September 13, 2021

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

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–1751–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2022 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 2022 Physician Fee Schedule (CMS-1751-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) and the Renal Physicians Association (RPA), 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, Northwest Renal Clinic, and San Antonio Kidney Disease Center. DVAC represents the majority of the non-hospital vascular access sector.

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

[1] Federal Register, 86 FR 39104 (July 23, 2021)

DVAC appreciates this opportunity to comment on the proposed regulations. As discussed in further detail below, **DVAC states at the outset of this comment that considering the second-order negative effects of PFS "budget neutrality" greatly outweigh incorporating new clinical labor data, we strongly recommend CMS not finalize the clinical labor policy at this time in the 2022 PFS Final Rule.**

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

- Impact of the PFS Rule on Office-Based Specialists
- Second-Order Effects Resulting in a PFS Ever More Out of Touch with Actual Costs
- Proposed Principles for Reform
- Allowance of Vascular Access Creation Services in the Office

I. IMPACT OF THE 2021 AND 2022 PFS RULES ON OFFICE-BASED SPECIALISTS

2021 Physician Fee Schedule Final Rule

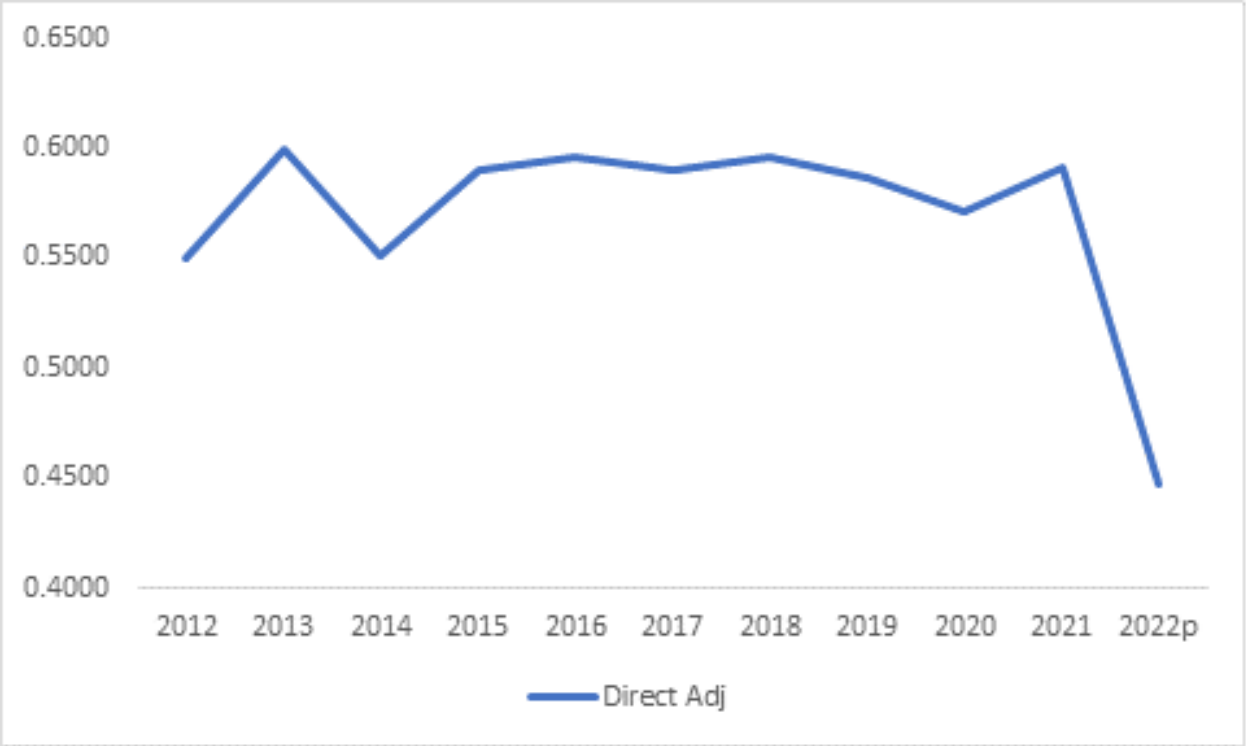
The 2021 PFS Rule increased payments starting in 2021 for E&M services (99202-99215), introduced an add-on code (HCPCS G2211) for complex care associated with evaluation and management "E&M," and adjusted "E&M-like" services codes. As a first order effect, updating data for such services seems logical. However, due to second order "budget-neutrality" effects to the conversion factor, huge cuts occurred to office-based specialists without regarding to patient outcomes, actual PFS provider resource needs, or any other rationale policy. While CMS and the AMA dedicated significant resources getting E&M data just right, there was no analysis of second-order effects to a wide group of providers from huge cut to conversion factor (see Table 1 below). These cuts were so significant that Congress took it upon itself to phase in the cuts through H.R. 133 so that the next round of cuts will occur on 1/1/2022 (3.75%) and the remaining cuts will occur on 1/1/2024 (~3%).

Table 1

Specialty	Impact of 2021 PFS
Radiology	-10%
Nurse Anes / Anes Asst	-10%
Chiropractor	-10%
Physical/Occupational Therapy	-9%
Pathology	-9%
Cardiac Surgery	-8%
Interventional Radiology	-8%
Anesthesiology	-8%
Nuclear Medicine	-8%
Thoracic Surgery	-8%
Critical Care	-7%
Plastic Surgery	-7%
Neurosurgery	-6%
Audiologist	-6%
General Surgery	-6%
Vascular Surgery	-6%
Emergency Medicine	-6%
Ophthalmology	-6%
Portable X-Ray Supplier	-6%
Radiation Oncology / Radiation Therapy Centers	-5%
Colon And Rectal Surgery	-5%
Independent Laboratory	-5%

2022 Physician Fee Schedule Proposed Rule

While the 2021 PFS budget-neutrality effect was due to the CMS policy of updating data for E/M services, the main driver of provider cuts in the 2022 PFS Proposed Rule relates to budget-neutrality effects of a CMS proposal to update clinical labor data. Like last year's E/M proposal, as a first order effect, updating clinical labor data in the CMS database seems logical sense. However, because of PFS "budget-neutrality," the incorporation of new clinical labor data actually results in **massive cuts of up to 20 percent to critical services in the PFS**.[2] Specifically, the updates to clinical labor data in the PE methodology cause the total direct cost pool to go up 32% and the "direct adjustment factor" to decrease from 0.5916 to 0.4468. Going back over the last decade, the direct adjustment factor has never been anywhere near as low (see chart below).



Here again, while CMS dedicated significant resources getting first order clinical labor data just right, there was no analysis of second-order effects to a wide group of providers from the huge cut to the direct adjustment factor (see Table 2 below).

[2] It is worth noting another area ripe for reform is the PFS "impact table," which does not disaggregate specialty impact by site-of-service, thereby masking the true impact of the PFS on office-based specialists in the 2022 PFS Proposed Rule and, historically, every other PFS rule.

Table 2	
Specialty	Impact of 2022 PFS
Peripheral Vascular Disease	-14%
Radiation Therapy Centers	-14%
Interventional Radiology	-13%
Vascular Surgery	-11%
Oral Surgery (Dentists)	-8%
Radiation Oncology	-8%
Medical Oncology	-6%
Clinical Laboratory	-6%
Hematology/oncology	-6%
Diagnostic Radiology	-6%
Nuclear Medicine	-5%
Allergy/Immunology	-5%
Cardiac Electrophysiology	-5%

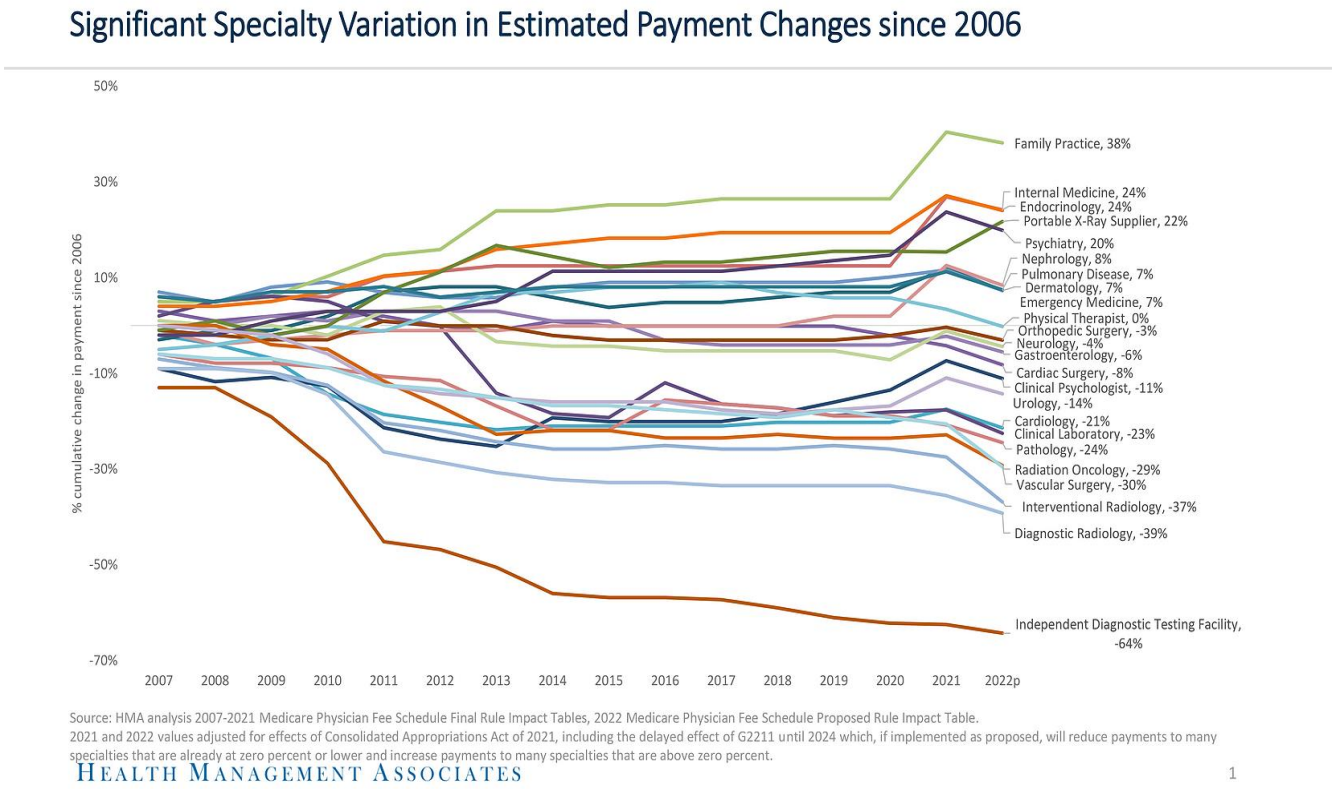
In sum, PFS second-order "factors" are outweighing the benefits of first order updates to the PFS. With respect to the 2021 PFS, whether or not new E&M data was accurate, the corresponding indiscriminate cut of 10% to the "conversion factor" is having huge second order effects that are not being considered. With respect to the 2022 PFS, whether or not new clinical labor data is accurate, a corresponding indiscriminate cut of 24% to the "direct adjustment factor" will have huge second order effects that are not being considered. With respect to the 2023 PFS, should CMS make significant changes to the "indirect practice expense" data in the 2023 PFS (as it is indicating it will), it will not analyze second order effects from whatever factor it uses to budget neutralize. The result is a PFS that is ever more out of touch with reality as "conversion factors," "direct adjustment factors," and other "factors" make the PFS less and less reflective of what it actually takes to provide services in the office.

II. SECOND-ORDER EFFECTS RESULTING IN A PFS EVER MORE OUT OF TOUCH WITH ACTUAL COSTS

While some characterize the PFS "budget-neutrality" provision as a "sometimes you win, sometimes you lose" policy, in fact, over the last decade, cumulative PFS redistributions clearly have negatively impact certain providers. For example, **cardiology, vascular surgery, radiation oncology, and radiology have endured cumulative cuts over the last decade in the PFS of between 20 and 40 percent (see chart below).[3] It is important to note that PFS Impact Tables do not disaggregate specialty impact by site-of-service, and, as a result, mask even worse cuts to office-based specialists.** Other times, the PFS "budget-neutrality" provision is characterized as rebalancing the PFS away from higher-paid providers and towards

[3] Health Management Associates, Analysis of the 2022 Physician Fee Schedule, 2021

lower paid providers. In fact, however, in the 2021 PFS, the lowest paid providers — physical therapists — received a 9 percent cut which was redistributed to other PFS providers making at least 170 percent more.[45] Indeed, given the strong correlation between ongoing cuts and reimbursement volatility for PFS providers vis-à-vis the health system consolidation trend, we believe the best characterization of the so-called PFS "budget neutrality" provision is that it is a driver of PFS center closures and *increased* costs to the Medicare program.



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

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 2022 PFS Proposed Rule serves 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.[6] The ongoing pandemic also has accelerated these trends with hospitals and corporate entities acquiring 20,900 additional physician practices over the last two years.[7] Given that the reimbursement for all specialists is, on average, more than $100,000 in a vertically integrated health system than in a physician office, the incentive is clear for beleaguered **PFS**

[4] Urban Institute and SullivanCotter, *Analysis of Physician Compensation*, January 2019.
[5] Bureau of Labor Statistics, *U.S. Department of Labor, Occupational Outlook Handbook, Physical Therapists*. 2021
[6] 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
[7] Avalere, *Hospitals and Corporations Own Nearly Half of U.S. Physician Practices: Covid-19 Accelerated Ownership Trend*, June 2021

providers who may no longer be able to sustain cuts in the 2022 PFS Proposed Rule to simply close their centers and continue the migration to large health systems.[8]

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

The proposed cuts in the 2022 PFS Proposed Rule will have profoundly negative effects on health equity. While President Biden's FY 2022 Budget contained many worthy provisions aimed at addressing health inequity through the elimination of disparities in health care, the 2022 PFS Proposed Rule actually threatens to undermine these initiatives in areas throughout the PFS as exemplified with several examples in Table 3 below.

Table 3		
Disease/Service	**Health Inequity**	**2022 PFS**
Venous Ulcer / Endovenous radiofrequency ablation	Black patients present with more advanced venous insufficiency than White patients[9]	Key Code (36475) Cut by 23%
ERSD / Dialysis Vascular Access	Black and Latino patients start dialysis with a fistula less frequently despite being younger[10]	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[11]	Key Code (G6015) Cut by 15%
Peripheral Artery Disease / Revascularization	Black Medicare beneficiaries are three times more likely to receive an amputation[12] Latino are twice as likely[13]	Key Codes (37225-37221) Cut by 22%
Fibroid / Uterine Fibroid Embolization	Uterine fibroids are diagnosed roughly three times more frequently in Black women[14]	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 learned since the start of the pandemic is that it is critical that hospitals be able to focus on our sickest pandemic patients. Yet many 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,

[8] Post, Brady PhD et al., *Hospital physician integration and Medicare's site-based outpatient payments*, Health Serv Res. 2021;56:7 15
[9] Vascular and Endovascular Surgery, *Advanced Chronic Venous Insufficiency: Does Race Matter?*, 26 December 2016
[10] *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. JAMA Surg.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287
[11] Cure, *Cancer Sees Color: Investigating Racial Disparities in Cancer Care*, Katherine Malmo, 16 February 2021
[12] Dartmouth Atlas, *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, 2014
[13] 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
[14] University of Michigan, *Understanding Racial Disparities for Women with Uterine Fibroids*, Beata Mostafavi, 12 August 2020

imaging, physical therapy, etc. that is critical to keeping them alive or out of the hospital.[15][16] 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.[17]

We also note that CMS itself in the 2022 ESRD Prospective Payment System (PPS) has raised concerns relating to the increase in catheter rates during the COVID-19 pandemic as follows:

- *Our analysis based on the available data indicates that long-term catheter use rates have increased significantly during the COVID–19 PHE.*[18]
- *We are concerned that the COVID–PHE impacted the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased health risks resulting therefrom, and that these contributed to the significant increase in long-term catheter use rates.*[19]

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.[20]

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.[21] Reducing the availability of office-based dialysis vascular access services through another 18% cut to 36902 will almost certainly result in another round of office-based center closures, cause additional utilization reductions in dialysis

[15] 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.
[16] 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.
[17] Hospitals in two states where COVID-19 is surging already have begun to delay elective surgeries again. See Becker's ASC Review, *Elective surgeries delayed at Florida, Louisiana hospitals amid COVID-19 surges*, 26 July 2001.
[18] 86 FR 36354
[19] Ibid
[20] Survey available for download here: https://7c6286a4-24ee-4fee-92b9-ed0f0d031061.filesusr.com/ugd/4d8e3a_450f824be03b407fbab027d9e60e9ff5.pdf
[21] MJBF Braid-Forbes Health Research, LLC, Medicare claims analysis of 36902, September 2021

vascular access repair and accelerate the aforementioned CMS concerns relating to increases in catheter rates.

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.[22]

REQUEST. Considering that the second-order negative effects of PFS "budget neutrality" strongly outweigh incorporating new clinical labor data, we strongly recommend CMS not finalize the clinical labor policy at this time in the 2022 PFS Final Rule. Moreover, considering PFS "budget neutrality" effects from the 2021 PFS Final Rule E/M policy are still causing negative impacts in the form of a scheduled 3.75 percent cut to the conversion factor in 2022, we urge you to work with Congress on fundamental reform to the PFS in order that we may better address the upcoming 3.75 percent cut in legislation later this year.

III. PROPOSED PRINCIPLES FOR REFORM

In the 2021 PFS Proposed Rule, CMS highlights the age of the data currently used for indirect practice expenses in the CMS database ("our current system for setting PE RVUs relies in part on data collected in the Physician Practice Information Survey (PPIS), which was administered by the AMA in CY 2007 and 2008."). The Agency also notes it is "interested in potentially refining the PE methodology and updating the data used to make payments under the PFS …. as soon as practicable." In the 2022 PFS Proposed Rule, CMS notes it continues to be interested in "potentially refining the PE methodology and updating the underlying data, including the PPIS data that are the data source that underpins the indirect PE allocation."

As DVAC noted in its 2021 PFS comment, approaches to updating the indirect practice expense data – and potentially the practice expense data overall – appear to break down along three general approaches:

- **Use of OPPS Data.** This approach appears to be favored by the RAND Corporation. In a 2018 report to CMS, Rand describes how macro-level hospital charge data could be used

[22] 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

to set overall practice expenses under the Physician Fee Schedule.[23] While such an approach could result in better price transparency and stability for office-based stakeholders, a key consideration would be to ensure OPPS data be used in a way that promotes the viability and stability of services in the office setting. For example, freestanding radiation oncology centers likely incur direct practice expenses approaching 100% of a hospital outpatient department and other office-based specialties similarly use the same high-cost supplies as a hospital. **DVAC believes concepts such as reimbursing the same for direct costs (i.e. equipment, supplies, or clinical labor), regardless of site of service, have merit.**

- **Use of Physician Survey Data in the Current PFS Practice Expense Methodology.** This approach involves the use of micro-level physician data compiled through a physician survey, similar to the previous 2007 / 2008 AMA survey which resulted in significant cuts to office-based specialties (e.g. cardiology [-13%], interventional radiology [-10%], radiation oncology [-5%]) when it was incorporated into the 2009 Physician Fee Schedule through the PE Methodology. As noted previously in this comment letter, it's likely that these aforementioned data pulled from the 2009 Physician Fee Schedule impact table mask *an even greater negative impact on office-based specialties* given that the Medicare impact tables aggregate the impacts of office-based and hospital-based providers. **Given that any new indirect practice expense physician survey data would be fed into the same 19-step PE methodology and result in yet another round of significant second-order budget neutrality cuts and disruption, DVAC would have grave reservations about such an approach.**

- **Use of "Market Data."** This approach, among others, is contemplated by CMS in the 2021 PFS Proposed Rule and would involve the use of "market-based information" similar to the market research conducted to update equipment and supply data through rulemaking in 2018 for the 2019 Physician Fee Schedule. CMS' approach in 2018 to derive direct practice expense data for supplies and equipment was grounded in the Agency's use of a contractor, StrategyGen, to arrive at such pricing. Unfortunately, this approach – sometimes referred to as a "secret shopper" methodology – currently suffers from a lack of transparency regarding exactly what kind of invoice data (e.g. manufacturer(s), setting, year, aggregation methodology, etc.) ultimately was used to arrive at the equipment and supply pricing currently included in the CMS database. **DVAC believes the StrategyGen pricing methodology suffers from a significant lack of transparency and urges CMS to describe precisely how CMS derives pricing for equipment and supplies in the CMS database as it relates to the manufacturer, the precise device or equipment the year, aggregation methodology, etc.).**

Proposed Principles for Reform

[23] Rand Corporation, Practice Expense Methodology and Data Collection Research and Analysis, 2018

DVAC believes CMS should recognize that the benefits of first-order updates to the current PFS are increasingly outweighed by the second-order negative impacts of concurrent, indiscriminate cuts to various factors under the PFS. We believe there are two key principles to which CMS should adhere as it explores a new methodology to update the PFS practice expense methodology.

First, DVAC believes CMS should be transparent and provide stakeholders the tools to understand how any proposed approach to update the PFS PE Methodology will impact reimbursement *before* implementing such a new PE Methodology. This principle is critical as many office-based specialists focus on discrete service lines. While this means that office-based specialists often can realize optimal patient outcomes as "centers of excellence," they are much more susceptible to reimbursement volatility than, for example, hospitals, which often provide a broad array of services.

Second, DVAC believes CMS should certify to the public and Congress that any new Agency action that results in a significant reduction to a given office-based specialty will not result in second-order effects that disrupt Medicare patient care (e.g. migration of services to a higher cost sites-of-service, significant reduction in patient access to specialty care, exacerbation of health inequities, etc.).

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***	
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.

REQUEST. 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.

CONCLUSION

DVAC's comments on the CY 2022 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 .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