September 11, 2023

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

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–1784–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2024 Physician Fee Schedule Proposed Rule

Dear Administrator Brooks-LaSure:

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 2024 Physician Fee Schedule (CMS-1784-P).[1] DVAC is a coalition of entities that provide vascular access services to individuals with advanced kidney disease and End-Stage Renal Disease (ESRD).

DVAC is a coalition of entities that provide vascular access services to individuals with advanced kidney disease and End-Stage Renal Disease (ESRD). DVAC represents societies and patient groups, including the American Society of Nephrology, American Society of Diagnostic and Interventional Nephrology (ASDIN), Home Dialyzors United, and the Renal Physicians Association (RPA); as well as provider organizations, including Arizona Kidney Disease and Hypertension Centers, Austin Kidney Associates, Azura Vascular Care, Balboa Nephrology Medical Group, Dallas Nephrology Associates, Dialysis Access Specialists, Lifeline Vascular Care, Nephrology Associates of Delaware, Nephrology Associates of Northern Illinois and Indiana, and Northwest Renal Clinic. DVAC represents the majority of the non-hospital vascular access sector, which provides the majority of vascular access services for ESRD patients on dialysis.[2]

Non-hospital vascular access centers (VACs) provide a wide variety of lifesaving, critical vascular access services for ESRD patients on dialysis. In order to access the patient's bloodstream, different vascular access options exist, including surgical and percutaneous creation

[1] Federal Register, 88 FR 52262 (August 27, 2023)
[2] For more information about DVAC, please see https://www.dialysisvascularaccess.org/about

of fistulas (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). In addition, vascular access centers provide placement services for peritoneal dialysis (PD) catheters (special tubes inserted in a patient's abdominal cavity to allow for home dialysis) and perform interventions to help mature and maintain fistulas.

DVAC appreciates this opportunity to comment on the 2024 PFS Proposed Rule. As discussed in further detail below, DVAC states at the outset that the 2024 PFS continues the trend of reimbursement cuts to specialty care in the office-based setting. These cuts, in turn, are contributing to:

- Reduced access to office-based specialty care, including in rural and underserved areas,
- Health system consolidation,
- The undermining of the Administration's efforts on addressing health equity issues,
- Higher Medicare beneficiary coinsurance, and
- The undermining of our Nation's pandemic resilience.

This letter will comment on the following issues:

- Ongoing Cuts to Office-Based Specialists Continue to Cause Dialysis Vascular Access Center Closures
- Percutaneous Arteriovenous Fistula Creation
- Allowance of Vascular Access Creation Services in the Office

I. ONGOING CUTS TO OFFICE-BASED SPECIALISTS CAUSE DIALYSIS VASCULAR ACCESS CENTER CLOSURES

2024 Physician Fee Schedule

The 2024 Medicare Physician Fee Schedule (PFS) Proposed Rule would impose yet another round of significant cuts to office-based specialists. "Budget-neutrality" remains a driver of cuts within the fee schedule as the 2024 PFS Proposed Rule incorporates:

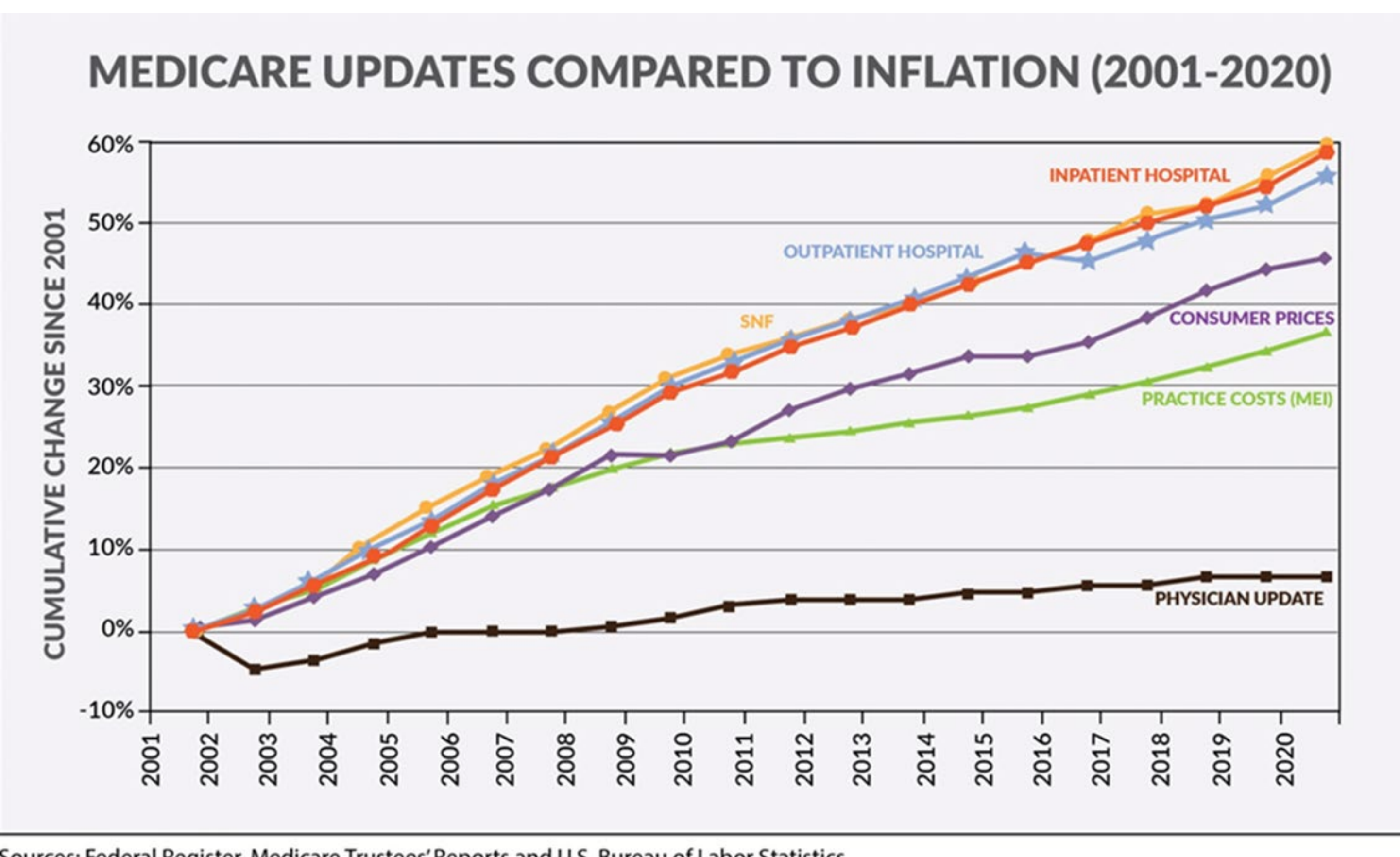
- A carry-over 3.4% cut to the conversion factor from the 2021 PFS E/M policy (and the incorporation of the G2211 code which had been delayed by Congress until 2024), and
- The third year of clinical labor cuts to office-based specialty relative value units (RVUs) stemming from the four-year phase-in through 2025 of the 2022 PFS clinical labor policy that cuts some specialists by another 3% in 2024.

*PFS physician payments equal conversion factor * RVUs.* As a result, office-based dialysis vascular access services will again be cut by another 6 - 7% in 2024 alone (see chart below). These year-over-year cuts are being implemented without regard to patient outcomes, actual PFS provider resource needs, or any other rationale policy.

		2023 Final Physician Fee Schedule	2023 Final Physician Fee Schedule (post H.R. 2617)	2024 Proposed Physician Fee Schedule	2024 Proposed Physician Fee Schedule	2024 Proposed RVU Difference	2024 Proposed Payment Difference
	Conversion Factor →		**$33.89**		**$32.75**		
CPT	Procedure Description	2023 Non-Facility Total RVU/Unit **(Final)**	2023 Non-Facility Total Payments **(Final)**	2024 Non-Facility Total RVU/Unit **(Proposed)**	2024 Non-Facility Total Payments **(Proposed)**	2024 Proposed vs 2023 Final	**2024 Proposed vs 2023 Final**
36901	Intro cath dialysis circuit	21	$719	21	$681	-2%	**-5%**
36902	Intro cath dialysis circuit	36	$1,231	36	$1,164	-2%	**-5%**
36903	Intro cath dialysis circuit	129	$4,371	125	$4,083	-3%	**-7%**
36904	Thrmbc/nfs dialysis circuit	55	$1,847	53	$1,742	-2%	**-6%**
36905	Thrmbc/nfs dialysis circuit	69	$2,326	67	$2,190	-3%	**-6%**
36906	Thrmbc/nfs dialysis circuit	164	$5,543	159	$5,191	-3%	**-6%**
36907	Balo angiop ctr dialysis seg	18	$602	17	$568	-2%	**-6%**
36908	Stent plmt ctr dialysis seg	43	$1,446	42	$1,360	-3%	**-6%**
36909	Dialysis circuit embolj	58	$1,954	56	$1,819	-4%	**-7%**

While "budget-neutrality" sounds like good policy, when it operates within a Physician Fee Schedule that has not kept up with inflation, it results in massive swings in reimbursement and punishes providers irrespective of the value they add to the healthcare system. As a result of budget-neutralizing an underfunded system, the 2021 Physician Fee Schedule (PFS) Rule cut the conversion factor by 10% after an update to E/M data, which had a disproportionate impact on non-primary care providers. Indeed, 2021 PFS cuts were so significant Congress phased them in through 2025. ***When finally phased-in, the 2025 conversion factor is projected to be $32.3433, a cut of more than 10% from the $36.09 conversion factor in 2020.***

The 2022 PFS cut office-based specialists still further due to a 24% cut to the PFS direct adjustment factor, again due to so-called "budget-neutrality" provisions relating to an update to clinical labor data. As a result of the 2022 PFS, office-based dialysis vascular access services will see their reimbursement decreased in some cases by more than 20% through 2025 on top of other aforementioned cuts to the conversion factor. Moreover, it is critical to understand that for many office-based specialists, these cuts also come on top of still further cumulative cuts of up to 50% since 2006 (see HMA's "Cumulative Impact of Changes in RVUs Since 2006" chart below.



Sources: Federal Register, Medicare Trustees' Reports and U.S. Bureau of Labor Statistics

Chronic PFS Underfunding is a Contributor to Office-Based Specialty Center Closure

An American Medical Association analysis of Medicare updates (above) shows significant underfunding of PFS updates relative to practice costs (MEI) since 2001. The black line in the chart labeled, "Physician Update," represents updates to the Physician Fee Schedule "conversion factor" going back to 2001. It clearly shows that the PFS is woefully underfunded relative to "Practice Costs," which are represented by the Medicare Economic Index (MEI). It is worth noting that other sites-of-service have been reimbursed well above MEI since 2001.

We note that Medicare Payment Advisory Commission (MedPAC) analyses also show a huge gap between PFS updates and MEI, but discount the gap by comparing MEI to Medicare PFS spending per FFS beneficiary.[3] We believe that comparing MEI (price) to "Medicare PFS spending per FFS beneficiary" (price * utilization/beneficiary) is inappropriate. Statements by MedPAC that "clinicians have been able to increase the volume and/or intensity of the services they deliver, which has helped to offset the gap" suggest the Commission believes at a macro-

[3] Medicare Payment Advisory Commission, *Assessing payment adequacy and updating payments: Physician and other health professional services and Supporting Medicare safety-net clinicians*, 3 December 2022. Presentation is available here: https://www.medpac.gov/wp-content/uploads/2021/10/Tab-E-Physician-Updates-8-Dec-2022.pdf

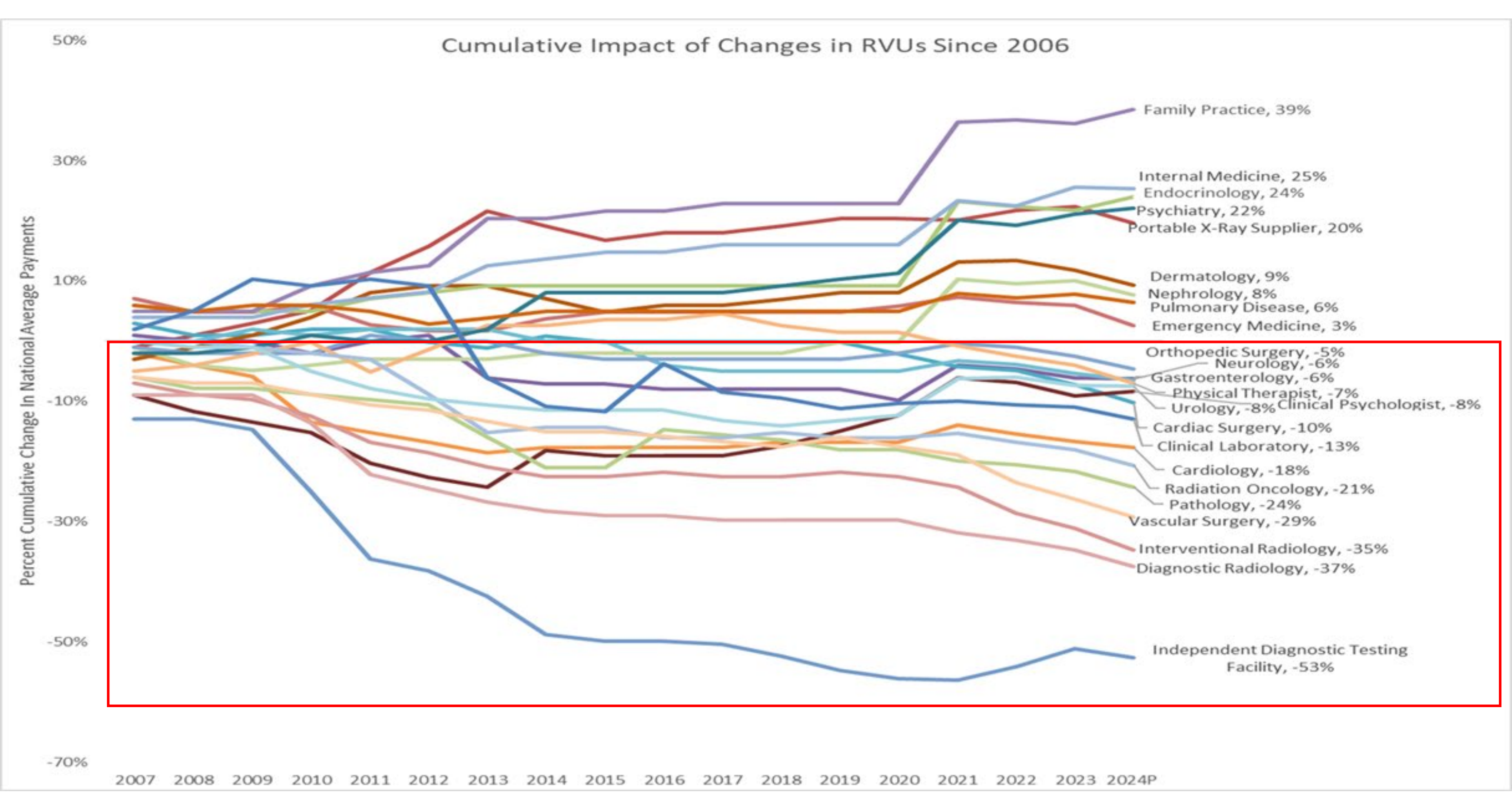
level:

- Clinicians working harder to deal with an aging population is reasonable as a means to offset underfunding in the PFS or
- Clinicians are overutilizing services in order to offset inflation increases.

We believe such views of provider behavior are misplaced and, even were they to be true, the gap between practice costs and reimbursement is too large for clinicians to reasonably view utilization strategies as a means to offset inflation. Most importantly, *specialty-level* analyses show that reimbursement cuts are correlated with specialty-level site-of-service migration and reductions in utilization. In summary, chronic underfunding of the PFS is a significant problem and *specialty-level site-of-service migration and impacts on utilization* should be a critical area of concern for policymakers.

Office-Based Dialysis Vascular Access Services Are Particularly Harmed by RVU Cuts under the PFS

*PFS physician payments equal conversion factor * RVUs.* As noted above, while PFS provider practice costs have far outstripped the PFS conversion factor updates overall, within the PFS, the office-based specialists have been particularly harmed by *RVU* cuts since 2006 as seen in the chart below.



Reduced Access to Office-Based Specialty Care

Ongoing cuts to office-based specialists are key contributors to center closures and health system consolidation. In February of 2023, a multi-societal survey distributed across multiple specialties, including vascular surgery, interventional radiology, and interventional cardiology, to predominately non-hospital physicians found:

- 87% of respondents "believe Medicare cuts have a moderate or greater impact on the practice,"
- 53% of respondents "believe the likelihood of the practice's success is unlikely,"
- 22% of respondents "are likely to become a hospital employee if cuts continue,"
- 21% of respondents "are likely to sell their practice if cuts continue,"
- 17% of respondents "are likely to retire if cuts continue," and
- 8% of respondents "retired, sold, or closed their practice from 2021 to 2022."[4]

Historical specialty-level analyses show that reimbursement cuts have been correlated with site-of-service migration to the hospital and/or reductions in office-based utilization for years. In the case of dialysis vascular access, a 39 percent reduction to a key dialysis vascular access code (36902) in the 2017 Physician Fee Schedule resulted in significant center closures in the office-based setting. An American Society of Diagnostic and Interventional Nephrology (ASDIN) survey in 2018 found that reimbursement levels were so inadequate that (1) more than 20 percent of respondents surveyed stated their centers had closed due to the cuts contained in the CY 2017 Physician Fee Schedule Final Rule and (2) more than 30 percent of respondents indicated their intention to close their center in the future.[5] Concurrent with these office-based closures, 2021 Medicare claims data confirmed a decrease in office-based vascular access services of more than 30 percent since 2017 **as well as an *overall* reduction in vascular access maintenance services of 12 percent counting all sites of service.**[6]

Reduced Access to Office-Based Specialty Care Has a Disproportionate Impact on Rural Areas

Ambulatory care, including office-based specialty care, is a critical component of rural healthcare in the US. A recent study found, however, that rural Medicare beneficiaries have less access to ambulatory care specialists. This study also revealed that reduced access to ambulatory care specialists contributes to the sizable difference in preventable hospitalization and mortality rates between rural and urban beneficiaries. The authors note that policies to expand primary care access in rural areas without specialty care access are unlikely to reduce rural health disparities.[7]

Reduced Access to Office-Based Specialty Care Has a Negative Impact on Health Equity

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[4] John Blebea, MD, MBA et al. Multi-Societal Survey on the Impact of Medicare Cuts to Physician Reimbursement, Presented at the 2023 Outpatient Endovascular and Interventional Society Annual Meeting

[5] Survey available for download here: https://7c6286a4-24ee-4fee-92b9-ed0f0d031061.filesusr.com/ugd/4d8e3a_450f824be03b407fbab027d9e60e9ff5.pdf

[6] MJBF Braid-Forbes Health Research, LLC, Medicare claims analysis of 36902, September 2021

[7] Johnston KJ. (2019, December). Lack of Access to Specialists Associated with Mortality and Preventable Hospitalizations of Rural Medicare Beneficiaries. Health Affairs. 38(12).

The proposed cuts in the 2024 PFS Proposed Rule will have profoundly negative effects on health equity. While the Administration has launched a number of initiatives aimed at addressing health inequity through the elimination of disparities in health care, the 2024 PFS Proposed Rule actually threatens to undermine these initiatives in areas throughout the PFS by continuing to phase in the 2022 PFS clinical labor cuts. The table below highlights reductions to a key dialysis vascular access code contained in the 2022 PFS Proposed Rule. While CMS decided to phase-in these cuts over four years, this just delays the ultimate impact to these services until 2025.

Disease/Service	**Health Inequity**	**2022 PFS**
ERSD / Dialysis Vascular Access	Black and Latino patients start dialysis with a fistula less frequently despite being younger[8]	Key Code (36902) Cut by18%

Reduced Access to Office-Based Specialty Care Has a Negative Impact on Medicare Beneficiary Coinsurance

Site-of-service migration also results in higher Medicare patient coinsurance. For the same code listed above, site-of-service differentials under the 2024 Hospital Outpatient PPFS and Physician Fee Schedule Proposed Rule are as follows:

Disease / Service	**Hospital***	**Medicare Beneficiary Coinsurance****	**Office***	**Beneficiary Coinsurance ****	**Higher Medicare Pay in the Hospital**	**Higher Medicare Beneficiary Coinsurance in the Hospital**
ERSD / Dialysis Vascular Access (36902)	$5,729	$1,146	$1,164	$233	**$4,565**	**$913**
* 2024 HOPPS/PFS Proposed Global Medicare payment including any technical and professional component ** 20% Medicare Coinsurance						

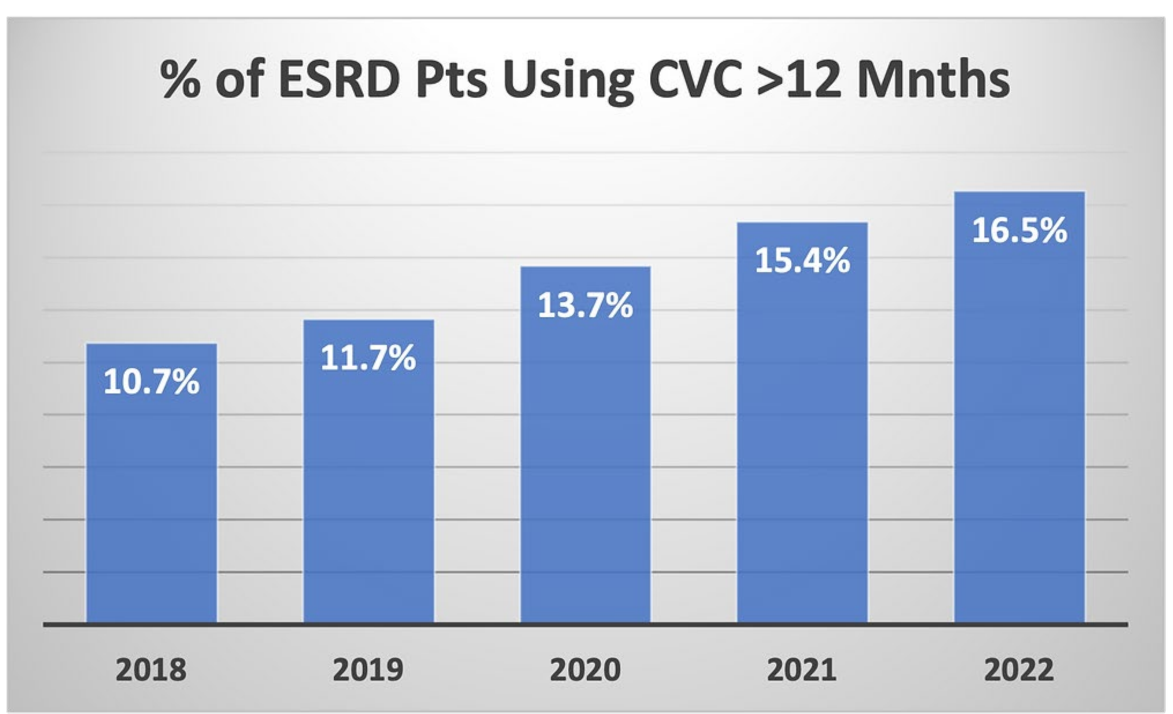
Undermining of our Nation's Pandemic Resilience

Ongoing cuts to office-based specialists under the PFS also are weakening our healthcare system's ability to deal with our country's pandemic resilience. A key lesson from the COVID-19 pandemic is that it is critical that hospitals have sufficient resources to care for their sickest patients. Office-based care under the PFS provides a critical site-of-service outside of the hospital to deal with non-pandemic cases so hospitals can focus on pandemic patients. For

[8] *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. JAMA Surg.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287

example, patients dealing with end-stage renal disease cannot wait for the dialysis vascular access repair services that are critical to keeping them alive or out of the hospital.[9][10]

CMS notes that the agency "continue(s) to consider both AV fistula and AV graft as preferable forms of vascular access to a long-term catheter, and evidence shows that long-term catheters should only be used when all other AV access options have been exhausted.[11] Unfortunately, recent data from Vasc-Alert shows that catheter rates continue to increase as seen in the chart below. This situation is an unfortunate reversal of the significant gains made by the CMS Fistula First Breakthrough Initiative launched in the mid-2000s.[12] While these increases to catheter rates began before the pandemic and are correlated with the closure of office-based vascular access centers after the significant reduction in dialysis vascular access reimbursement in the 2017 Physician Fee Schedule, they also are correlated with the COVID-19 pandemic.



REQUEST: In the 2024 PFS Proposed Rule, CMS states continued interest in promoting "stability and predictability" in the PFS. We believe it would be best for CMS to truly "prioritize stability and predictability over ongoing updates" by temporarily freezing the

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[9] See, for example, the March 2020 CMS "Adult Elective Surgery and Procedures Recommendations," which listed several "do not postpone" procedures such as most cancers, cardiac patients with symptoms, limb threatening vascular surgery, etc.

[10] See also August 2020 CMS "Key Components for Continued COVID-19 Management for Dialysis Facilities," which effectively lists dialysis vascular access as a "do not postpone" procedure.

[11] 88 FR 42500

[12] Lee T. Fistula First Initiative: Historical Impact on Vascular Access Practice Patterns and Influence on Future Vascular Access Care. Cardiovasc Eng Technol. 2017 Sep;8(3):244-254. doi: 10.1007/s13239-017-0319-9. Epub 2017 Jul 10. PMID: 28695442; PMCID: PMC5693683.

implementation of further policy updates – including the clinical labor policy in 2024 through 2025 and the implementation of G2211 in 2024 – that will result in further cuts to dialysis vascular access centers. Instead, we urge CMS to focus on fundamental PFS reform.

II. PERCUTANEOUS ARTERIOVENOUS FISTULA (pAVF) CREATION (CPT CODES 36836 AND 36837)

We would like to thank CMS and the AMA CPT for the newly approved Category I CPT codes, 36836 and 36837, to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach. The codes went into effect on January 1, 2023 with relative value units (RVUs) established for both facility and non-facility site of service. Unfortunately, we note that the non-facility reimbursement is significantly undervalued for CPT 36836 (Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation). DVAC notes that the valuation of 36836 needs to be updated in relation to two inputs: (1) equipment (use of the ultrasound room rather than the more appropriate angiography room) and (2) supplies (the CMS database amount for the Ellipsys Vascular Access Catheter).

- **36836 Should Utilize the Angiography Room (EL011).** Both 36836 and 36837 include angioplasty at the time of creation which requires the angiography room. We request that the angiography room (EL011) be included in the equipment item inputs for CPT 36836 as it is correctly included in CPT 36837 (Wavelinq device).
- **36836 Should Utilize Updated Pricing Data for the Ellipsys Vascular Access Catheter (SD351).** The 2023 PFS Final Rule noted a price of $6,000 for the Ellipsys device which is not representative of the current cost of the device.[13] We believe that this has contributed to the undervaluation of 36836. We have obtained a number of invoices from DVAC members, which we have sent to PE_Price_Input_Update@cms.hhs.gov per the process outlined in the 2024 PFS Proposed Rule.[14] These data – including 80 invoices obtained in 2023 – show that the average price is $7,378.75. We would request that the input price for the supply item (SD351) for 36836 be updated to reflect the supply price based on more recent and robust data.

III. ALLOWANCE OF VASCULAR ACCESS CREATION SERVICES IN THE OFFICE

Non-hospital VACs provide services in the ambulatory surgical center (ASC) and physician office setting as described in the table below.

Sites-of-Service for Dialysis Vascular Access Services		
Setting	***Description***	***Services***

[13] 87 FR 69584
[14] 88 FR 52273

HOPD	• Vascular access services part of broad range of services. • Sub-optimal in terms of quality, cost to patient, cost to Medicare, and patient wait times. • Frequent post procedure hospital admission, lack of continuity of care, prolonged recovery period.	Vascular Access Creation	36818, 36819, 36820, 36821, 36825, 36830
		Vascular Access Preservation	36901 – 36909
NON-HOSPITAL VASCULAR ACCESS CENTERS			
Ambulatory Surgical Center	• Same physician and site-of-service providing creation and preservation services for optimal care. • Comprehensive site-of-service easiest for patient access.	Vascular Access Creation	36818, 36819, 36820, 36821, 36825, 36830
		Vascular Access Preservation	36901 – 36909
Physician Office	• Centers focused primarily on the preservation of fistulas. • Critical to patient care continuum in states w/CON barriers or significant rural population.	Vascular Access Creation	Not Payable (Except for pAVF)
		Vascular Access Preservation	36901 – 36909

Vascular Access ASCs provide a comprehensive set of vascular access services, including (1) services relating to the creation of fistulas and (2) the preservation of fistulas over time. While the physician office setting focuses primarily on the preservation and maturation of fistulas as well as pAVF, it is critical to the ongoing stability of an ESRD patient's vascular access and essential in areas where CON laws, rural considerations, or other issues make an ASC center impossible. For example, 35 states have certificate-of-need requirements for ASCs which often means a physician office alternative is the only possible non-hospital vascular access option in many states.

With the recent CMS coverage of percutaneous AV fistula creation in an office-based setting we can envision a full suite of creation services, whether percutaneous or open surgical, as well as repair services in the office-based settings. As has been previously accomplished with vascular access repair services, providing the appropriate financial incentives to encourage surgical creation in an office-based setting will enhance timely access creation and ultimately decrease costs relative to HOPD care.

REQUEST. DVAC requests that CMS consider allowing reimbursement for other surgical vascular access creation codes (36818, 36819, 36820, 36821, 36825, 36830) in the office-based setting in future rulemaking.

CONCLUSION

DVAC's comments on the CY 2024 Physician Fee Schedule Proposed Rule seek to ensure ongoing access to vascular access services. We look forward to continuing to work with CMS to maintain and improve access to ESRD patient-focused vascular access services. If you have additional questions regarding these matters and the views of the DVAC, please contact Jason McKitrick at (202) 465-8711 or jmckitrick@libertypartnersgroup.com .