DIALYSIS VASCULAR ACCESS COALITION

September 10, 2018

Submitted electronically via: http://www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1693–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019

Dear Administrator Verma:

The Dialysis Vascular Access Coalition (DVAC) appreciates the opportunity to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule for the CY 2019 Physician Fee Schedule (CMS-1693-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 Arizona Kidney Disease and Hypertension Centers, Azura Vascular Care and Lifeline Vascular Care. **DVAC represents well over 50% of the office-based sector.**

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

- Impact of the 2017 Physician Fee Schedule
- Need for Reimbursement Stability for Vascular Access Services
- Need to Update the Fistula-Related Breakthrough Initiative

[1] Federal Register, 83 FR 35704 (July 27, 2018)

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 vascular access options exist where the two main options are the surgical creation of a fistula (surgical connection of an artery to a vein) or less preferred approaches such as the insertion of a central line catheter (an external tube) or arteriovenous grafts (AVG) (connecting an artery to a vein with a tube). Non-hospital vascular access centers (VACs) provide vascular access services for ESRD patients on dialysis, a population with severe health challenges.

Non-hospital VACs provide ESRD patient-focused services which specialize in fistula creation and preservation services in the ambulatory surgical center (ASC) or physician office setting. ASCs provide a comprehensive set of vascular access services, including (1) services relating to the creation of fistulas (which can only be performed in an ASC) and (2) the preservation of fistulas over time. The physician office setting focuses primarily on the preservation of fistulas and is critical to the ongoing stability of an ESRD patient's vascular access. DVAC strongly believes in the importance of maintaining the physician office setting for vascular access preservation 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. The comments in this letter focus on the importance of the preservation of vascular accesses after they have been created.

I. IMPACT OF THE 2017 PHYSICIAN FEE SCHEDULE

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), which is used more than 50% of the time, was cut by 39% from 2016 to 2017. The 2018 Physician Fee Schedule Final Rule and the 2019 Physician Fee Schedule Proposed Rule do

not correct for the significant payment disparity between the hospital outpatient department and the physician office and ambulatory surgical center settings, as evidenced by the chart below.

CPT/HCPCS	Bundled Procedure	2019 Proposed HOPD Rate ǂ	2019 Proposed Office Rate *	2019 Proposed ASC Rate ¥	**Office/ASC as a % of HOPD**
36902	Angio / angioplasty dialysis circuit	$5,009	$1,325	$1,378	**26%-27%**
ǂ *Hospital Outpatient PPS Payment Rate + PFS Facility Total* * *Physician Fee Schedule Nonfacility Total* ¥ *Ambulatory Surgical Center PPS Payment Rate + PFS Facility Total*					

A. Impact on Access

An American Society of Diagnostic and Interventional Nephrology (ASDIN) survey in 2017 found that reimbursement levels that CMS continues to propose for non-hospital vascular access services are so inadequate that a number of these centers have closed or believe they will be closing in the future. In August 2018, ASDIN updated this survey and found similar results:

- More than 20 percent of respondents surveyed ***already have closed*** due to the cuts contained in the CY 2017 Physician Fee Schedule Final Rule.
- Patients already are being subjected to significant additional drive times:
    - 50 percent of respondents who indicated their center has already closed indicated that their patients would have to drive more than 30 additional miles to receive vital vascular access services.
    - One-third of patients would have to drive an hour or more.
    - Some respondents indicated additional drive times of up to 6 hours or a potential loss of access altogether to these services in rural areas.
- More than 30 percent of respondents surveyed indicated their intention to close their center in the future due to these cuts.

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. As the CY 2019 proposed reimbursement rates illustrate, the rates for performing the same procedures in the HOPD setting are well in excess of those provided in the non-hospital setting. 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.

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 of vascular access care across sites found, by comparison to patients treated in hospital outpatient departments (HOPDs), patients treated in non-hospital 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.[2]

Based on the evidence, ESRD patients forced to HOPDs to receive needed vascular access services as a result of the cuts to non-hospital 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."

II. NEED FOR REIMBURSEMENT STABILITY FOR VASCULAR ACCESS SERVICES

In light of the aforementioned reimbursement instability the vascular access sector has experienced, DVAC believes there are a number of steps CMS could take to support reimbursement stability in future years. These including the following:

- Properly valuing work RVUs
- Properly valuing practice expense RVUs

A. Properly Valuing Work RVUs

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 Physician Fee Schedule 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. Finally, DVAC provided evidence of the need for CMS to reevaluate the crosswalk used for vascular access work RVUs in light of American Society of Anesthesiologists (ASA) Health Scores which showed that CMS crosswalks used to value vascular access work RVUs were to significantly healthier patients than the typical ESRD patient that vascular access centers treat.

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).

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

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

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 ** 74% - 84% of patients in CMS crosswalks are ASA 1/2			

In the 2018 Physician Fee Schedule Final Rule, CMS recognized these concerns and provided minor relief to vascular access codes by using RUC-recommended valuations, rather than CMS-modified valuations. **While we are grateful for CMS' recognition that physician work RVUs were undervalued, we continue to believe there are 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).**[4]

B. Properly Valuing Practice Expense RVUs

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 what the industry knows is the case for a typical patient based on auditable, verifiable data pulled from electronic patient records.

Supply Data

In the 2019 Physician Fee Schedule Proposed Rule, CMS proposes to update equipment and supply *pricing* data in the CMS database. DVAC believes that supply *quantity* data also may be misvalued in the case of vascular access services. Because DVAC 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 *quantity* data by procedure type for procedures performed in DVAC centers from January – June 2017 for the family of codes 36901 – 36909. **We urge CMS to use the industry supply *quantity* data collected by the DVAC to correct current inputs in the CMS database. These data are included as "Addendum 3" to this letter.**

Clinical Labor Data

As part of our ongoing discussions with CMS, DVAC collected clinical labor data and provided it to CMS with a request that such clinical labor data be updated in the CMS database. DVAC's collected data for clinical labor inputs show, among other things, that the rate per minute used by CMS for the registered nurses who help with vascular access procedures may be undervalued by about 40% on average. We note that as part of its proposal to update equipment and supply pricing

[4] For example, to determine the work RVU for 36902, the RUC compared the code to 43253, an esophagogastroduodenoscopy procedure, rather than specialty recommended revascularization procedures. https://www.ama-assn.org/sites/default/files/media-browser/february-2016-ruc-recommendations.pdf

under the Physician Fee Schedule, CMS also states, "To maintain relativity between the clinical labor, supplies, and equipment portions of the PE methodology, we believe that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment. We seek public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment, for example, to avoid other potentially large shifts in PE RVUs during the 4-year pricing transition period." **We commend CMS for updating clinical labor cost data and would recommend such data be updated during the 4-year pricing transition for supplies and equipment. These data are included below.**

hcpcs	source	labor_code	description	**CMS Database: Rate per minute**	**DVAC Data: Rate per minute**
36901	CMS	L037D	RN/LPN/MTA	0.37	0.66
36901	CMS	L041A	Angio Technician	0.41	0.62
36902	CMS	L041A	Angio Technician	0.41	0.62
36902	CMS	L037D	RN/LPN/MTA	0.37	0.66
36903	CMS	L041A	Angio Technician	0.41	0.62
36903	CMS	L037D	RN/LPN/MTA	0.37	0.66
36904	CMS	L037D	RN/LPN/MTA	0.37	0.66
36904	CMS	L041A	Angio Technician	0.41	0.62
36905	CMS	L037D	RN/LPN/MTA	0.37	0.66
36905	CMS	L041A	Angio Technician	0.41	0.62
36906	CMS	L037D	RN/LPN/MTA	0.37	0.66
36906	CMS	L041A	Angio Technician	0.41	0.62
36907	RUC	L037D	RN/LPN/MTA	0.37	0.66
36907	RUC	L041A	Angio Technician	0.41	0.62
36908	RUC	L041A	Angio Technician	0.41	0.62
36908	RUC	L037D	RN/LPN/MTA	0.37	0.66
36909	RUC	L037D	RN/LPN/MTA	0.37	0.66
36909	RUC	L041A	Angio Technician	0.41	0.62

Recommendation: We ask that CMS continue its efforts to properly value vascular access services in the physician office setting, particularly through the acceptance, as appropriate, of industry-provided practice expense data.

III. 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.[5] 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

[5] http://fistulafirst.esrdncc.org/wp-content/uploads/2015/11/LLFL-Team-Approach-for-Achieving-Catheter-Freedom.pdf

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.[6] [7] Additionally, almost twice (1.9 X) as many AVFs will be open at 2 years when maintained as compared to those without secondary procedures.[8] **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 initiative to include preservation as an equally important component of the Fistula First / Catheter last initiative.**

CMS Cuts to Vascular 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, non-hospital VACs have opened over the past decade to provide ESRD patient-focused services specializing in fistula creation and preservation services. Due to providers' responses to provide early and timely vascular care for patients with ESRD, 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 vascular access 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 vascular access preservation services (including for fistulas) are causing significant patient harm due to:

- Longer drive times for dialysis access services as non-hospital providers close;
- Lower quality of care (e.g. higher 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.

[6] Miller PE, et al. Predictors of adequacy of arteriovenous fistulas in hemodialysis patients. Kidney Int. 1999;56(1):275-280
[7] 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
[8] Ayez, N et al. Secondary interventions in patients with autologous arteriovenous fistulas strongly improve patency rates, Journal of Vascular Surgery, October 2011

Conclusion

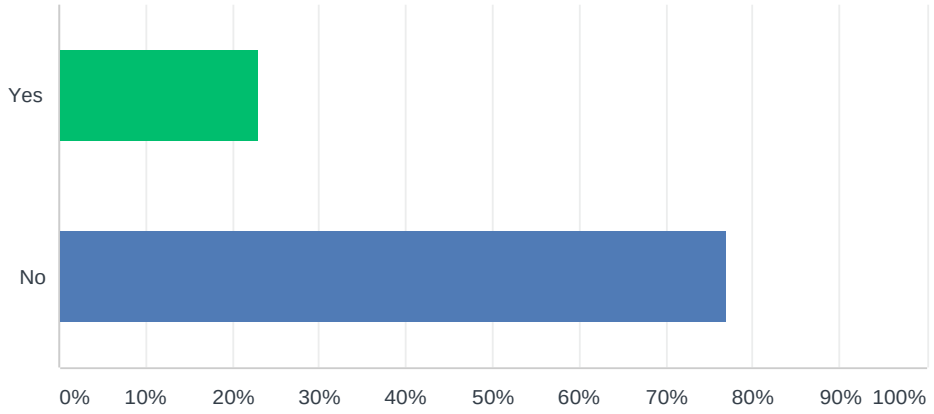
DVAC's comments on the CY 2019 Physician Fee Schedule Proposed Rule seek to ensure ongoing access to vascular access services. We look forward to continuing to work with CMS to (1) maintain and improve access to ESRD patient-focused vascular access services which specialize in fistula creation and preservation 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.

ADDENDUM 1

ASDIN/DVAC Retrospective Survey - 2018

Q1 Have you closed your nonhospital center (physician office or ambulatory surgical center) due to cuts since 2017 under Medicare for vascular access services?

Answered: 65 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	23.08%	15
No	76.92%	50
TOTAL		65

Q2 For Medicare patients that have lost 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?

Answered: 33 Skipped: 32

#	RESPONSES	DATE
1	60-90 minutes	8/6/2018 11:07 AM
2	30 min	8/6/2018 11:03 AM
3	1 hour	8/6/2018 6:22 AM
4	30 miles	8/2/2018 7:49 PM
5	20 min	8/1/2018 2:46 PM
6	No loss of access	8/1/2018 10:21 AM
7	2 days	7/31/2018 6:15 PM
8	Two hours	7/31/2018 5:19 PM
9	45 min -1.5 hrs	7/31/2018 2:54 PM
10	30 to 60 minutes	7/31/2018 12:30 PM
11	20 min	7/31/2018 7:10 AM
12	1-2 hours	7/31/2018 4:16 AM
13	5 miles	7/30/2018 5:47 PM
14	45 min	7/30/2018 4:51 PM
15	No Medicare patients lost coverage at my centers	7/30/2018 3:52 PM
16	30 minutes	7/30/2018 3:20 PM
17	4 to 5 hours	7/30/2018 3:10 PM
18	No increase	7/30/2018 2:21 PM
19	1 hour to 1.5 hours	7/30/2018 2:15 PM
20	na	7/30/2018 1:48 PM
21	No difference	7/30/2018 1:16 PM
22	One hour	7/30/2018 1:11 PM
23	30 to 40 mins	7/30/2018 1:03 PM
24	No significant increase	7/30/2018 1:02 PM
25	60 min	7/30/2018 12:56 PM
26	1 hour	7/30/2018 12:40 PM
27	30 minutes	7/30/2018 12:31 PM
28	3 hours	7/30/2018 12:31 PM
29	10 minutes	7/30/2018 12:24 PM
30	2 Hours	7/30/2018 12:22 PM
31	45 minutes	7/30/2018 12:21 PM
32	45 miles.	7/30/2018 12:21 PM

33	Up to 30 miles	7/30/2018 12:20 PM

Q3 Comments:

Answered: 21 Skipped: 44

#	RESPONSES	DATE
1	- CMS Needs to understand the need to provide dialysis access services ESRD patients, in an outpatient care setting. - As an interventional nephrologist for last years, I believe that the work I do achieves following objectives: 1st: improves quality of life of our ESRD patients 2nd: Improve access to high quality care in "non-hospital setting". 3rd: Avoid hospital / ER visits and / or admissions with issues related to dialysis access. - I am not aware of ANY health care model (including hospitals and other health systems) or any other business for that matter, that could survive such drastic cuts in payment over such a short time and still be able to "survive" -- especially when the goal and mission is to provide high quality affordable health care with aimed to reduce patient morbidity, mortality and improve patient centered care outcomes!! Given the drastic volatility in rates we projected no longer affording to run our office based facility. To continue service, we have incurred $400,000 of debt just to convert to an ASC and were just about to open doors. If these cuts go through, the ASC will close, we will be stuck with this debt, and patients will go to the hospital for procedures (many people with access issues were admitted as inpatients in our city before an outpatient access center opened). In addition to drive time I suggest you also discuss with CMS the delays in access care, hospitalizations, and ultimately lost vascular accesses for this vulnerable population.	8/6/2018 11:07 AM
2	We are currently trying to survive due to the deep cuts in 2016. As we prepare to convert to an ASC at great expensive we are hit with this change. We are currently trying to determine if we will be able to continue operating our center under the proposed changes. We have not closed yet, however may be pending as my physicians have incurred over a 6 figure debt to convert to ASC this year based on cuts and have taken the 25% cut in reimbursement for EOP while doing so.	8/6/2018 11:03 AM
3	The proposed Medicare cuts with will be crippling for our dialysis access center. We would project to be operating at a deficit. Hospitals in our area are ill-equipped to compensate for the volume that we currently provide, and patients will suffer due to increased risk of loss of their vascular access and its related morbidities.	8/6/2018 8:08 AM
4	We converted 2 offices to ambulatory surgery centers because we would not have been able to stay open as offices. The cuts in reimbursement resulted in us taking a loss at both centers in 2017.	8/3/2018 12:40 PM
5	If the goal is to reduce costs this will have the opposite effect. It has been shown time and again that outcomes and cost are less for outpatient procedures. This change will cause many centers to shut down. This will limit access to outpatient facilities and lead to more hospitalizations for ESRD patients due issues with vascular access. This will drive up cost and TDC use.	8/3/2018 10:48 AM
6	The great majority of patients will go to the hospital, not another vascular access center.	8/2/2018 7:49 PM
7	Missed treatment increased Length of stay in hospital increased Increased hospitalization rate	7/31/2018 5:19 PM
8	we didn't close, but are barely surviving by adding arterial procedure with a Vascular MD. We are trying to keep our center open because our patients will tremendously suffer from closure as there are NO other practical our not overly costly options for them.	7/31/2018 11:00 AM
9	We operated 2017 at a significant lose while we converted from EOP to ASC. We are just getting payor contracts in place. If ASC rates are reduced to the current EOP rates are center will not be sustainable and we will need to close. This will result in many patients being hospitalized in order to get access care, as our local hospital networks are not well equipped to offer urgent care to outpatients.	7/30/2018 8:11 PM
10	Trying to keep it open but any more cuts will likely require closure and undoubtedly lead to increased admissions and emergent surgical needs for these patients.	7/30/2018 4:53 PM
11	We have decided as a group not to pursue developing an ASC/VAC due to possible impending further reimbursement cuts	7/30/2018 4:51 PM
12	Patients now are referred to the hospital setting. Drive time is the same, but they are admitted to hospital and Interventional Radiology works on the access the following day or two and then they get dialysis and at discharged home.	7/30/2018 2:21 PM

13	With the new cuts, our center is facing the decision as to whether it will continue to be viable to operate beyond 2018. We are the only OP center in Central ohio servicing columbus and surrounding cities. The only other center in the city closed after the 2017 reimbursement cuts. 100% of Ckd/esrd patients in columbus will return to the hospital for all access related services should our center close.	7/30/2018 1:20 PM
14	However, going to the hospital for these procedures is much more inconvenient for the patients. They end up waiting in the waiting room for hours. Also, scheduling an emergent procedure is much more difficult and requires a lot of time and effort	7/30/2018 1:16 PM
15	We have not closed however we continue to face extreme hardship due to reimbursement cuts. If they are cut any more we will need to discuss other options. This patient populations should be advised under the transparency rules how hospitals are raking in unbelievable charges for the exact same procedure, hospitals do not have to be cost effective or negotiate pricing with vendors just to stay in business. We provide excellent service, zero infection rate, care for and about our patients. We are fully accredited and if anyone with any medical and financial sense looked at the rate differences for hospitals no one would wonder why Medicare is going broke, it is because they clearly favor hospitals. There are times when hospital care is necessary however for these procedures (that are safer and cost effective in office setting even at a much higher rate) they should reimburse us a fair rate and save the big payouts to hospitals for urgent cases that can only be done in that setting	7/30/2018 1:07 PM
16	We operate 3 centers and just converted to ASCs within the last 12 months to avoid closing. Based upon the proposed 2019 fee schedule, I am not sure whether we will be able to continue to operate our centers and may have to close them if these become the final rule	7/30/2018 12:57 PM

17	Eastern Nephrology Associates is the largest nephrology practice in Eastern North Carolina, and has focused on caring for chronic kidney disease (CKD) and end-stage renal disease (ESRD) patients since 1975. We have 18 nephrologists, including 3 interventional nephrologists, 3 main offices in Greenville, New Bern, and Kinston along with 8 satellite offices throughout the region. Currently we have over 1300 ESRD patients at 22 dialysis units who rely on dialysis to preserve and prolong their lives. Many of you already know that ESRD patients require a disproportionately expensive amount of medical treatment. Collectively, they are less than 1% of Medicare beneficiaries but they represent more than 7% of total Medicare expenditures. People with ESRD are medically complex with lots of co-morbidities, and their survival requires them to undergo hemodialysis three times per week. Eastern Nephrology is on the cutting edge of caring for this difficult and vulnerable population. We participate in CMS's "Comprehensive ESRD Care Model" through our participation in an ESRD Seamless Care Organization or "ESCO," which is an Accountable Care Organization specifically focused on ESRD patients. ESCOs are accountable for clinical quality outcomes and financial outcomes for ESRD patients, including all Medicare spending for those patients. CMS recognizes importance of coordination and quality of care, and ENA partners with other nephrologists and dialysis facilities through the ESCO to provide best quality care while reducing expenditures for the Medicare program. One critical factor in caring for a dialysis patient is their vascular access (usually an arteriovenous fistula or graft, and sometimes a catheter), through which the patient's blood is filtered using a dialysis machine. Dialysis accesses are essential for their survival, but they are prone to dysfunction, infection, stenosis and thrombosis that frequently need interventions to maintain their patency and function to provide life saving dialysis treatment. The need for an intervention is usually unexpected, and interventions must happen very quickly, or the patient deteriorates rapidly since they are unable to dialyze until their vascular access is restored. We know from our years of experience that ESRD patients benefit enormously from a specialized, coordinated team providing care in a dedicated ambulatory setting, as opposed to receiving their care in a hospital for their dialysis access care. Our community hospitals provide incredible care every day to all types of patients, but when it comes to the specific challenges of the dialysis population, numerous studies have shown that patients have better outcomes, better patient satisfaction, and fewer hospitalizations, and all at lower cost to the healthcare system, if their care can be provided outside the hospital. Eastern Nephrology provides interventions to correct vascular access dysfunction in the office setting, but providing this care in the office setting is not enough. First, CMS does not allow dialysis access creation procedures in office setting. Access creation procedures are currently done in a hospital setting but having them placed in an outpatient setting such as an ambulatory surgical center (ASC) can markedly decrease the cost to the healthcare system. Also, since 2017, drastic reimbursement cuts between 30%-40% by CMS threaten our ability to do vascular access procedures in the office at all. These cuts have drastically affected our ability to practice medicine in this office setting since the financial constants have severely restricted our ability to perform certain vital procedures due to negative profit margin. CMS's reimbursement changes were certainly intended to control cost, but cuts will ultimately have the opposite effect, as vascular access centers (VACs) must close or cut back on vascular access services to stay afloat. Either way, care for dialysis patients will be forced back to hospitals. That will result in much higher costs and worse outcomes, with more complications and admissions, which will hurt patient outcomes and drive up total care costs for ESRD patients even further. This will increase the likelihood that the ESCO model will fail to provide cost savings to the healthcare system for dialysis patients. Ambulatory surgery centers would seem to be the logical choice to perform creation and maintenance of dialysis access. CMS reimburses dialysis access interventions at a sustainable level in an ambulatory surgical center. ASC's can perform dialysis access creation procedures, and ASC reimbursement costs the healthcare system far less than doing the same procedures in a hospital.	7/30/2018 12:56 PM
18	We spent 1.5 years planning and constructing a freestanding ambulatory surgical center to better serve our patients. We were about to start our first cases in the center after a significant investment of personal resources, time, effort, and an outside loan. Now with the cuts, we will not be able to support the center. Patients will continue to suffer delayed interventions, delayed access placements, and missed dialysis due to these changes. Numerous staff members will lose jobs, and I fear patient outcomes will continue to suffer. CMS did not allow adequate time or notice for these decreases in reimbursement at such short intervals.	7/30/2018 12:40 PM
19	We have moved our practice to an ASC.	7/30/2018 12:24 PM
20	Our access center is an extension of practice and we started the process of conversion into an ambulatory surgery center but at this point, we are considering closure of the center. We have been providing dialysis access care for dialysis patients for 10 years	7/30/2018 12:23 PM

21	These vital services to patients prevents hospitalizations and reduces total medicare spend per dialysis beneficiaries. CMS is effectively driving patients to the hospitals where cost of care is higher and prevalent catheter rates will surely increase.	7/30/2018 12:21 PM

Q4 Your Location (City/State):

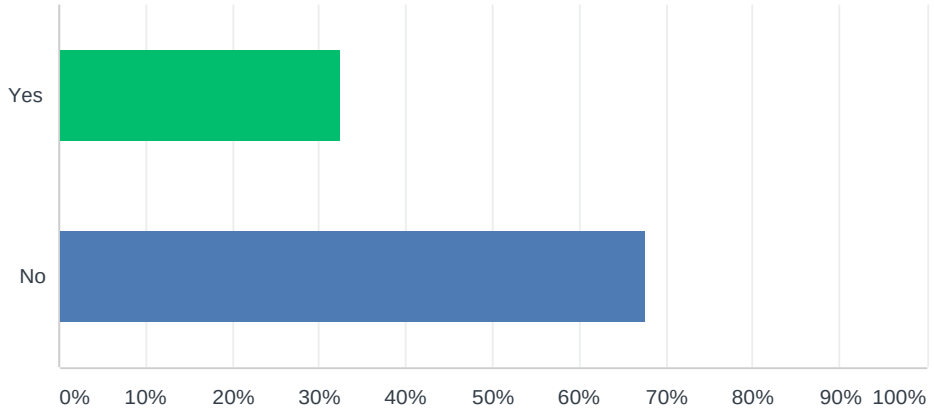
Answered: 52 Skipped: 13

#	RESPONSES	DATE
1	Columbus Ohio	8/6/2018 11:07 AM
2	Kansas city/Kansas	8/6/2018 11:03 AM
3	Philadelphia, PA	8/6/2018 8:08 AM
4	Cincinnati, OH	8/6/2018 6:22 AM
5	Baltimore, Maryland	8/3/2018 12:40 PM
6	Cincinnati Ohio	8/3/2018 10:48 AM
7	Houston, Texas	8/2/2018 7:49 PM
8	Landover, MD	8/1/2018 2:46 PM
9	Newington, CT	8/1/2018 10:21 AM
10	Brooklyn NY	7/31/2018 6:15 PM
11	Allen park	7/31/2018 5:19 PM
12	bronx, NY	7/31/2018 2:54 PM
13	Saint Louis Missouri	7/31/2018 12:30 PM
14	Wichita, KS	7/31/2018 11:00 AM
15	NY/NJ	7/31/2018 7:10 AM
16	AZ	7/31/2018 4:16 AM
17	FresnoCA	7/30/2018 11:55 PM
18	Cincinnati, Oh	7/30/2018 8:28 PM
19	Bethlehem, PA	7/30/2018 8:11 PM
20	long beach/ california	7/30/2018 5:47 PM
21	Alabama	7/30/2018 4:53 PM
22	Gainesville FL. Leesburg FL	7/30/2018 4:51 PM
23	new york new york	7/30/2018 4:01 PM
24	Memphis, TN	7/30/2018 3:52 PM
25	San Diego, CA	7/30/2018 3:20 PM
26	Phoenix, AZ	7/30/2018 3:10 PM
27	Detroit, mi	7/30/2018 2:48 PM
28	Roanoke, VA	7/30/2018 2:21 PM
29	Ottawa, IL	7/30/2018 2:15 PM
30	va	7/30/2018 1:48 PM
31	Columbus/ Ohio.	7/30/2018 1:20 PM
32	Naperville , IL	7/30/2018 1:16 PM
33	Huston, Texas	7/30/2018 1:11 PM
34	Great Neck, NY	7/30/2018 1:07 PM
35	michigan,Ypsilanti	7/30/2018 1:03 PM

36	Mesa, AZ	7/30/2018 1:02 PM
37	Phoenix and Tucson AZ	7/30/2018 12:57 PM
38	New Bern, NC	7/30/2018 12:56 PM
39	Houston, TX	7/30/2018 12:46 PM
40	Humble, Texas	7/30/2018 12:40 PM
41	Atlanta/Georgia	7/30/2018 12:39 PM
42	chicago, Illinois	7/30/2018 12:31 PM
43	San Antonio	7/30/2018 12:31 PM
44	Clearwater, FL	7/30/2018 12:30 PM
45	Hattiesburg, MS	7/30/2018 12:24 PM
46	Boston, MA	7/30/2018 12:24 PM
47	Boardman, Ohio	7/30/2018 12:23 PM
48	Raleigh, NC	7/30/2018 12:22 PM
49	Union, NJ	7/30/2018 12:21 PM
50	Milford Delaware	7/30/2018 12:21 PM
51	Dallas TX	7/30/2018 12:20 PM
52	San Antonio, TX	7/30/2018 12:20 PM

Q1 Do you anticipate closing your nonhospital center (physician office or ambulatory surgical center) due to cuts since 2017 under Medicare for vascular access services?

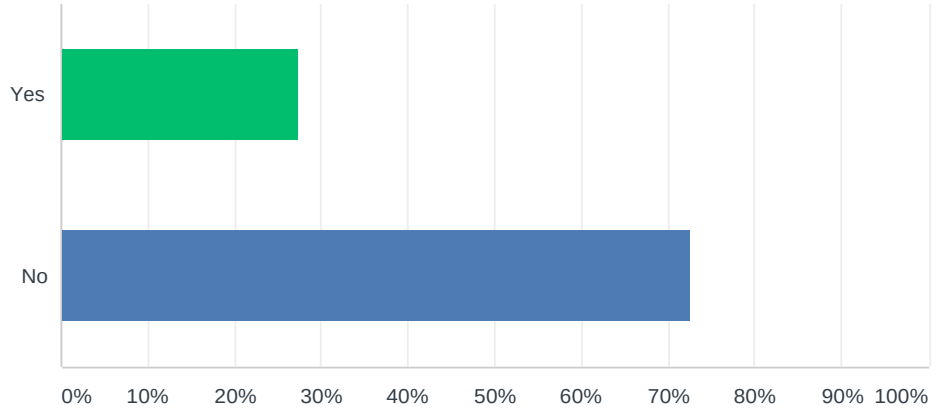
Answered: 40 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	32.50%	13
No	67.50%	27
TOTAL		40

Q2 Do you plan on limiting the number of Medicare patients you serve due to cuts under Medicare for vascular access services?

Answered: 40 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	27.50%	11
No	72.50%	29
TOTAL		40

Q3 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?

Answered: 21 Skipped: 19

#	RESPONSES	DATE
1	Drive time increase minimal	8/6/2018 9:06 AM
2	it would occupy their half a day at least in other site of service; instead of max 1 hour in our facility	8/5/2018 5:47 PM
3	One to 2 hours.	8/3/2018 11:20 PM
4	1 hour	8/3/2018 8:25 PM
5	60-90 minutes	8/3/2018 7:26 PM
6	60 minutes	8/3/2018 5:52 PM
7	Increased drive time of 10-30mins but the inconvenience of the hospital is the real driving factor.	8/3/2018 5:52 PM
8	1hr	8/3/2018 5:39 PM
9	20mins	8/3/2018 5:38 PM
10	10 minutes	8/2/2018 11:45 AM
11	10-15 miles	8/1/2018 11:23 PM
12	20 minutes	8/1/2018 7:08 PM
13	30 miles	8/1/2018 6:10 PM
14	30 to 60 minutes	7/31/2018 1:55 PM
15	45 minutes	7/31/2018 11:22 AM
16	Additional 10-15 miles	7/30/2018 10:12 PM
17	5 miles	7/30/2018 5:48 PM
18	None	7/30/2018 4:23 PM
19	6 hours	7/30/2018 4:09 PM
20	unclear	7/30/2018 4:03 PM
21	Same drive time	7/30/2018 3:56 PM

Q4 Comments:

Answered: 19 Skipped: 21

#	RESPONSES	DATE
1	We have few patients with true 'commercial' insurance. Medicare is our highest payer- either in 'straight' form or as a marketplace alternative. While we do not plan to close the center at this time we may well be forced to do so given out experience with revenue last year (before converting to an ASC). We do some PAD and are hoping to expand that in order to stay open so that we can provide a viable access care for our patients. I think the situation is dire.	8/6/2018 10:53 AM
2	What will happen to our patients is the following: 1. Increased hospitalization 2. Delay in Care 3. Increased Catheter rate 4. Increased wait time for a procedure 5. Reduced patient satisfaction 6. Increase in missed dialysis treatments 7. Poorer outcomes. From a Practice standpoint: 1. Major reduction in workforce, cutting staff etc. 2. Relocation of Physicians due to inadequate income based on labor 3. Increased hospital workload and Physician burn out We are expected to upgrade our practice with major expenses including EMR, increasing insurance premiums, meeting MIPS/MACRA etc., And upgrading from an OBL to an ASC Which have all been very costly, yet our procedure revenue will be cut by up to 50% for certain procedures??? Name an industry that will survive with such cuts. The federal government/CMS has been cutting the reimbursement for many "high dollar" procedures over the years, and the cost of healthcare has continued to rise. Your formulas and methodology are flawed. You have created a volume driven atmosphere in the world of medicine. To help reduce cost to the system and more outpatient facilities should be encouraged with meaningful metrics.	8/6/2018 9:06 AM
3	If cuts continue I will have no choice but to close. The proposed cut to ASC fees is inappropiate. It does not take into account the increased costs and regulatory burdens of an ASC as compared to an office setting. This needs to be pointed out to CMS. Procedures done in an ASC are more accountable due to the obligatory reporting.	8/3/2018 11:20 PM
4	In addition to increase drive time, the patients will be backlogged and delays in getting procedures done in a timely fashion. More emergency room visits and clearly more hospital admissions.	8/3/2018 8:25 PM
5	This will vastly limit access to care, increased hospital admissions, ED visits, missed dialysis ,treatment to the ESRD patients. I am shocked to learn about these disastratous changes.	8/3/2018 7:26 PM
6	Further cuts will greatly limit our practice growth. Whereas we may not close as an immediate result of further cuts there will most cerainly be changes to personel and possibly lost jobs.	8/3/2018 5:52 PM
7	Most abrupt and unthougtfu act by CMS to put Medicare patients in jeopardy	8/3/2018 5:39 PM
8	More than drive time lack of timely interventions leading to thrombosis,inadequate dialysis and increase in Catheter rates(with associated complications) and increased hospitalization	8/3/2018 5:38 PM
9	In the near term (2109) we will remain open as ambulatory surgery centers, however, we cannot operate the centers at a loss which is what we are forecasting if these proposed reimbursement cuts come to fruition. We would most likely consider closing the centers in 2020.	8/3/2018 12:45 PM
10	Acceptance of the lower reimbursement rates for vascular access procedures. Only result is lower physician earnings. No change in patient volume.	8/2/2018 10:21 AM
11	Some patient will have to be admitted to the hospital and some will have to drive extra 10-15 miles to get access work done. However, there will be loss of prompt service as well.	8/1/2018 11:23 PM
12	Many will end up going to a local hospital for care of their vascular access.	8/1/2018 6:10 PM
13	ASDIN should advocate for INs doing PAD work.	7/31/2018 3:08 PM

14	More than the driving time, these patients hates to go to the hospital to get these procedures done due to the senseless admission ordeals, hours of waiting to get the procedure done, undue emphasis/senseless NPO rules, too much of waisted interaction with the hospital staff/personal and the poor quality of the procedure performed on these patients. Many of the patients have to undergo another procedure at some other place due to the poor quality work and outcomes. If a declotting procedure fails, these patients do not get a catheter inserted for hemodialysis at the same sitting. They have to come back another day or get admitted to the hospital inpatient service and get the procedure done on another day. Patient taking anticoagulation have to go through unnecessary and meaningless ordeals before they can undergo the procedure in the hospital setting. If the patients have contrast allergy, it becomes another crazy time or days losing/waiting ordeals before they can get the procedure done. I find it crazy, meaningless and stupid for the dialysis patients to get the day-to-day procedures in an hospital setting (unless it require a very complicated intervention or needing a general anesthesia). Moreover, it is ironical to know that CMS is happy to pay higher charge to the hospitals when the same procedure can be done with efficiency/lesser complication rate/lesser infection rate at a lesser time frame and to the comforts of the patients at a lesser expense, despite which the CMD keeps on making these unmindful cuts in the payments.	7/31/2018 1:55 PM
15	7% of my patients have non-legal status in the USA and are receiving hemodialysis via an emergency medicaid program. We have up until the 2017 CMS reimbursement cuts provided access care for free in our outpatient office lab; this is no longer financially possible.	7/31/2018 11:22 AM
16	we are completely lost in terms of future planning as Extension of practice is barely breaking even after renting out our space to a vascular MD, and there is a lot of cost involved in transforming to an ASC with apparently dubious improvement. And we frankly don't know who and how decisions are made in regards to payments. We are the ONLY link that is squeezed both ways: vendors can increase their prices without consequence to them, payors can lower their payments as they please and we are left to foot the bill both ways as the patients think "we are making the big bucks". I truly feel that our voices are not heard and ignored, and the sad thing it doesn't look anything will change in the foreseeable future...	7/31/2018 11:06 AM
17	We have a second, smaller, low-volume center in less densely populated south DE. This facility is “probably” losing money, depending on how we do the accounting, as the overhead & staffing expenses are split & can be attributed variably to the center. One way or another, it is not a profitable business right now, and any further negative financial pressure could force it to close. In that case, patient travel could be as much as 80-90 miles, 1.5-2 hours to come to our north DE center. Or they would go to one of the hospitals where timeliness, quality, cost-effectiveness, and continuity would all be adversely affected	7/31/2018 7:19 AM
18	we are not sure as of yet of we are going to limit the number of patients but we are considering it if we are unable to break even with costs	7/30/2018 4:03 PM
19	The issue is not drive time. It is inconvenient to go to hospital, incur higher patient costs and use lengthier methods on non-dialysis days. So I have noticed more thrombectomies and less compliance regarding access procedures.	7/30/2018 3:56 PM

Q5 Your Location (City/State):

Answered: 35 Skipped: 5

#	RESPONSES	DATE
1	Philadelphia;PA	8/6/2018 10:53 AM
2	San Antonio, TX	8/6/2018 9:06 AM
3	Decatur, GA	8/6/2018 9:02 AM
4	Tyler, TX	8/5/2018 5:47 PM
5	Huntsville, AL	8/5/2018 10:53 AM
6	Norwood Ohio	8/4/2018 1:57 PM
7	Mobile, AL	8/4/2018 10:51 AM
8	Houston Texas	8/3/2018 11:20 PM
9	Providence/Rhode Island	8/3/2018 8:25 PM
10	Sacramento, CA	8/3/2018 7:26 PM
11	Columbus, GA	8/3/2018 6:56 PM
12	Indianapolis IN	8/3/2018 5:52 PM
13	Macon, GA	8/3/2018 5:52 PM
14	Fort Worth	8/3/2018 5:39 PM
15	Concord ,Ca	8/3/2018 5:38 PM
16	Baltimore, Maryland	8/3/2018 12:45 PM
17	Winston-Salem, NC	8/2/2018 11:45 AM
18	St. Louis, Missouri	8/2/2018 10:21 AM
19	Houston	8/1/2018 11:23 PM
20	Fairfax/VA	8/1/2018 7:08 PM
21	Houston, Texas	8/1/2018 6:10 PM
22	Metairie, LA	7/31/2018 3:08 PM
23	Dallas, TX	7/31/2018 1:55 PM
24	Raleigh, NC	7/31/2018 11:22 AM
25	Wichita, KS	7/31/2018 11:06 AM
26	DE	7/31/2018 7:19 AM
27	Chapel Hill, NC	7/30/2018 10:12 PM
28	Houston/TX	7/30/2018 8:03 PM
29	Fort Worth, TX	7/30/2018 7:50 PM
30	long beach, CA	7/30/2018 5:48 PM
31	OH	7/30/2018 4:57 PM
32	Lafayette, Louisiana	7/30/2018 4:09 PM
33	new york new york	7/30/2018 4:03 PM
34	Chattanooga/Tennessee	7/30/2018 3:56 PM
35	San Diego, CA	7/30/2018 3:39 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.

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

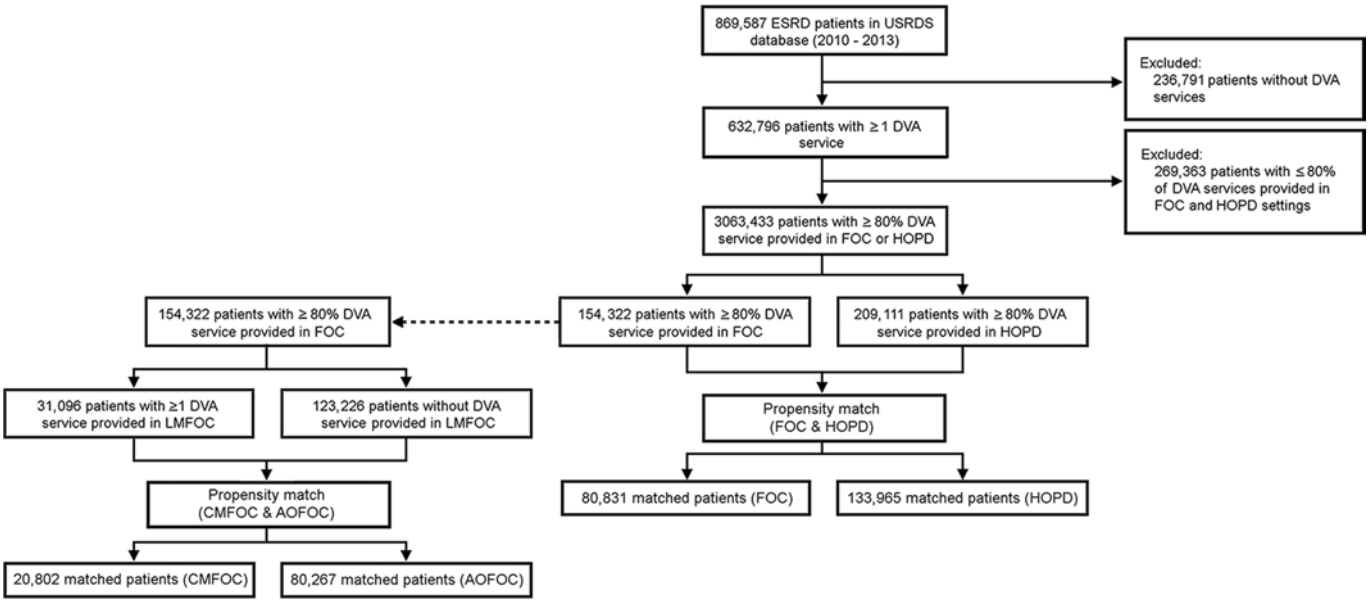

Fig. 1 - Study population. Flow diagram of patient selection.

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

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.

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.

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.

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

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.

Disclosures

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ADDENDUM 3

			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 (Saf	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, Sanizi	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, Sanizi	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 (Saf	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, Sanizi	oz	0.163	1	1.0
36903	SC058	syringe w-needle, OSHA compliant (Saf	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, Sanizi	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 (Saf	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 (Saf	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, Sanizi	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

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 (Saf	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