September 6, 2022

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

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–1770–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2023 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 2023 Physician Fee Schedule (CMS-1770-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 represents specialty societies, including the American Society of Diagnostic and Interventional Nephrology (ASDIN), the American Society of Nephrology (ASN), and the Renal Physicians Association (RPA); patient groups, including Home Dialyzors United and the Renal Support Network; as well as industry providers, including American Vascular Associates, 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.[2]

Non-hospital vascular access centers (VACs) provide vascular access services for ESRD patients on dialysis. In order to access the patient's bloodstream, different vascular access options exist where options include the 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). In addition, vascular

[1] Federal Register, 87 FR 45860 (July 29, 2022)
[2] For more information about DVAC, please see https://www.dialysisvascularaccess.org/about

access centers provide placement services for peritoneal dialysis (PD) catheters (special tubes inserted in a patient's abdominal cavity to allow for home dialysis).

DVAC appreciates this opportunity to comment on the proposed regulations. As discussed in further detail below, DVAC states at the outset that ongoing cuts to office-based specialists under the Physician Fee Schedule are contributing to office-based center closures, health system consolidation and, as a result, undermining this Administration's efforts on addressing health equity issues.

This letter will comment on the following issues:

- Ongoing Cuts to Office-Based Specialists Cause Center Closures
- 2023 PFS Proposed Rule Continues Historical Cuts to Dialysis Vascular Access
- Principles and Options for PFS Reform
- Allowance of Vascular Access Creation Services in the Office
- Percutaneous Arteriovenous Fistula Creation (CPT codes 368X1 and 368X2)

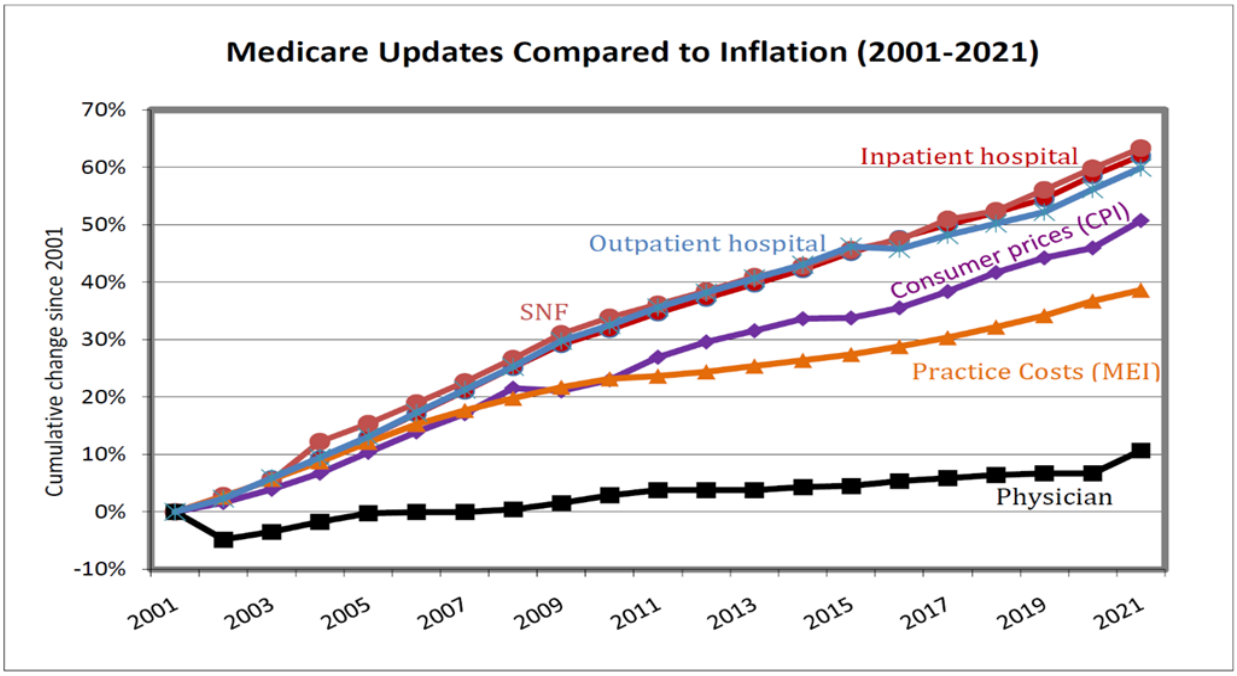
I. ONGOING CUTS TO OFFICE-BASED SPECIALISTS CAUSE CENTER CLOSURES

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. This is because, while reimbursement under the overall Physician Fee Schedule has increased 11 percent over the last two decades, the cost of running a medical practice has increased 39 percent over that same period (see AMA's "Medicare Updates Compared to Inflation" chart below).

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. For example, physical therapists, who make on average roughly $89,000 per year, were cut 9% while primary care providers, who make $241,000 per year, saw a historic increase in reimbursement.[3] Indeed, 2021 PFS cuts were so significant Congress phased them in with the first tranche occurring in 2021, the second tranche occurring in 2022 and the next tranches now set to occur in 2023 (3%) and 2024 (3%).[4]

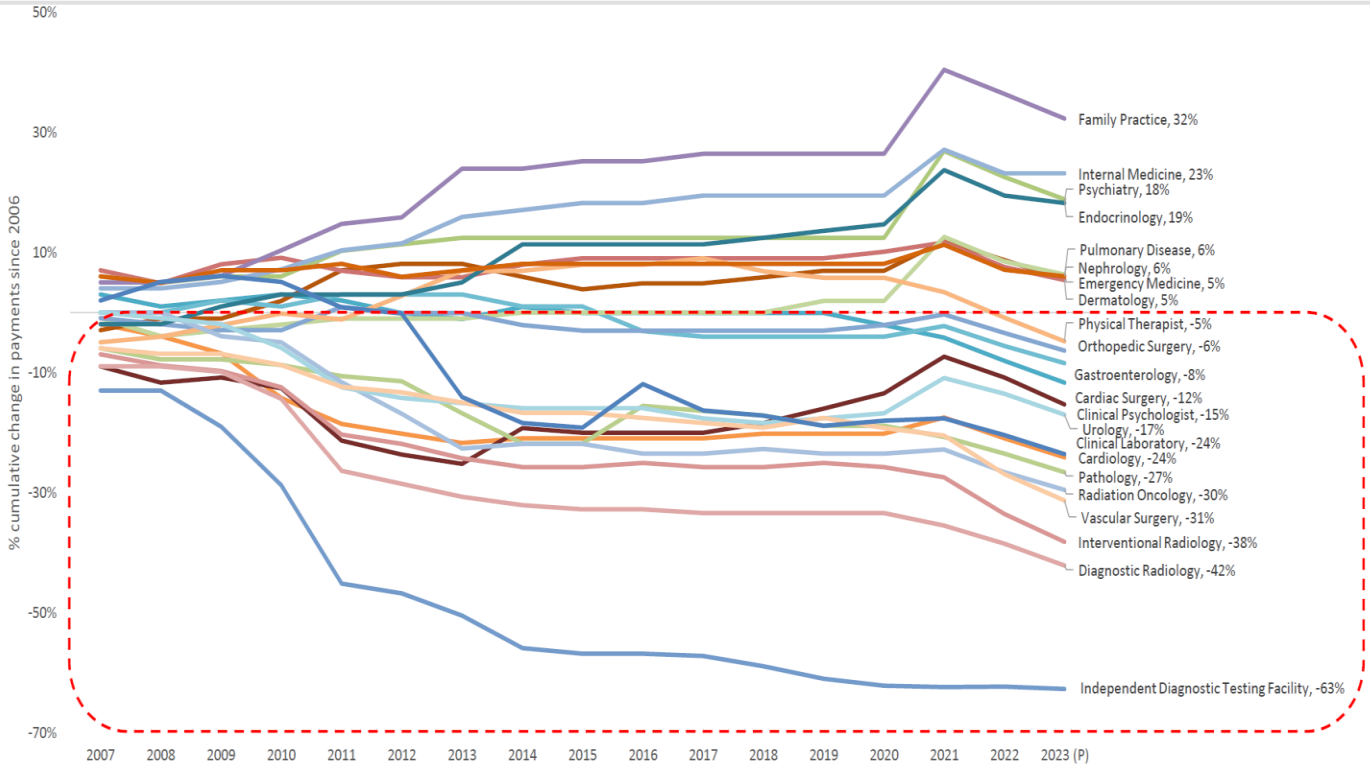
The 2022 PFS cut office-based specialists still further due to a 24% cut to the PFS direct adjustment factor, again due to so-called "budget-neutrality" provisions relating to an update to clinical labor data. As a result of the 2022 PFS, office-based specialists providing care to patients with cancer, end-stage renal disease, fibroids, as well as limb salvage and venous ulcer needs, 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 60% since 2006 (see HMA's "Significant Specialty Variation" chart below).

[3] Primary care has kept up with practice costs (e.g. family practice has seen cumulative PFS increases of 36% since 2006). It is non-primary care providers, particularly those utilizing innovative technologies, which have been most impacted by the underfunding of practice costs in the PFS..
[4] Cuts were phased-in through H.R. 133 in 2020 and S. 610 in 2021.



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

Significant Specialty Variation in Estimated Payment Changes since 2006



Source: HMA analysis 2007-2022 Medicare Physician Fee Schedule Final Rule Impact Tables and 2023 Medicare Physician Fee Schedule Proposed Rule Impact Table.
2021 and 2022 values adjusted for effects of Consolidated Appropriations Act of 2021, including the delayed effect of G2211 until 2024 which, if implemented as proposed, will reduce payments to many specialties that are already at zero percent or lower and increase payments to many specialties that are above zero percent. The 2023 values reflect the changes in RVUs and overall reduction in conversion factor (including the expiration of the one time 3% CF update for 2022).

HEALTH MANAGEMENT ASSOCIATES 1

Ongoing Cuts to Office-Based Specialists as a Driver of Health System Consolidation

In the Proposed Rule, CMS is requesting comments on "possible consolidation of group practices, or burden on small group or solo practitioners" and "discussion of any possible health

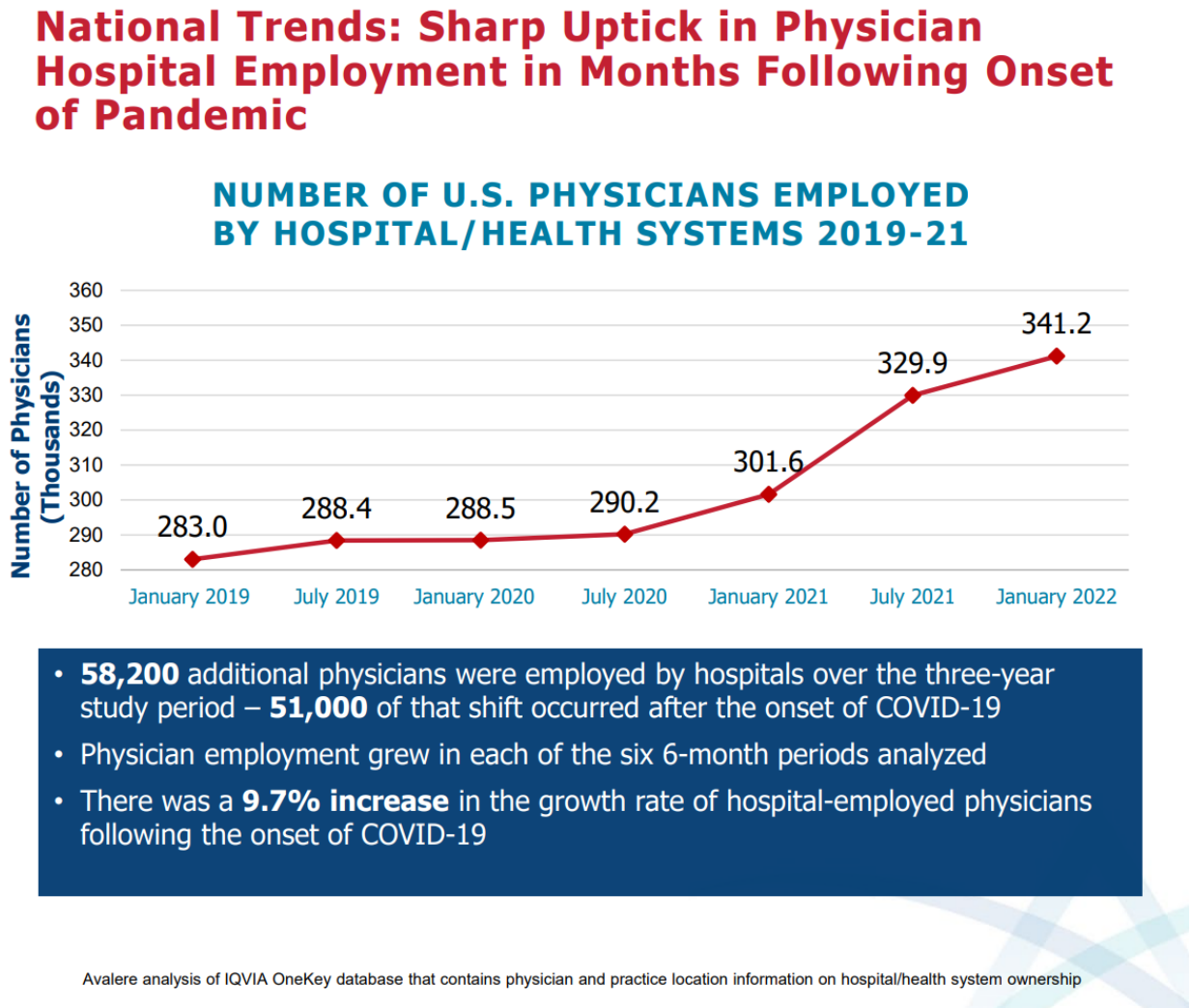
equity impacts." While President Biden's *Executive Order on Promoting Competition in the American Economy* makes it clear that this Administration is concerned with health system consolidation, the 2023 PFS Proposed Rule continues to undercut this initiative. **According to the American Medical Association, the share of physicians working for a hospital increased from 29.0 percent in 2012 to 39.8 percent in 2020.**[5] The ongoing pandemic also has accelerated these trends with hospitals and acquiring 58,200 additional physicians over the last three years (see chart on next page).[6] Given that the reimbursement for medical specialties is, on average, $178,000 more in a vertically integrated health system, the incentive is clear for beleaguered **PFS providers who may no longer be able to sustain further cuts in the 2023 PFS Proposed Rule to simply close their centers and continue the migration to large health systems.**[7] As noted by the Medicare Payment Advisory Commission (MedPAC), "the preponderance of evidence suggests that hospital consolidation leads to higher prices."[8]

As CMS is aware, a huge 39 percent reduction to the 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. 50 percent of respondents who indicated their center already had closed indicated that their patients would have to drive more than 30 additional miles to receive vital vascular access services.[9]

Concurrent with these office-based closures, 2021 Medicare claims data have 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 in all sites of service, which, while likely exacerbated by the pandemic, began in 2017.[10] A 2022 joint study by the Outpatient Endovascular and Interventional Society / American Vein & Lymphatic Society to examine the effects of the COVID-19 pandemic and decreased Medicare physician payments found that 27% of respondents were likely or very likely to close their interventional practice within the next two years. **Reducing the availability of office-based dialysis vascular access services through ongoing cumulative cuts of 18% to 36902 through 2025 will almost certainly result in another round of office-based center closures, cause additional utilization reductions in dialysis vascular access repair and accelerate the aforementioned CMS concerns relating to increases in catheter rates.**

[5] American Medical Association, *Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less Than 50 Percent of Physicians in 2020*, Carol K. Kane, PhD, June 2021
[6] Physicians Advocacy Institute, *Covid-19's Impact on Acquisitions of Physician Practices and Physician Employment*, April 2022 [Prepared by Avalere, see link here.]
[7] Post, Brady PhD et al., *Hospital physician integration and Medicare's site-based outpatient payments*, Health Serv Res. 2021;56:7 15
[8] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2022
[9] Survey available for download here: https://7c6286a4-24ee-4fee-92b9-ed0f0d031061.filesusr.com/ugd/4d8e3a_450f824be03b407fbab027d9e60e9ff5.pdf
[10] MJBF Braid-Forbes Health Research, LLC, Medicare claims analysis of 36902, September 2021

As cumulative cuts to specialists under the PFS have continued to put office-based providers out of business, office-based providers effectively have three choices in response: (1) close their office-based center, (2) join a hospital, or (3) convert to an ASC. As noted above, many physicians already have chosen to join hospital systems and, while some providers have been able to convert to an ASC, due to up-front costs, CON laws, business licensure, etc., setting up an ASC is impossible in many areas of the country. In this light, we believe another round of office-based dialysis vascular access center closures not only would be likely to drive vascular access repair utilization lower, such closures also would begin to drive utilization back to the hospital. Not only would such a result obviously cost Medicare patients and the Medicare program much more, but it would also further undermine patient outcomes given that peer-reviewed data has shown that patients who receive vascular access care in the office have better outcomes than those patients treated in the hospital outpatient setting.[11]



[11] Audrey M. El-Gamil et al., *What is the best setting for receiving dialysis vascular access repair and maintenance services?*, Journal of Vascular Access, 2017

Ongoing Cuts to Office-Based Specialists as a Driver of Health Inequities

The proposed cuts in the 2023 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 2023 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 code reductions 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.

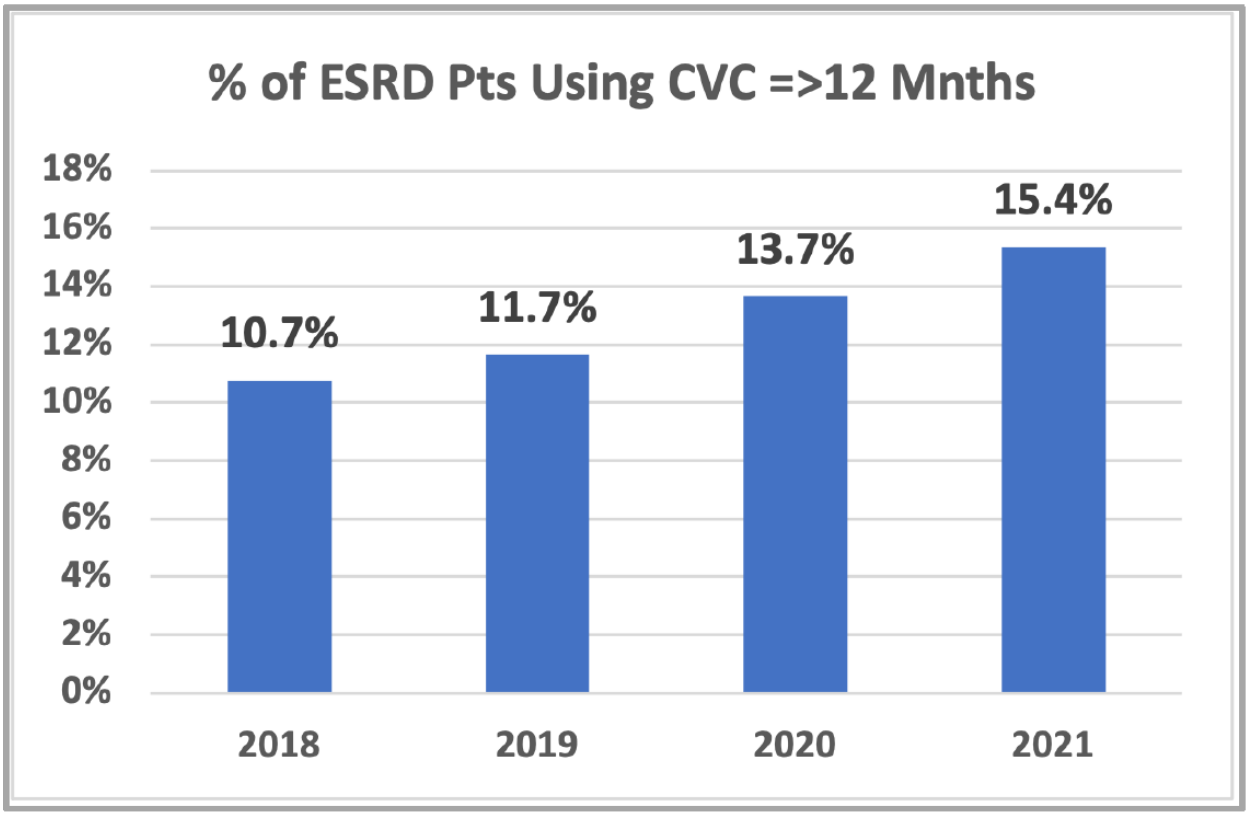
Disease/Service	**Health Inequity**	**2022 PFS**
Venous Ulcer / Endovenous radiofrequency ablation	Black patients present with more advanced venous insufficiency than White patients[12]	Key Code (36475) Cut by 23%
ERSD / Dialysis Vascular Access	Black and Latino patients start dialysis with a fistula less frequently despite being younger[13]	Key Code (36902) Cut by18%
Cancer / Radiation oncology	Black men are 111 percent more likely to die of prostate cancer; Black women are 39 percent more likely to die of breast cancer[14]	Key Code (G6015) Cut by 15%
Peripheral Artery Disease / Revascularization	Black Medicare beneficiaries are three times more likely to receive an amputation[15] Latino are twice as likely[16]	Key Codes (37225-37221) Cut by 22%
Fibroid / Uterine Fibroid Embolization	Uterine fibroids are diagnosed roughly three times more frequently in Black women[17]	Key Code (37243) Cut by 21%

Ongoing Cuts to Office-Based Specialists Weaken Our Nation's Pandemic Response

Ongoing cuts to office-based specialists under the PFS also are weakening our healthcare system's ability to deal with the ongoing COVID-19 pandemic. A key lesson from the pandemic is that it is critical that hospitals have sufficient resources to care for their sickest patients. Yet other patients dealing with cancer, end-stage renal disease, coronary disease, and other post-acute issues cannot wait for the cancer care, dialysis vascular access repair, imaging, physical therapy, etc. that is critical to keeping them alive or out of the hospital.[18][19] Office-based care under the PFS provides a critical site-of-service outside of the hospital to deal with non-COVID cases so hospitals can focus on a resurging pandemic; ongoing cuts to PFS providers threaten the viability of the critical office-based setting during the COVID-19 pandemic.

[12] Vascular and Endovascular Surgery, *Advanced Chronic Venous Insufficiency: Does Race Matter?*, 26 December 2016
[13] *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. JAMA Surg.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287
[14] Cure, *Cancer Sees Color: Investigating Racial Disparities in Cancer Care*, Katherine Malmo, 16 February 2021
[15] Dartmouth Atlas, *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, 2014
[16] J. A.Mustapha, *Explaining Racial Disparities in Amputation Rates for the Treatment of Peripheral Artery Disease (PAD) Using Decomposition Methods*, J. Racial and Ethnic Health Disparities (2017) 4:784–795
[17] University of Michigan, *Understanding Racial Disparities for Women with Uterine Fibroids*, Beata Mostafavi, 12 August 2020
[18] 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.
[19] 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.

We also note that CMS itself in the 2023 ESRD Prospective Payment System (PPS) has proposed to suppress the long-term catheter use rate measure for the second consecutive year due to concerns relating the COVID-19 PHE.[20] However, recent data from Vasc-Alert shows that increases to catheter rates began before the pandemic began with a fully one percentage point increase between 2018 and 2019 (see chart below).[21]



II. 2023 PFS PROPOSED RULE CONTINUES HISTORICAL CUTS TO DIALYSIS VASCULAR ACCESS

The 2023 PFS Proposed Rule continues these historical cuts to office-based specialists by reducing the 2023 Medicare conversion factor by about 4.5% from $34.6062 to $33.0775. This is largely a result of:

- The expiration of the 3% increase to the conversion factor at the end of calendar year 2022 pursuant to S. 610.
- Yet another round of budget neutrality related cuts from revaluations of EM codes families, including hospital, emergency medicine, nursing facility and home visits. These

[20] 87 FR 38534

[21] Vasc-Alert treatment data is derived from kidney machine output and stored in the medical record. We receive this data for every dialysis session from over 300 dialysis facilities, both LDO and independent weekly.

changes are estimated to require an additional reduction of about 1.5% to the 2023 Medicare conversion factor due to statutory budget neutrality requirements.

In addition, CMS is continuing with the second year of the 2022 clinical labor policy which adds additional cuts to dialysis vascular access providers of another 4.5% so that these providers will be subject to cuts of up to 9% in 2023 alone.

	2022 Final Physician Fee Schedule	**2022 Final Physician Fee Schedule (post S. 610)**	**2023 Proposed Physician Fee Schedule**	**2023 Proposed Physician Fee Schedule**	**2023 Proposed RVU Difference**	**2023 Proposed Payment Difference**
CF		34.61		$33.08		
CPT	2022 Non-Facility Total RVU/Unit **(Final)**	2022 Non-Facility Total Payments **(Final)**	2023 Non-Facility Total RVU/Unit **(Proposed)**	2023 Non-Facility Total Payments **(Proposed)**	2023 Proposed vs 2022 Final	2023 Proposed vs 2022 Final
36901	22	$753	21	$698	-3%	-7%
36902	37	$1,295	36	$1,197	-3%	-8%
36903	135	$4,661	129	$4,268	-4%	-8%
36904	56	$1,933	54	$1,797	-3%	-7%
36905	71	$2,451	68	$2,263	-3%	-8%
36906	170	$5,894	163	$5,407	-4%	-8%
36907	18	$632	18	$585	-3%	-7%
36908	44	$1,530	43	$1,408	-4%	-8%
36909	60	$2,090	58	$1,908	-4%	-9%

We are pleased to note that CMS has begun to acknowledge the need to track the viability of office-based specialists. CMS stated in the 2023 PFS Proposed Rule:

- *We have received requests from interested parties for CMS to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented high-level information to CMS suggesting that Medicare payment policies are directly responsible for the consolidation of privately owned physician practices and free standing supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in the delivery of health care, especially concerning independent versus facility-based practices. In response to interested party feedback, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty.*

While an important first step, we note that there also are many shortcomings with the way the office-based (or "nonfacility") data has been presented, including 1) a lack of historical context and 2) missing data in Tables 139 and 148.

- **Lack of Historical Context.** As shown in the above chart, "Significant Specialty Variation in Estimated Payment Changes," some specialties could experience double digit reductions in payments under the PFS and still be well above the historical average while other specialties already have experienced cuts of 20 to 40% or more. It's

important to note that the specialty variation shown in the chart is by specialty and not by site-of-service (as CMS has not historically presented such data). It is likely if CMS had presented such data historically, it would have shown even worse impacts to office-based specialists.

- **Missing Data in Tables 139 and 148.** While Table 139 appears to show a fairly benign cut of -1% to nonfacility providers and increase of +2% to facility providers, in fact, the table leaves out the 3% cut to the conversion factor that occurs in 2023 due to the expiration of provisions in S. 610. As a result, cuts to office-based providers are closer to -4% overall and facility providers also will be subject to a -2% cut. Similarly, Table 148 appears to show a +2% increase to nonfacility providers and a -4% increase to facility providers, but does not include the third tranche of the 3% cuts to the conversion factor to occur in 2024 due to the implementation of G2211 or ongoing clinical labor cuts through 2025. Together these policies likely would result in still further cuts to office-based providers even with the inclusion of considered MEI rebasing and revising by CMS.

In the 2023 PFS Proposed Rule, CMS notes "In light of feedback from interested parties, CMS has prioritized stability and predictability over ongoing updates." However, the historical data and the experiences of the 2021 EM policy resulting in a 10% cut to the conversion factor and the 2022 clinical labor policy resulting in a 24% cut to the direct adjustment factor show that ongoing updates indeed are causing huge unrelated and undeserved cuts to office-based specialists.

REQUST: We believe it would be best for CMS to truly "prioritize stability and predictability over ongoing updates" and temporarily freeze the implementation of further policy updates – including the clinical labor policy in 2023 through 2025, EM revisions in 2023 and the implementation of G2211 in 2024 – that will result in further significant redistributions to the Physician Fee Schedule and focus on fundamental PFS reform.

III. PRINCIPLES AND OPTIONS FOR PFS REFORM

Given significant funding gaps between practice costs and PFS reimbursement, CMS PFS reform concepts have focused on *practice expense* (PE) RVUs. In June 2021, CMS held a Town Hall on "Improving Practice Expense Data & Methods"[22] where the agency explained:

- PFS Reimbursement = (work RVUs + PE RVUs + MP RVUs) * conversion factor.
- PE RVUs = direct PE RVUs (supplies, equipment and labor) + indirect PE RVUs (administrative, overhead, nonclinical labor, rent, information technology).[23]

We believe PFS reform principles should promote stability, alignment and transparency as it relates to contemplated reforms of direct and indirect practice expenses as follows:

[22] https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods
[23] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/Test.pdf

- **Stability.** Medicare providers should have stable reimbursement so they can focus their time on treating patients. Unfortunately, Medicare reimbursement has been particularly unstable in the Physician Fee Schedule for many years. Any new system should promote stability.
- **Alignment Across Ambulatory Settings.**[24] Medicare should reimburse for *direct* practice expenses equally, regardless of setting (HOPD, ASC, or office): a stent used in an office is the same stent used in a hospital; a CT machine used in an ASC is the same machine used in a hospital; a nurse working in an office on Monday and a hospital on Thursday is the same nurse. For *indirect* practice expense, CMS should recognize differential overhead needs by setting (e.g. a typical hospital has more overhead than a typical primary care office).
- **Transparency.** The PFS PE methodology is a 19-step algorithm that is exceedingly complex and opaque and much of the data used in the methodology derives from an AMA RUC process which is not publicly accessible. CMS should promote transparency in any new PFS system.

Applying PFS Reform Principles to Two Distinct Options for PFS Reform

In the 2023 PFS Proposed Rule, CMS notes that it believes, "Of the various PE data inputs, we believe that indirect PE data inputs, which reflect costs such as office rent, IT costs, and other non-clinical expenses, present the opportunity to build consistency, transparency, and predictability into our methodology to update PE data inputs" and notes that the primary source for indirect PE information – the Physician Practice Information Survey (PPIS) – reflects 2006 data. **We disagree and note that the last time the PPIS survey was conducted in 2007/2008, it resulted in yet another huge redistribution in the Physician Fee Schedule.**[25] **Moreover, we believe the *direct* PE portion of the Physician Fee Schedule presents the best opportunity for consistency, transparency, and predictability.**

Two distinct, mutually exclusive, PE related PFS reform options have been proposed in recent years: (1) using new HOPPS data for PERVUs or (2) removing PERVUs from the PFS:

- **Using HOPPS Data for PFS PERVUs.** In a 2021 report, Rand describes using data from the Hospital Outpatient Prospective Payment System (HOPPS) for PFS PERVUs.[26] Due to OPPS "ancillary services," however, CMS either would overstate costs in the PFS if APC values are used or understate cost if CPT values are used. In order to promote reimbursement stability, alignment across ambulatory settings, and transparency, CMS should (1) derive direct costs from HOPPS data in a transparent manner for inclusion in the PFS on an equivalent basis through a new methodology which promotes alignment across settings and (2) exempt this new data from underlying budget-neutrality and other provisions in the PFS. Given that direct costs should be equivalent across settings, we

[24] MedPAC explored this issue in an April 2022 briefing, "Aligning fee-for-service payment rates across ambulatory settings"
[25] The previous 2007 / 2008 AMA survey resulted in significant cuts to office-based specialties (e.g. cardiology [-13%], interventional radiology [-10%], radiation oncology [-5%]) when incorporated in the 2009 Physician Fee Schedule.
[26] https://www.rand.org/pubs/research_reports/RRA1181-1.html

believe the use of HOPPS data should require using HOPPS data at 100% of its HOPPS value (likely requiring a new methodological process).

- **Removing PERVUs from the PFS.** At a 2020 RUC meeting, the AMA RUC recommended CMS separately identify and pay for high-cost disposable supplies.[27] Since 2019, CMS has been using a contractor (StrategyGen) to provide equipment and supply pricing data for PFS direct costs. Removing PERVUs from the PFS could necessitate a new, technical fee schedule for all ambulatory settings and promote stability and alignment across settings, but CMS should strengthen transparency of the StrategyGen process through public comment on how exactly how CMS arrives at pricing data (GPO discounts, setting, etc.) for specific equipment and supplies.

It's important to note that while the HOPPS and ASC Fee Schedules include only technical payments (e.g., the high-technology equipment, supplies and other interventions that have been a hallmark of the U.S. healthcare system) for HOPDs and ASCS, the PFS includes technical payments for office-based providers *plus* professional payments for physicians in all settings (e.g. HOPD, ASC and office). As a result, PFS technical payments currently "budget-neutralize" office-based supplies and equipment to *dissimilar* items such as professional payments for physician work in the hospital. This dynamic is a significant contributor to the payment volatility within the PFS.

Included in PFS Budget Neutrality:

- Office Technical Component
- Office Professional Component
- Hospital Professional Component
- ASC Professional Component

Not Included in PFS Budget Neutrality:

- Hospital Technical Component
- ASC Technical Component

REQUEST: We agree with CMS' focus on practice expenses as the main source of volatility in the PFS, but urge CMS and Congress to focus on direct practice expenses in the Physician Fee Schedule as the best opportunity for PFS payment stability.

IV. 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***

[27] https://www.ama-assn.org/system/files/oct-2020-ruc-recommendations.pdf

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
		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 (which can only be performed in an ASC) and (2) the preservation of fistulas over time. While the physician office setting focuses primarily on the preservation of fistulas, 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.

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

V. PERCUTANEOUS ARTERIOVENOUS FISTULA CREATION (CPT CODES 368X1 AND 368X2)

In October 2021, the AMA created CPT codes 368X1 and 368X2 to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach with the intention that these codes would replace HCPCS codes G2170 and G2171. A DVAC review of contractor pricing earlier this year found the following contractor prices for G2170 and G2171 as follows:

Predecessor Code	**Average of Contractor Pricing**	***Palmetto***	***FCSO***	***NGS***	***Noridian***	***WPS***	***CGS***	***Novitas***
G2170	$8,617	*$12,500*	*$8,080*	*$8,250*	*$8,500*	*$6,128*	*NA*	*$8,247*
G2171	$8,907	*$12,500*	*$8,080*	*NA*	*$8,500*	*$7,206*	*NA*	*$8,247*

When comparing proposed 2023 PFS rates for new replacement codes (368X1 and 368X2), CMS is proposing a 19% reduction relative to contractor pricing for 368X1 and an 11% increase for 368X2 as follows:

			2023 Proposed Physician Fee Schedule		
			Conversion Factor →	33.08	
Predecessor Code	Average of Contractor Pricing	New Code	2023 Non-Facility Total RVU/Unit (Proposed)	2023 Non-Facility Total Payments (Proposed)	**Difference Between Predecessor Code and New Code**
G2170	$8,617	368X1	210.13	$6,951	**-19%**
G2171	$8,907	368X2	299.18	$9,896	**11%**

DVAC notes the following as it relates to the valuation of the new 368X1 and 368X2 codes:

- SD149 (catheter, balloon inflation device) and SD152 (catheter, balloon, PTA) Supply Inputs for 368X1 and 368X2. In the proposed rule, CMS is seeking information to inform the agency on why the supply items should be considered "typical" for 368X1 and 368X2 and how often they are used. Angioplasty using a balloon and inflation device (SD149 and SD152) during the procedure 368X1 is used more than 90% of the time according to the literature and case reports from various physicians. We cannot find evidence of typical use (50% or greater) of these two products during procedure 368X2.
- Use of the Ultrasound Room Rather Than the Angiography Room. DVAC notes that the Angiography Room is listed as an equipment input for 368X1 rather than the Angiography Room, although the Angiography Room is listed as an equipment input for 368X2. Although the 368X1 creation procedure is done under ultrasound, the typical location for this procedure is in an angiography room given the angioplasty performed after the creation more than 90% of the time.
- Pricing Data for SD351 (Ellipsys Vascular Access Catheter) for 368X1. DVAC notes that CMS is using only a single invoice of $6,000 for SD351 (Ellipsys Vascular Access Catheter) and we believe this pricing is unrepresentative for this device. We urge CMS to work with the manufacturers to collect additional invoices to arrive at more appropriate pricing for SD351.
- Pricing Data for Ellipsys EndoAVF generator (EQ404) used for CPT code 368X1 and Wavelinq EndoAVF generator (EQ403) used for CPT code 368X2. CMS is requesting additional information on why EQ403 is priced at $18,580 and EQ404 is priced at

$3,000. We cannot understand the difference between the power source prices and urge CMS to work with the manufacturers to collect additional pricing data.

- Coil Embolization Use. The literature indicates that coils are used more than 70% of the time in 368X2, but there are no references that indicate multiple coils are used when embolizing the brachial vein. We believe the typical direct PE input is for one SF056 (detachable coil) and that SF057 (non-detachable embolization coil) is not a typical use.

CONCLUSION

DVAC's comments on the CY 2023 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 .

DIALYSIS VASCULAR ACCESS COALITION

AKDHC Arizona Kidney Disease & Hypertension Centers

AKA Austin Kidney Associates

American Vascular

ASDIN American Society of Diagnostic and Interventional Nephrology

ASN American Society of Nephrology

azura vascular care

BNMG Balboa Nephrology Medical Group

Dallas Nephrology Associates Comprehensive Kidney Care

Dialysis Access Specialists

HDU Home Dialyzors United

Lifeline Vascular Care

NANI Nephrology Associates of Northern Illinois and Indiana

Nephrology Associates delawarekidney.com

Northwest Renal Clinic, Inc.

RPA Renal Physicians Association

Renal Support Network RSNhope.org