial disaster for CMS and drive the quality of life for our patient population to new lows. | 8/25/2017 5:19 PM |
| 47 | I agree with reduction in reimbursement. | 8/25/2017 5:10 PM |
| 48 | Cuts are making it challenging to continue operating our center. The closing of outpatient vascular centers will only lead to an increase in hospital admissions for our patients, which is very unfortunate. Seems like CMS is missing the big picture here. | 8/25/2017 5:02 PM |
| 49 | If our center closes patients will have hospital-based procedures and many admissions for access-related issues | 8/25/2017 4:59 PM |

| | | |
|---|---|---|
| 50 | Patient care will shift from the outpatient setting to the inpatient setting. We are sending far more of our vascular access cases to the hospital and reserving our outpatient suites for PAD and embolization cases. | 8/25/2017 4:54 PM |
| 51 | Wait times will add hours to days to obtain service. We are waiting to see what happens with the rates before deciding to close or not. We can not add more lucrative services and are stuck with just access work | 8/25/2017 4:53 PM |

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ORIGINAL RESEARCH ARTICLE

ASDIN

# What is the best setting for receiving dialysis vascular access repair and maintenance services?

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**ABSTRACT**

**Introduction:** Advances in dialysis vascular access (DVA) management have changed where beneficiaries receive this care. The effectiveness, safety, quality, and economy of different care settings have been questioned. This study compares patient outcomes of receiving DVA services in the freestanding office-based center (FOC) to those of the hospital outpatient department (HOPD). It also examines whether outcomes differ for a centrally managed system of FOCs (CMFOC) compared to all other FOCs (AOFOC).

**Methods:** Retrospective cohort study of clinically and demographically similar patients within Medicare claims available through United States Renal Data System (USRDS) (2010-2013) who received at least 80% of DVA services in an FOC (n = 80,831) or HOPD (n = 133,965). Separately, FOC population is divided into CMFOC (n = 20,802) and AOFOC (n = 80,267). Propensity matching was used to control for clinical, demographic, and functional characteristics across populations.

**Results:** FOC patients experienced significantly better outcomes, including lower annual mortality (14.6% vs. 17.2%, p<0.001) and DVA-related infections (0.16 vs. 0.20, p<0.001), fewer hospitalizations (1.65 vs. 1.91, p<0.001), and lower total per-member-per-month (PMPM) payments ($5042 vs. $5361, p<0.001) than HOPD patients. CMFOC patients had lower annual mortality (12.5% vs. 13.8%, p<0.001), PMPM payments (DVA services) ($1486 vs. $1533, p<0.001) and hospitalizations ($1752 vs. $1816, p<0.001) than AOFOC patients.

**Conclusions:** Where nephrologists send patients for DVA services can impact patient clinical and economic outcomes. This research confirmed that patients who received DVA care in the FOC had better outcomes than those treated in the HOPD. The organizational culture and clinical oversight of the CMFOC may result in more favorable outcomes than receiving care in AOFOC.

**Keywords:** Dialysis, Dialysis access, ESRD, Freestanding office-based center, Hospital outpatient department, USRDS

## Introduction

Over the past two decades, significant changes in dialysis vascular access (DVA) have occurred. There has been a progressive change from primarily arteriovenous grafts (AVGs) to primarily arteriovenous fistulas (AVFs) (1, 2). There has also been an increasing number of endovascular procedures performed for DVA maintenance. The profile of these procedures has changed from approximately equal numbers of angioplasties and thrombectomies performed on AVG to primarily angioplasties performed on AVF (3). Site of service has also changed progressively toward the freestanding outpatient facility (FOC) dedicated to DVA from hospital outpatient departments (HOPD). In the FOC, fluoroscopically guided, endovascular treatments are being performed, utilizing sedation/analgesia in an outpatient environment primarily by interventional nephrologists. Questions arise about their effectiveness, safety, quality, and economy.

In a previous study (4), based on Medicare claims and United States Renal Data System (USRDS) data from 2006 to 2009, a large cohort of cases receiving DVA management care in an FOC was compared using propensity score matching with a cohort of cases managed in an HOPD. This study showed significantly better outcomes for the FOC setting, including fewer vascular access-related infections, fewer septicemia-related hospital admissions, and fewer related and unrelated hospital admissions than those who received care in a HOPD (p<0.001 for each metric). Furthermore, FOC cases had significantly lower mortality and lower per-member-per-month (PMPM) Medicare payments than HOPD cases.

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Since the period covered by this report, medical practice as related to DVA has continued to evolve. AVF utilization in prevalent patients has continued to increase under the Centers for Medicare & Medicaid Services' (CMS') Fistula First Breakthrough Initiative designed to improve the AVF rate and reduce catheter use (5). The number of AVF maintenance procedures (3) has also increased. With an increasing percentage of AVF procedures has come an increased level of complexity. According to 2015 Medicare claims data, approximately one-third of these procedures take place in an FOC. In addition, the patient population has changed with a continuing increase in the percentage of elderly patients having a higher penetration of comorbidities (6, 7). There has also been the creation of larger bundles for dialysis services including drugs and other items previously billed in addition to the dialysis treatment and the beginning of the Medicare Meaningful Use incentives and the Physician Quality Reporting System (PQRS) (8).

It is not clear how these changes may have affected the comparison of FOC-based treatment versus that provided in the HOPD. The purpose of this study is to first replicate the previous analysis using more recent data reflecting current practice patterns and to determine if the changing profile of DVA has affected the site-of-service comparison. A secondary purpose is to determine if differences in the quality and economy of DVA services existed within the FOC group.

## Methods

### *Study design and patient selection*

This retrospective cohort study was based on Medicare claims and data from the USRDS for 2010-2013. USRDS database contains all health-care utilization and Medicare payment claims for end-stage renal disease (ESRD) patients, as well as select clinical information including ESRD-specific lab values, patient functional status, and comorbidities.

The study sample was drawn from all incident and prevalent ESRD patients with Medicare fee-for-service coverage between 2010 and 2013. A single episode of care that captured all DVA and dialysis-related services, and all related or unrelated hospitalizations during the whole study period was created for each patient. This included services across all settings, including inpatient and outpatient hospitals, skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, long-term care hospitals, physicians, hospices, and durable medical equipment (Tab. I). An episode started with the first DVA-related service during the study period and ended either with patient death or the end of the study period.

Place of service (POS) was determined from CMS designations. Patients who did not receive at least 80% of their DVA maintenance and placement services in either a FOC (POS 11) or a hospital-associated outpatient environment, including HOPD (POS 22), emergency departments (POS 22), emergency departments (POS 23), dialysis centers (POS 65), and state/local public-health clinics (POS 71) were excluded. The study had two phases. In the first phase, the study population was divided into two cohorts: patients who received 80% or more of DVA services in an FOC, and patients who received 80% or more of DVA services in an HOPD.

**TABLE I -** Dialysis vascular access services included in analysis

| Description | CPT codes (unless otherwise noted) |
|---|---|
| DVA placement services | |
| Creation of fistula | 36821, 36818, 36819, 36820, 36825 |
| Creation of graft | 36830 |
| Catheter placement | 36558 |
| DVA maintenance services | |
| Catheter exchange | 36581 |
| Catheter repair | 36575, 36796 |
| Thrombectomy | 36870 |
| Vein cannulation with contrast injection | 36005 |
| Ultrasound of vein and artery | 93931, 93930, 93970, 93971 |
| Vessel mapping | G0365 |
| Catheter removal | 36589 |
| Arteriogram of extremity | 75710 |
| Stent placement | 37205 & 75960 |
| Arterial/venous angioplasty | 35475 & 75962, 35476 & 75978 |
| Cannulation of dialysis access with angiogram | 36147 |
| Venous angiogram | 75791, 75825, 75827, 75898 |
| Dialysis | |
| Dialysis | 90935-90947, 90999 |
| Hospitalizations | |
| Septicemia-related | MS-DRGs 870-872 |
| ESRD-related | MS-DRGs: 316-317; ICD-9s: 585, 586 |
| Unrelated | All other MS-DRGs |

CPT = current procedural terminology; DVA = dialysis vascular access; ESRD = end-stage renal disease.

In the second phase of this study, a homogeneous subgroup of centrally managed FOCs (CMFOC) using standardized policies and practices was identified and compared to all other members of the FOC group (AOFOC) using propensity score matching. The attributes of the CMFOC include: (i) central oversight of the quality and utilization of its physicians through a single electronic health system; (ii) comparison of center and physician utilization rates with feedback provided at regular intervals; (iii) one-on-one patient education to identify risk factors for adverse events and ensure patient satisfaction; (iv) central training of clinical staff to reduce process variation in routine clinical scenarios; (v) accreditation to provide consistent quality, safety, and leadership; and (vi) review of complicated cases through a robust peer-review process.

A list of Medicare beneficiaries who received at least one DVA service in the CMFOC between 2010 and 2013 was used. URSDS cross-walked the Medicare beneficiary identifier to the USRDS encrypted patient identifier to allow the study team to identify CMFOC in the USRDS claims.

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The study was Health Insurance Portability and Accountability Act compliant. As the study only consisted of medical claims data, without patient identifiers, the study was deemed to be research without human subjects. No formal institutional review board approval was required.

### *Outcome measurements*

Three types of outcomes were compared over the four-year study period. The primary metrics were health indicators such as all-cause mortality rate (annually and across the study period), and the number of 21-day infection episodes due to dialysis vascular device, implant, or graft (ICD-9 996.62) and bloodstream infections due to central venous catheter (ICD-9 999.32). The 21-day metric ensured that infections that required, on average, 21-days to be treated, were not measured as multiple infection events. The second outcome included the average annual rate of DVA-related services provided per patient; rate of septicemia-related, ESRD-related, and unrelated hospitalizations; and dialysis treatments (expressed as a weekly rate). The third outcome was average PMPM Medicare payment including DVA-related care, inpatient hospitalizations, and dialysis treatments.

### *Statistical analysis*

Propensity statistics were used to match cohorts based on a series of variables that directly impact the way in which patients receive DVA care. A propensity score for each patient was calculated to indicate the probability of a patient receiving care in the FOC (for FOC vs. HOPD) or of receiving care in the CMFOC (for CMFOC vs. AOFOC). This statistical method isolated the impact of site of service from other causal factors on all three types of outcomes. Propensity score matching techniques are widely used in observational studies when randomized controlled trials (RCTs) are not available or are unethical or impractical to administer (9). Literature suggests that applying this technique to observational studies is one approach for removing observable selection bias among treatment and comparison groups and can result in findings that mimic RCTs (10-13).

Metrics used in calculating the propensity score included patient demographics, clinical characteristics, and historical DVA-related and unrelated health-care utilization. Patient demographic characteristics included: age, gender, race, geographic region of the patient's residence, dual eligibility for Medicare and Medicaid, and smoking and alcohol or drug dependence. Clinical and functional characteristics included: comorbidities used to calculate CMS Hierarchical Condition Category (HCC) scores, history of kidney transplant, body mass index (BMI), and whether the patient was institutionalized and needs assistance with activities of daily living (ADLs). Historical DVA-related and unrelated health-care utilization included: years since first ESRD service, whether the patient first received placement or maintenance services within the study episode, whether the patient had a confirmed fistula or graft during the episode to ensure that outcomes were not due to a disproportionate use of catheters as the primary access type of a given setting, and whether the patient had a catheter as the sole dialysis access. All matching variables, except the confirmed access type, were defined and identified by USRDS.

Patients were matched using an algorithm that compares their propensity score to guarantee the closest match across groups. Matches were made in intervals of probability less than 0.2 standard deviations of estimates of the logit function that determined their propensity score, an approach consistent with the literature (14). Patients who were not able to be matched were excluded from the analysis.

## Results

Between 2010 and 2013, 869,587 ESRD patients were identified in the USRDS database, representing the universe of patients for the study. After removing patients with fewer than 80% of their DVA services in FOC or HOPD, 154,322 FOC patients and 209,111 HOPD patients were considered for propensity score matching. Of the FOC population, 61,695 patients received at least one DVA-related service in the CMFOC, with the remaining population (123,226) representing AOFOC (Fig. 1). The propensity match yielded 80,831 FOC and 133,965 HOPD patients, and 20,802 CMFOC and 80,267 AOFOC patients.

### *FOC versus HOPD: patient characteristics*

Following propensity score matching, patient demographics for FOC and HOPD were very similar (Tab. II). Both had an average age of 63 years, 45% female, 60% white, and 16% dually eligible for Medicare and Medicaid. The populations had the same proportion of incident ESRD patients (12%) as defined by the proportion of patients with an access placement as their first DVA service. There were no meaningful differences in the geographic distribution of patients. Despite matching, FOC patients were more likely to have had a transplant (5.0% vs. 4.3%, $p<0.01$), had lower BMI (29.46 vs. 29.57, $p<0.01$), had lymphatic, head, neck, brain or other major cancer (2.2% vs. 2.0%, $p<0.01$), and were less likely to have had congestive heart failure (31.2% vs. 31.7%, $p<0.01$) than HOPD patients. FOC patients were less likely to need assistance with ADLs (8.9% vs. 9.2%, $p<0.01$).

### *FOC versus HOPD: health indicators, utilization, and costs*

Across all outcome measures, FOC patients had better outcomes than those treated in the HOPD (Tab. III). The annual mortality rate for FOC patients was 15.1% lower (14.6% vs. 17.2%, $p<0.001$) than HOPD patients and the overall mortality across the entire study period was 10.9% lower (37.5% vs. 42.1%, $p<0.001$).

FOC patients received, on average, fewer DVA-related services than HOPD patients. Patients treated in the FOC had fewer placement services, including fistula, graft, catheter, and catheter exchanges than HOPD patients ($p<0.001$). FOC patients received slightly more vessel mapping services (0.06 vs. 0.05, $p<0.001$). They also received significantly fewer dialysis treatments per week (2.91 vs. 2.99, $p<0.001$). This difference may have had greater economic significance (i.e., the overall cost of dialysis treatments) than clinical relevance since both groups essentially received three treatments per week.

FOC patients had fewer related and unrelated hospitalizations per patient per year than patients treated in the

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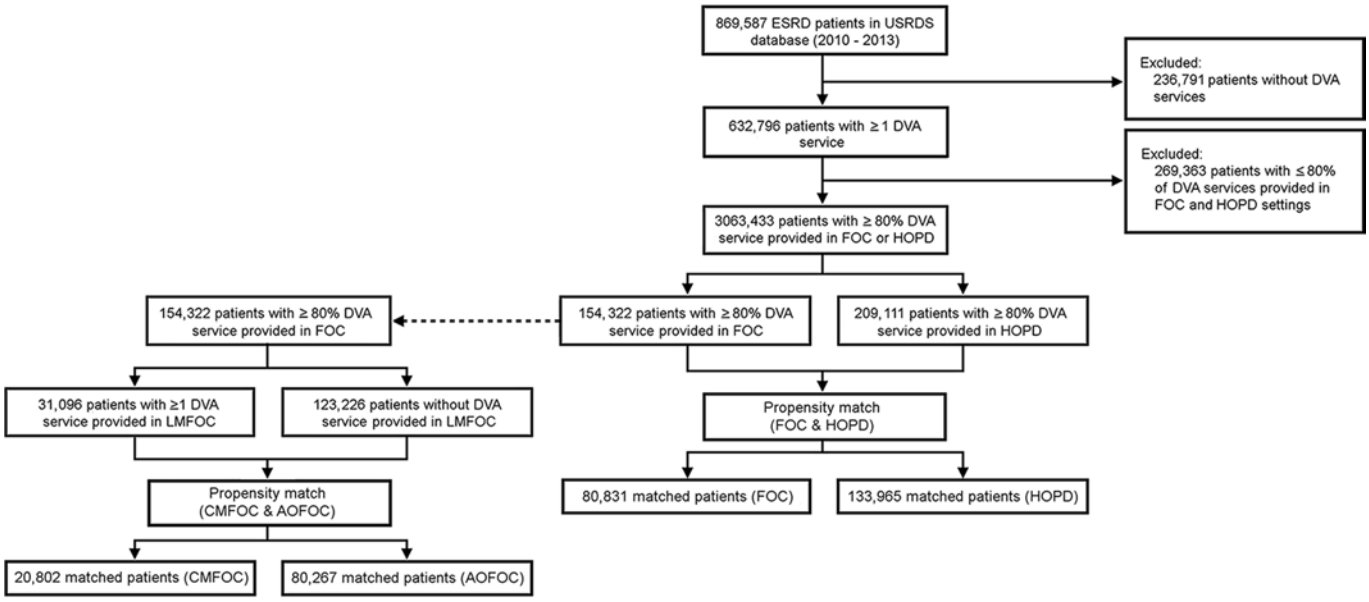


**Fig. 1 -** Study population. Flow diagram of patient selection.

HOPD. This difference was predominately driven by unrelated hospitalizations (1.56 vs. 1.81, p<0.001). However, FOC patients also had lower rates of septicemia-related hospitalizations (0.08 vs. 0.10, p<0.001).

Because of fewer total hospitalizations and dialysis treatments, matched FOC patients had an average total Medicare PMPM payment (including DVA services, hospitalizations, and dialysis treatments) that was $318 lower than HOPD patients ($5042.70 vs. $5360.97, p<0.001). This difference was primarily due to the differences in hospitalizations ($1958.35 vs. $2250.65, p<0.001) and dialysis ($1588.60 vs. $1613.67, p<0.001), as the cost of DVA services were similar.

### *CMFOC versus AOFOC: patient characteristics*

The FOC population was subdivided and further analyzed to determine if there were significant differences between cases treated in a CMFOC and those treated in AOFOC. Following propensity score matching, CMFOC patients were demographically similar to AOFOC patients. Average age was 62 years, with 43% female, 56% white, and 15% dually eligible for Medicare and Medicaid. CMFOC patients had a higher kidney transplant rate (4.3% vs. 3.9%, p<0.05) and had ESRD for a longer period (3.26 vs. 3.24 years, p<0.01). There was no statistical difference in the rate of DVA placement as the first vascular access service between the two groups, nor in the geographic distribution of patients, their comorbidities, or the functional status (Tab. IV).

### *CMFOC versus AOFOC: health indicators, utilization, and costs*

Compared to patients who received care in AOFOCs, CMFOC patients had comparable hospitalizations, and PMPM spending. However, they had a 9.4% lower annual mortality rate (12.5% vs. 13.8%, p<0.001) and 6.1% lower overall mortality (33.6% vs. 35.8%, p<0.001) (Tab. V). In addition, CMFOC patients were statistically more likely to have an infection (0.16 vs. 0.15, p<0.01).

There were statistically significant differences in the utilization of DVA services between these populations, but the clinical significance of these differences is questionable. CMFOC patients received fewer fistulas (0.09 vs. 0.10, p<0.001), but more catheter exchanges (0.14 vs. 0.09, p<0.001) than AOFOC patients. They also received fewer ultrasounds of veins and arteries (0.33 vs. 0.37, p<0.001) and vessel mapping services (0.06 vs. 0.05, p<0.001), neither of which the authors feel are clinically significant. CMFOC patients received more dialysis treatments per week (2.97 vs. 2.94, p<0.001); however, while this could have an economic impact, it is doubtful that it is of clinical significance.

CMFOC patients had lower PMPM payments for DVA services ($1485.82 vs. $1533.31, p<0.001) and hospitalizations ($1751.92 vs. $1816.47, p<0.001), which was largely due to the cost of unrelated hospitalizations. Higher dialysis treatments per week also resulted in higher dialysis PMPM payments for CMFOC patients ($1676.88 vs. $1574.44, p<0.001).

## Discussion

Hemodialysis access has been referred to as the patient's lifeline; however, this access is not without problems. Over the study period, Medicare payments per patient increased disproportionately to the increase in the number of patients being treated (6, 7). A significant portion of this expenditure has been dedicated to the maintenance of dialysis access (treatment of access dysfunction). These services have been, and continue to be, provided in multiple medical settings. Questions arise as to whether there are significant differences in the quality and cost between different settings.

This study examined a large cohort of patients treated in an FOC matched to patients treated in an HOPD. The propensity

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**TABLE II -** Patient characteristics of matched populations for variables included in propensity score matching: FOC versus HOPD

| Patient characteristics | FOC (n = 80,831) | HOPD (n = 133,965) | Difference[a] |
|---|---|---|---|
| Age (y) | 62.88 | 62.96 | -0.08 |
| Gender (% female) | 45.3% | 45.4% | -0.1% |
| Dual eligible | 16.0% | 16.2% | -0.2% |
| Geographic region | | | |
| New England | 3.9% | 3.9% | 0.0% |
| Middle Atlantic | 14.3% | 14.3% | 0.0% |
| East North Central | 12.5% | 12.6% | -0.1% |
| West North Central | 4.3% | 4.5% | -0.2% |
| South Atlantic | 24.7% | 24.3% | 0.4%* |
| East South Central | 7.3% | 7.5% | -0.1% |
| West South Central | 14.5% | 14.5% | 0.0% |
| Mountain | 5.5% | 5.3% | 0.2% |
| Race | | | |
| White | 60.7% | 60.5% | 0.2% |
| Black | 33.5% | 33.6% | -0.1% |
| Asian | 4.2% | 4.2% | -0.1% |
| Native American | 1.3% | 1.3% | 0.0% |
| Historical DVA services | | | |
| Placement as first vascular access service | 12.3% | 12.6% | -0.2% |
| Fistula/graft access type | 32.9% | 33.4% | -0.5%* |
| Catheter, no history of fistula/graft | 23.9% | 24.6% | -0.7%◊ |
| Time since first ESRD service (y) | 3.24 | 3.21 | 0.03† |
| History of transplant | 5.0% | 4.3% | 0.7%† |
| Years since last transplant (y) | 9.51 | 10.02 | -0.51† |
| Comorbidities | | | |
| Body mass index | 29.46 | 29.57 | -0.10◊ |
| Metastatic cancer and acute leukemia | 0.9% | 0.9% | 0.0% |
| Lung, upper GI, and other severe cancers | 1.0% | 1.0% | 0.0% |
| Lymphatic, head and neck, brain, and other major cancers | 2.2% | 2.0% | 0.1%◊ |
| Breast, prostate, colorectal and other cancers and tumors | 5.1% | 5.1% | 0.0% |
| Diabetes without complication | 52.3% | 52.4% | -0.1% |
| Diabetes with renal or peripheral circulatory manifestation | 34.4% | 34.7% | -0.3% |
| Diabetes with neurologic or other specified manifestation | 14.4% | 14.5% | -0.1% |
| Congestive heart failure | 31.2% | 31.7% | -0.5%◊ |
| Acute myocardial infarction | 2.5% | 2.6% | 0.0% |
| Vascular disease | 22.7% | 23.0% | -0.3% |
| Chronic obstructive pulmonary disease | 14.5% | 14.7% | -0.2% |
| Chronic ulcer of skin, except decubitus | 7.3% | 7.4% | -0.1% |
| Specified heart arrhythmias | 15.1% | 15.2% | -0.1% |
| Functional status/independence | | | |
| Institutionalized | 5.8% | 5.9% | -0.1% |
| Institutionalized - assisted living | 0.5% | 0.5% | 0.0% |
| Institutionalized - nursing home | 4.9% | 5.1% | -0.1% |
| Institutionalized - other institution | 0.4% | 0.4% | 0.0% |
| Needs assistance with daily activities | 8.9% | 9.2% | -0.3%◊ |

† Statistically significant at p<0.001.
◊ Statistically significant at p<0.01.
* Statistically significant at p<0.05.
[a] Difference represents the percentage point difference of FOC minus HOPD.
FOC = freestanding office; HOPD = hospital outpatient department; DVA = dialysis vascular access; ESRD = end-stage renal disease; GI = gastrointestinal.

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**TABLE III -** Distribution of outcomes by matched population: FOC versus HOPD

| Outcome measures | FOC (n = 80,831) | HOPD (n = 133,965) | Difference[a] |
|---|---|---|---|
| Health indicator | | | |
| Mortality during episode | 37.5% | 42.1% | -4.6%[†] |
| Mortality per year | 14.6% | 17.2% | -2.6%[†] |
| 21-day infection episodes per year (count) | 0.16 | 0.20 | -0.04[†] |
| Vascular access related services (count) (per year, unless otherwise noted) | | | |
| Fistula | 0.11 | 0.14 | -0.03[†] |
| Graft | 0.05 | 0.06 | -0.01[†] |
| Catheter placement | 0.35 | 0.44 | -0.09[†] |
| Catheter exchange | 0.10 | 0.11 | -0.01[†] |
| Ultrasound of vein and artery | 0.41 | 0.49 | -0.09[†] |
| Vessel mapping | 0.06 | 0.05 | 0.01[†] |
| Catheter removal | 0.22 | 0.23 | -0.01[†] |
| Thrombectomy | 0.00 | 0.00 | 0.00 |
| Dialysis (per week) | 2.91 | 2.99 | -0.08[†] |
| Inpatient admissions per year | | | |
| All inpatient admissions | 1.65 | 1.91 | -0.26[†] |
| Vascular-related | 0.00 | 0.00 | 0.00 |
| Septicemia-related | 0.08 | 0.10 | -0.01[†] |
| Unrelated | 1.56 | 1.81 | -0.25[†] |
| PMPM cost | | | |
| Total PMPM | $5042.70 | $5360.97 | -$318.27[†] |
| DVA | $1495.75 | $1496.65 | -$0.90 |
| Inpatient admissions | $1958.35 | $2250.65 | -$292.30[†] |
| Vascular related inpatient | $0.05 | $0.11 | -$0.06 |
| Septicemia-related inpatient | $109.08 | $123.44 | -$14.36[†] |
| Unrelated inpatient | $1849.21 | $2127.10 | -$277.89[†] |
| Dialysis | $1588.60 | $1613.67 | -$25.07[†] |

[†] Statistically significant at p<0.001.
[a] Difference represents the percentage point difference of FOC minus HOPD.
FOC = freestanding office; HOPD = hospital outpatient department; DVA = dialysis vascular access; PMPM = per-member-per-month.

score model controls for selection bias across different sites of service by matching on observable clinical and demographic characteristics, making the cohorts essentially "twin-like" (Tabs. III, V). There are a few metrics where statistically significant differences were noted. These were not issues that would affect DVA and were not felt by the authors to be clinically significant. Literature indicates that applying this matching technique to an observational study can result in findings that closely correlate with those from an RCT (10-13).

The results from the comparison of FOC-treated to HOPD-treated patients confirmed the findings of our previous report based on 2006 to 2009 data (4). Patients who received DVA care in an FOC had significantly better outcomes, including lower all-cause mortality, fewer infections, and fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD. In addition, patients treated in the FOC had lower average total PMPM payments including DVA services, dialysis, and hospitalizations than patients treated in an HOPD.

Facilities that identify as FOCs represent a heterogeneous group. They vary in size, organization, practice pattern, and staffing. Physicians working in these facilities vary by medical specialty, and degree and type of training in DVA maintenance procedures. The CMFOC group was studied to determine if significant differences existed within the FOC. CMFOC was selected because it represented a homogeneous group characterized by having a uniform system of peer review, an organized program for quality improvement and utilization, a formal accredited training program for clinical staff and operator physicians utilizing a standardized curriculum, and an organized program for DVA education of individual patients and supported dialysis clinics.

Comparison of outcomes for the CMFOC and AOFOC cohorts identified a 9.4% lower annual mortality rate and a 6.1% lower overall mortality in the CMFOC cohort. Other statistically significant differences were felt to not be of clinical significance. CMFOC demonstrated an economic advantage in the DVA-service category and for overall hospitalizations.

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**TABLE IV -** Patient characteristics of matched population for variables included in propensity score matching: CMFOC versus AOFOC

| Patient characteristics | CMFOC (n = 20,802) | AOFOC (n = 80,267) | Difference[a] |
|---|---|---|---|
| Age (y) | 62.23 | 62.36 | -0.14 |
| Gender (% female) | 42.5% | 42.8% | -0.2% |
| Dual eligible | 14.7% | 14.9% | -0.2% |
| Geographic region | | | |
| New England | 0.2% | 0.2% | 0.0% |
| Middle Atlantic | 10.6% | 10.9% | -0.4% |
| East North Central | 12.6% | 12.5% | 0.1% |
| West North Central | 3.6% | 3.5% | 0.1% |
| South Atlantic | 27.2% | 27.4% | -0.3% |
| East South Central | 7.3% | 7.4% | 0.0% |
| West South Central | 16.3% | 16.2% | 0.1% |
| Mountain | 6.4% | 6.4% | 0.0% |
| Race | | | |
| White | 56.5% | 56.3% | 0.2% |
| Black | 38.1% | 38.3% | -0.3% |
| Asian | 4.5% | 4.4% | 0.1% |
| Native American | 0.7% | 0.7% | -0.1% |
| Historical DVA services | | | |
| Placement as first vascular access service | 10.4% | 10.7% | -0.3% |
| Fistula/graft access type | 27.4% | 28.0% | -0.6% |
| Catheter, no history of fistula/graft | 21.7% | 22.5% | -0.8%◊ |
| Time since first ESRD service (y) | 3.26 | 3.24 | 0.02◊ |
| History of transplant | 4.3% | 3.9% | 0.3%* |
| Years since last transplant (y) | 10.26 | 10.21 | 0.05 |
| Comorbidities | | | |
| Body mass index | 29.45 | 29.41 | 0.04 |
| Metastatic cancer and acute leukemia | 0.7% | 0.7% | 0.0% |
| Lung, upper GI, and other severe cancers | 0.8% | 0.8% | 0.0% |
| Lymphatic, head and neck, brain, and other major cancers | 1.8% | 1.8% | 0.1% |
| Breast, prostate, colorectal and other cancers and tumors | 4.9% | 4.8% | 0.1% |
| Diabetes without complication | 51.4% | 51.5% | -0.1% |
| Diabetes with renal or peripheral circulatory manifestation | 34.3% | 35.0% | -0.7% |
| Diabetes with neurologic or other specified manifestation | 13.6% | 13.7% | 0.0% |
| Congestive heart failure | 28.2% | 28.5% | -0.3% |
| Acute myocardial infarction | 2.2% | 2.2% | 0.0% |
| Vascular disease | 21.5% | 21.5% | 0.0% |
| Chronic obstructive pulmonary disease | 12.4% | 12.5% | -0.1% |
| Chronic ulcer of skin, except decubitus | 6.2% | 6.4% | -0.2% |
| Specified heart arrhythmias | 12.8% | 12.8% | 0.0% |
| Functional status/independence | | | |
| Institutionalized | 4.6% | 4.8% | -0.1% |
| Institutionalized - assisted living | 0.4% | 0.4% | 0.0% |
| Institutionalized - nursing home | 3.9% | 4.1% | -0.1% |
| Institutionalized - other institution | 0.3% | 0.3% | 0.0% |
| Needs assistance with daily activities | 7.6% | 7.8% | -0.3% |

◊ Statistically significant at p<0.01.
* Statistically significant at p<0.05.
[a] Difference represents the percentage point difference of CMFOC minus AOFOC.
CMFOC = centrally managed freestanding office; AOFOC = all other FOCs; DVA = dialysis vascular access; ESRD = end-stage renal disease; GI = gastrointestinal.

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**TABLE V -** Distribution of outcomes by matched population: CMFOC versus AOFOC

| Outcome measures | CMFOC (n = 20,802) | AOFOC (n = 80,267) | Difference[a] |
|---|---|---|---|
| Health indicator | | | |
| Mortality during episode (%) | 33.6% | 35.8% | -2.1%[†] |
| Mortality per year (%) | 12.5% | 13.8% | -1.3%[†] |
| 21-day infection episodes per year (count) | 0.16 | 0.15 | 0.01[◊] |
| Vascular access related services (count) (per year, unless otherwise noted) | | | |
| Fistula | 0.09 | 0.10 | -0.01[†] |
| Graft | 0.05 | 0.04 | 0.00 |
| Catheter placement | 0.31 | 0.31 | 0.00 |
| Catheter exchange | 0.14 | 0.09 | 0.05[†] |
| Ultrasound of vein and artery | 0.33 | 0.37 | -0.04[†] |
| Vessel mapping | 0.06 | 0.05 | 0.01[†] |
| Catheter removal | 0.20 | 0.20 | 0.00 |
| Thrombectomy | 0.00 | 0.00 | 0.00 |
| Dialysis (per week) | 2.97 | 2.94 | 0.03[†] |
| Inpatient admissions per year | | | |
| All inpatient admissions | 1.53 | 1.55 | -0.01 |
| Vascular-related | 0.00 | 0.00 | 0.00 |
| Septicemia-related | 0.07 | 0.08 | 0.00 |
| Unrelated | 1.46 | 1.47 | -0.01 |
| PMPM cost | | | |
| Total PMPM | $4914.62 | $4924.22 | -$8.69 |
| DVA | $1485.82 | $1533.31 | -$47.49[†] |
| Inpatient admissions | $1751.92 | $1816.47 | -$64.55[†] |
| Vascular-related inpatient | $0.03 | $0.05 | -$0.02 |
| Septicemia-related inpatient | $93.99 | $99.51 | -$5.52 |
| Unrelated inpatient | $1657.90 | $1716.91 | -$59.01[◊] |
| Dialysis | $1676.88 | $1574.44 | $102.44[†] |

[†] Statistically significant at p<0.001.
[◊] Statistically significant at p<0.01.
[a] Difference represents the percentage point difference of CMFOC minus AOFOC.
CMFOC = centrally managed freestanding office; AOFOC = all other FOCs; DVA = dialysis vascular access; PMPM = per-member-per-month.

However, differences in PMPM payments for hospitalizations were primarily due to unrelated conditions. CMFOC patients had higher PMPM payments for dialysis than AOFOC patients, as expected due to receiving significantly more dialysis treatments per week.

An explanation for the superiority of CMFOC's mortality rate is not readily apparent; however, it is characterized by its organization as a homogeneous, centrally managed group of facilities with standardized practices and policies. The culture of medical organizations has been shown to be important in the care of chronic illnesses (15). Organizational cultures that emphasize group affiliation, teamwork, and coordination have been associated with greater implementation of quality improvement practices (16), adoption of group practice guidelines (17), and enhancement of the delivery of patient-centered medical care (18).

A major strength of this study is the large number of patients included. In addition, the methodology allows for rigorous matching of patient cohorts across settings to ensure that comparisons are being made on clinically and demographically similar populations. There are, however, limitations to this approach. First, the study was limited to Medicare claims and USRDS data. The use of medical records would have increased the ability to identify DVA-related outcomes with greater specificity. Second, a reliance on administrative claims over a fixed period precludes examining the patients' health-care utilization prior to the study period. Therefore, prior complications or historical utilization could not be included in the propensity score model. Third, while a characterization of the facilities comprising the CMFOC subgroup was possible, such a characterization was not possible for those facilities in the AOFOC group.

## Conclusion

Management of DVA dysfunction is an important part of medical care required by the hemodialysis patient. The site

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at which these DVA-services are provided has a direct impact on patient clinical and economic outcomes. Patients receiving care in an FOC have lower all-cause mortality, fewer infections, and fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD. This improved quality of care is also more economically favorable. Within the FOC facilities, a homogeneous subgroup of centrally managed facilities has a lower annual and overall mortality rate when compared to all other FOCs.

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| | | | Unit | Price | CMS Data: Quantity in Office | DVAC Data: Quantity in Office |
|---|---|---|---|---|---|---|
| 36901 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36901 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36901 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36901 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36901 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36901 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36901 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36901 | SM013 | disinfectant, surface (Envirocide, Saniziı | oz | 0.163 | 1 | 1.0 |
| 36901 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36901 | SD136 | vascular sheath | item | 20.5 | 1 | 1.3 |
| 36901 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36901 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36901 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36901 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36901 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36901 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |
| 36901 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |
| 36901 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36901 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36901 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36901 | SG095 | Hemostatic patch | item | 35.75 | 1 | 2.0 |
| 36901 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36901 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36901 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36901 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36901 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 1.0 |
| 36901 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36901 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36901 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |
| 36901 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.0 |
| 36901 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |
| 36901 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36902 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36902 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36902 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36902 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36902 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36902 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |
| 36902 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 1.0 |
| 36902 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36902 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36902 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36902 | SM013 | disinfectant, surface (Envirocide, Saniz | oz | 0.163 | 1 | 1.0 |
| 36902 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36902 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36902 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36902 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36902 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |
| 36902 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |
| 36902 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36902 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36902 | SD136 | vascular sheath | item | 20.5 | 1 | 1.3 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36902 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36902 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36902 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |
| 36902 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36902 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.0 |
| 36902 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36902 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 1.5 |
| 36902 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36902 | SD089 | guidewire, hydrophilic | item | 35.5 | 1 | 1.0 |
| 36902 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36902 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36902 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36902 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |
| 36902 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36902 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 5 | 5.0 |
| 36902 | SG095 | Hemostatic patch | item | 35.75 | 1 | 2.0 |
| 36902 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36902 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36903 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36903 | SD254 | covered stent (VIABAHN, Gore) | item | 3768 | 1 | 1.3 |
| 36903 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.0 |
| 36903 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36903 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36903 | SG095 | Hemostatic patch | item | 35.75 | 1 | 2.0 |
| 36903 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36903 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |
| 36903 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36903 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |
| 36903 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36903 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36903 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36903 | SD249 | Sterile Radio-opaque ruler (le Maitre, d | item | 46.95 | 1 | 1.0 |
| 36903 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 1.5 |
| 36903 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36903 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36903 | SM013 | disinfectant, surface (Envirocide, Saniziı | oz | 0.163 | 1 | 1.0 |
| 36903 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36903 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36903 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |
| 36903 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36903 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36903 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36903 | SD136 | vascular sheath | item | 20.5 | 1 | 1.3 |
| 36903 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36903 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36903 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36903 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36903 | SD089 | guidewire, hydrophilic | item | 35.5 | 1 | 1.0 |
| 36903 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36903 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36903 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36903 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36903 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36903 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 1.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36903 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36903 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36903 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 5 | 5.0 |
| 36903 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |
| 36904 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36904 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36904 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36904 | SC057 | syringe 5-6ml | item | 0.15 | 1 | 4.0 |
| 36904 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |
| 36904 | SM013 | disinfectant, surface (Envirocide, Saniziı | oz | 0.163 | 1 | 1.0 |
| 36904 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |
| 36904 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36904 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36904 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.0 |
| 36904 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36904 | SG095 | Hemostatic patch | item | 35.75 | 2 | 2.0 |
| 36904 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |
| 36904 | SF036 | suture, nylon, 3-0 to 6-0, c | item | 2.401 | 1 | 1.0 |
| 36904 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36904 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36904 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 2.0 |
| 36904 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 5 | 5.0 |
| 36904 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36904 | SD136 | vascular sheath | item | 20.5 | 1 | 2.3 |
| 36904 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36904 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36904 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36904 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36904 | SD089 | guidewire, hydrophilic | item | 35.5 | 1 | 1.0 |
| 36904 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36904 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36904 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36904 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36904 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36904 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36904 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36904 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36904 | SA015 | kit, for percutaneous thrombolytic devi | kit | 487.5 | 1 | 1.0 |
| 36904 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36904 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36904 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |
| 36904 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36904 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36905 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36905 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36905 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |
| 36905 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36905 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36905 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36905 | SA015 | kit, for percutaneous thrombolytic devi | kit | 487.5 | 1 | 1.0 |
| 36905 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 2.0 |
| 36905 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36905 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |
| 36905 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36905 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36905 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36905 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36905 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36905 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36905 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36905 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |
| 36905 | SM013 | disinfectant, surface (Envirocide, Sanizi( | oz | 0.163 | 1 | 1.0 |
| 36905 | SC057 | syringe 5-6ml | item | 0.15 | 1 | 4.0 |
| 36905 | SD089 | guidewire, hydrophilic | item | 35.5 | 1 | 2.0 |
| 36905 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36905 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36905 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36905 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36905 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36905 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36905 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 2.2 |
| 36905 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36905 | SD136 | vascular sheath | item | 20.5 | 1 | 2.3 |
| 36905 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36905 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36905 | SF036 | suture, nylon, 3-0 to 6-0, c | item | 2.401 | 1 | 1.0 |
| 36905 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 5 | 5.0 |
| 36905 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36905 | SG095 | Hemostatic patch | item | 35.75 | 2 | 2.0 |
| 36905 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36905 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36905 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36905 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.2 |
| 36905 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36906 | SH047 | lidocaine 1%-2% inj (Xylocaine) | ml | 0.035 | 10 | 10.0 |
| 36906 | SD136 | vascular sheath | item | 20.5 | 1 | 2.3 |
| 36906 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 5 | 5.0 |
| 36906 | SB001 | cap, surgical | item | 0.209 | 3 | 5.0 |
| 36906 | SJ088 | swab, patient prep, 3.0 ml (chloraprep) | item | 1.81 | 2 | 3.0 |
| 36906 | SM021 | sanitizing cloth-wipe (patient) | item | 0.037 | 1 | 2.0 |
| 36906 | SB024 | gloves, sterile | pair | 0.84 | 2 | 3.0 |
| 36906 | SH069 | sodium chloride 0.9% irrigation (500-10 | item | 2.074 | 1 | 1.2 |
| 36906 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 2.2 |
| 36906 | SM013 | disinfectant, surface (Envirocide, Saniz | oz | 0.163 | 1 | 1.0 |
| 36906 | SC053 | syringe 20ml | item | 0.558 | 2 | 3.0 |
| 36906 | SB022 | gloves, non-sterile | pair | 0.084 | 1 | 8.0 |
| 36906 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36906 | SB019 | drape-towel, sterile 18in x 26in | item | 0.282 | 2 | 6.0 |
| 36906 | SD172 | guidewire, cerebral (Bentson) | item | 14.5 | 1 | 1.0 |
| 36906 | SB014 | drape, sterile, three-quarter sheet | item | 3.83 | 1 | 1.0 |
| 36906 | SB008 | drape, sterile, c-arm, fluoro | item | 4.504 | 1 | 1.0 |
| 36906 | SD171 | guidewire bowl w-lid, sterile | item | 3 | 1 | 1.0 |
| 36906 | SG095 | Hemostatic patch | item | 35.75 | 2 | 2.0 |
| 36906 | SD249 | Sterile Radio-opaque ruler (le Maitre, d | item | 46.95 | 1 | 1.0 |
| 36906 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36906 | SC057 | syringe 5-6ml | item | 0.15 | 1 | 4.0 |
| 36906 | SC051 | syringe 10-12ml | item | 0.184 | 2 | 4.0 |
| 36906 | SB028 | gown, surgical, sterile | item | 4.671 | 2 | 3.0 |

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|---|---|---|---|---|---|---|
| 36906 | SB044 | underpad 2ft x 3ft (Chux) | item | 0.23 | 1 | 2.0 |
| 36906 | SB039 | shoe covers, surgical | pair | 0.338 | 3 | 4.0 |
| 36906 | SB034 | mask, surgical, with face shield | item | 1.199 | 2 | 4.0 |
| 36906 | SB033 | mask, surgical | item | 0.196 | 1 | 2.0 |
| 36906 | SC058 | syringe w-needle, OSHA compliant (Safe | item | 0.435 | 2 | 4.0 |
| 36906 | SA048 | pack, minimum multi-specialty visit | pack | 1.143 | 1 | 1.0 |
| 36906 | SA016 | kit, guidewire introducer (Micro-Stick) | kit | 23 | 1 | 2.0 |
| 36906 | SC010 | closed flush system, angiography | item | 11.88 | 1 | 1.0 |
| 36906 | SG009 | applicator, sponge-tipped | item | 0.139 | 4 | 3.0 |
| 36906 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36906 | SA015 | kit, for percutaneous thrombolytic devi | kit | 487.5 | 1 | 1.0 |
| 36906 | SG055 | gauze, sterile 4in x 4in | item | 0.159 | 6 | 10.0 |
| 36906 | SD089 | guidewire, hydrophilic | item | 35.5 | 1 | 2.0 |
| 36906 | SF036 | suture, nylon, 3-0 to 6-0, c | item | 2.401 | 1 | 1.0 |
| 36906 | SF007 | blade, surgical (Bard-Parker) | item | 0.535 | 1 | 1.0 |
| 36906 | SD254 | covered stent (VIABAHN, Gore) | item | 3768 | 1 | 1.2 |
| 36906 | SH065 | sodium chloride 0.9% flush syringe | item | 0.811 | 2 | 2.0 |
| 36906 | SA019 | kit, iv starter | kit | 1.6 | 1 | 1.0 |
| 36906 | SG079 | tape, surgical paper 1in (Micropore) | inch | 0.002 | 12 | 12.0 |
| 36907 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36907 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 1.2 |
| 36907 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36907 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36907 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 2 | 2.0 |
| 36908 | SH039 | heparin 1,000 units-ml inj | ml | 0.193 | 2 | 2.0 |
| 36908 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36908 | SD152 | catheter, balloon, PTA | item | 243.5 | 1 | 1.3 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 36908 | SD149 | catheter, balloon inflation device | item | 24.9 | 1 | 1.0 |
| 36908 | SA103 | stent, vascular, deployment system, Co | kit | 1645 | 1 | 1.2 |
| 36908 | SD252 | guidewire, Amplatz wire 260 cm | item | 47 | 1 | 1.0 |
| 36909 | SD147 | catheter, (Glide) | item | 62 | 1 | 1.0 |
| 36909 | SF056 | Detachable coil | item | 935 | 1 | 2.1 |
| 36909 | SF057 | Non-detachable embolization coil | item | 170 | 2 | 2.5 |