DIALYSIS VASCULAR ACCESS COALITION

October 5, 2020

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

The Honorable Seema Verma Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1734–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2021 Physician Fee Schedule Proposed Rule

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 2021 Physician Fee Schedule (CMS-1734-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, San Antonio Kidney Disease Center, and Vascular Access Centers. 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). In other words, non-hospital VACs are a cornerstone of the Administration's efforts to advance American kidney health.

[1] Federal Register, 85 FR 48772 (August 12, 2020)

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
- Critical Need for Stability for Office-Based Specialists
- Allowance of Vascular Access Creation Services in the Office
- Hemodialysis Access Creation Episode-Based Measure
- Collection of Clinical Labor Data
- MIPS Value Pathways

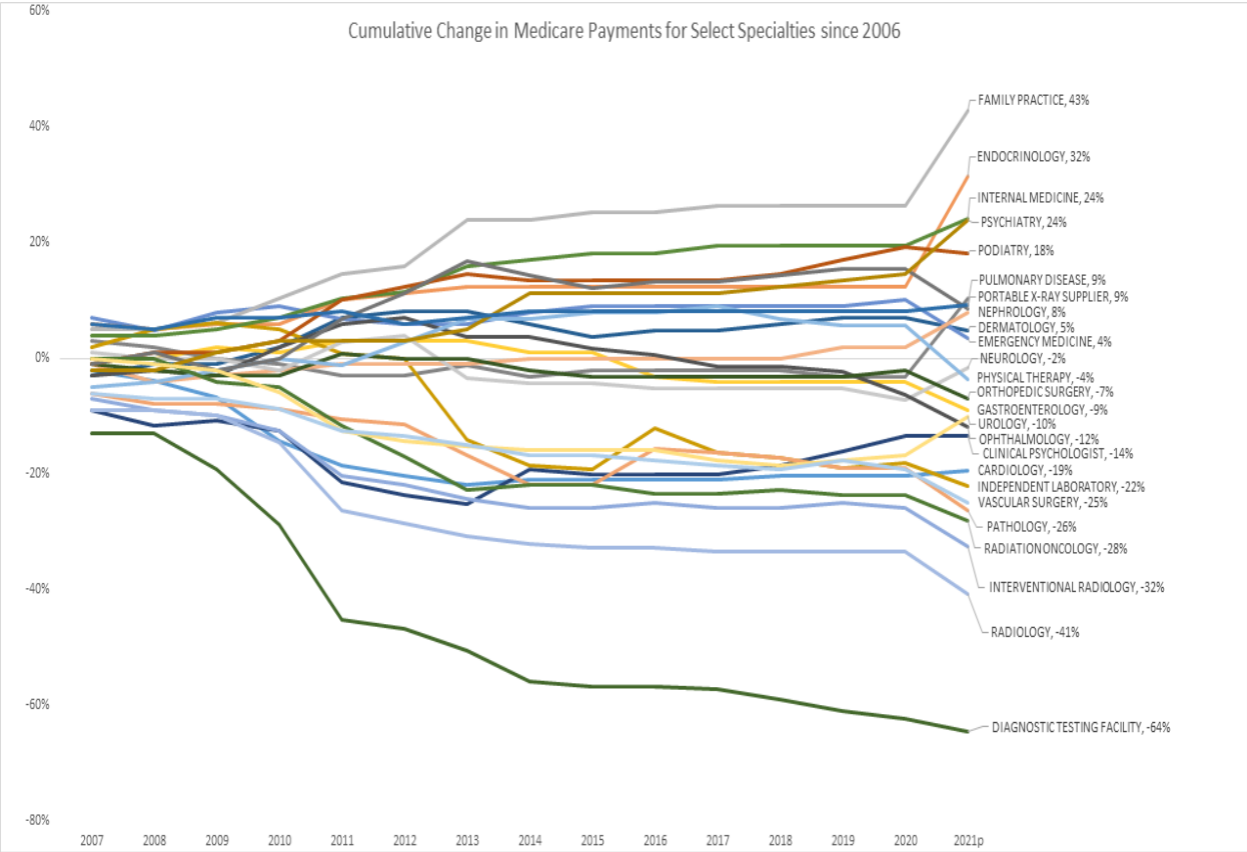
I. IMPACT OF THE PFS RULE ON OFFICE-BASED SPECIALISTS

In the CY 2020 PFS Final Rule, CMS finalized its proposal to increase payments starting in 2021 for office & outpatient E&M services (CPTs 99202-99215) in-line with recommendations from the American Medical Association (AMA) Relative Value Scale Update Committee (RUC). CMS also finalized its proposal to introduce a new add-on code (HCPCS GPC1X) for complex care associated with E&M services and adjusted "E&M-like" services codes to maintain relativity to new and existing E&M services. In large part due to these changes the 2021 PFS Proposed Rule would implement, 16 specialties would see a decrease of 7 percent or more in payments, while another 13 specialties could see an increase of 7 percent or more, **resulting in one of the most significant redistributions of Medicare physician payments ever implemented by CMS and a 10% cut to peritoneal catheter creation services as well as other significant (4 – 16%) cuts to dialysis vascular access repair services.** These cuts also would undermine a key component of the Administration's "Advancing American Kidney Health" initiative: to increase home dialysis rates across the country. Moreover, they would threaten patient access to office-based dialysis vascular access services during a pandemic and a time in which every effort should be made to keep vulnerable ESRD patients out of the hospital. Finally, DVAC notes that in August, the AMA sent a letter to the White House that "many physician practices will fail" if repayments for the Accelerated and Advance Payment Program loans are required to be paid back over the next several months. Massive cuts to office-based specialties in the PFS rule similarly will cause practices to fail.

Cumulative Impact of PFS Redistributions Since 2006

Unfortunately, this redistribution of Medicare physician payments away from certain office-based specialists is not a new occurrence. Many of these office-based specialists, particularly cardiology, pathology, physical therapy, radiation oncology, radiology, and surgery, among others, have seen significant redistributions under the PFS away from their services since 2006 with such redistributions growing over time. The chart below shows the results of PFS impact tables since 2006 with specialties highlighted that have had significant changes over the last 14

years.[2] These redistributions away from office-based specialties have amounted to approximately $10 billion.



These cumulative changes derive in large part from the outmoded "budget neutrality" provisions under Section 1848 of the Social Security Act which aims to keep spending within the Physician Fee Schedule "budget neutral" to itself. As history has shown, however, this siloed, anachronistic approach to Medicare policy ignores the effects of the volatility and sustained cuts to office-based specialists stemming from the policy. When office-based specialists are forced to close their centers and such care moves to higher cost sites-of-service, "budget neutrality" is not the outcome. **The outcome is <u>higher</u> costs to the Medicare program and its beneficiaries, upheaval to patients' healthcare continuum, and an overall diminution in patient access.**

This situation is only exacerbated by the ongoing COVID-19 pandemic. At a time when CMS has stated that dialysis vascular access is critical, such proposed cuts to dialysis vascular access are simply unconscionable. Said CMS only two months ago with respect to guidance relating to the pandemic:

[2] Health Management Associates, HMA analysis of 2006-2021 Medicare Physician Fee Schedule Proposed and Final Rule Impact Tables.

- "CMS previously released guidance to defer nonessential planned surgical procedures. Following the release of this guidance, we have received feedback that providers are experiencing difficulties scheduling for placement or repair of Arteriovenous Fistulas, Arteriovenous Grafts, and Peritoneal Dialysis catheters. We wish to clarify that these planned procedures are essential in that establishing vascular access is crucial for End Stage Renal Disease (ESRD) patients to receive their life-sustaining dialysis treatments. Without this, temporary access would be established using catheters, which pose a significantly higher risk of infection, morbidity and mortality."[3]

RECOMMENDATION: DVAC urges in the strongest possible terms that CMS waive budget neutrality under the PFS for 2021 and spare vulnerable dialysis patients – and the office-based dialysis vascular access specialists who treat them – from huge cuts during a pandemic. DVAC has consistently commented since 2017 regarding ongoing payment volatility to dialysis vascular access codes. In 2017, for example, CMS cut the key dialysis vascular access code by 39%. A subsequent American Society of Diagnostic and Interventional Nephrology (ASDIN) survey 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. Additional cuts in 2021 to dialysis vascular access are unsustainable.

In addition, DVAC urges CMS to take steps to address more fundamental issues with the so-called "budget neutrality" provision in the Physician Fee Schedule. Put simply, "budget neutrality" is a misnomer, which often results in *reduced* Medicare beneficiary access to office-based specialists and can force such patients to receive necessary care at a *higher* cost site of service. While we realize that fundamental changes to budget neutrality may require Congressional intervention to allow for long-term reform, we urge the Agency to begin working now with stakeholders on options to address this issue.

II. CRITICAL NEED FOR STABILITY FOR OFFICE-BASED SPECIALTIES

In the 2021 PFS Proposed Rule, CMS indicates 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." 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 to set overall practice expenses under the Physician Fee Schedule. While such an approach could result in better price transparency and stability for office-based

[3] Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group; *Key Components for Continued COVID-19 Management for Dialysis Facilities;* 17 August 2020

stakeholders, a key consideration would be setting the percent of OPPS rates per specialty in a way that promoted the viability and stability of services in the office setting. For example, freestanding radiation oncology centers likely incur practice expenses approaching 100% of a hospital outpatient departments costs and other office-based specialties similarly use the same high-cost supplies as a hospital.

- **Use of AMA Data.** This approach appears to be favored by the AMA and would involve the use of micro-level physician data compiled through a physician survey. The previous 2007 / 2008 AMA survey resulted in drastic cuts to office-based specialties (e.g. cardiology [-13%], interventional radiology [-10%], radiation oncology [-5%]) when incorporated in the 2009 Physician Fee Schedule. Moreover, it's worth noting that these data pulled from the 2009 Physician Fee Schedule impact table likely masked an even greater negative impact on office-based specialties given that the Medicare impact tables include both office-based and hospital-based physicians. In addition, any new indirect practice expense data would be fed into CMS' complicated 19 step Practice Expense Methodology ultimately making any new rate-setting for office-based specialties based on such data a mystery beyond its ultimate impact to a given office-based specialty.
- **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 – suffers from a lack of transparency on exactly what kind of invoice data (e.g. manufacturer(s), setting, year, aggregation methodology) ultimately was used to arrive at the equipment and supply pricing currently included in the CMS database.

We believe there are two key principles to which CMS must adhere before choosing any new methodology to update the PFS practice expense methodology. **First, CMS must be transparent and provide stakeholders the tools to understand how any proposed approach to update the PFS practice expense methodology will impact reimbursement *before* implementing 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.

The second principle, which builds off the first principle, is that CMS must publicly certify that any new Agency action that results in more than a 1 percent reduction to a given office-based specialty will not result in a migration of services to a higher cost site-of-service. For years, office-based specialists have suffered under significant payment volatility under the PFS and have been forced to make perennial entreaties to the Agency and Congress that cuts to office-based specialists will cause center closures, a reduction in patient access, and likely increases to the Medicare program due to migration of services to other settings. In some

cases, the Agency and Congress have responded – after the fact – to mitigate or reverse proposed cuts. Too often, however, actual cuts, or the simple volatility caused by proposed cuts, have caused the very center closures and migration of services DVAC profoundly hopes to avoid in the future.

As noted in a 2019 American Medical Association (AMA) report, 2016 was the first year in which less than half of practicing physicians (47.1 percent) had an ownership stake in their practice and 2018 marked the first year in which there were fewer physician owners (45.9 percent) than employees (47.4 percent). The report also noted that between 2012 and 2018 the percentage of physicians in practices with 10 or fewer physicians dropped from 61.4 percent to 56.5 percent with much of that change driven by a shift away from solo practice.[4]

The COVID-19 pandemic only has accelerated these trends. An April 2020 survey by the Medical Group Management Association (MGMA) found that "a significant number of medical practices have already been forced to layoff and furlough staff in response to the financial challenges of COVID-19."[5] A more recent survey completed by The Physicians Foundation completed in August 2020, found:

- 8% of respondents have closed their practices, with more than three-quarters of this group being specialists, equating to as many as 16,000 practices nationally based on SK&A market research data.[6]

- Another 4% said they plan to close their practices within 12 months as a result of COVID-19.[7]

RECOMMENDATION: DVAC urges that any new approach by CMS to update the practice expense methodology be transparent and provide stakeholders the tools to understand – before implementation – how such changes will impact stakeholder reimbursement. Second, DVAC urges that any new significant regulatory action that by CMS that results in more than a 1 percent reduction to an office-based specialty under the Physician Fee Schedule must be accompanied by a public certification by the Agency, after consultation with affected specialties and other stakeholders, that such action will not cause a migration of services to a higher cost site-of-service.

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.

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[4] American Medical Association, *Policy Research Perspectives Updated Data on Physician Practice Arrangements: For the First Time*, Fewer Physicians are Owners Than Employees, 2019

[5] Medical Group Management Association, *Covid-19 Financial Impact on Medical Practices*, 2020

[6] American Hospital Association, *Specialist and Private Practices Take Severe Blow During Pandemic*, 2020

[7] The Physicians Foundation, *2020 Survey of America's Physicians: COVID-19 Impact Edition*, 2020

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.

pAVF Procedures (G-2170 and G-2171) in the Office Setting

DVAC notes, however, that AVF creation procedures for many patients now can be done safely and effectively outside of hospitals in "vascular access centers" that are either ASC or specially equipped physician offices. Most recently, CMS has undertaken to cover percutaneous arterio-venous fistula (AVF) creation services in the office at a carrier pricing-based level through new individual G-codes (G-2170 and G-2171). While traditionally fistulas have been created through "open surgery," which disrupts surrounding tissues, a percutaneous approach involves needle-

puncture of the skin with a specialized device so there is no need for an incision. **DVAC strongly supports coverage of pAVF in the office-based setting.**

While we are pleased that CMS agrees to maintain these codes, we are puzzled by the decision not to create certainty around them by leaving the rates at contractor pricing. We believe it is time and there is sufficient evidence for CMS to create a set fee schedule amount for these codes. Doing so will help incentivize the placement of fistulas by creating certainty and predictability. Leaving the codes to contractor discretion leads to uncertainty and confusion among providers. It is not clear how CMS setting a rate, as it does for nearly all other physicians services, places beneficiaries at risk of infection, which the preamble suggests is the reason for maintaining contractor pricing. The same standards that apply to determining when an institutional setting is required versus when an office setting is appropriate would apply regardless of whether CMS sets the rate or contractor pricing is maintained. Therefore, we encourage CMS to work with DVAC and other stakeholders to establish the appropriate national rates for these codes.

Traditional Vascular Access Creation Services in the Office Setting

In addition, for those patients who are not candidates for percutaneous AV fistula creation, open surgical AV fistula creation is necessary. The traditional surgical procedure utilizes small incisions and is similar in complexity to many other procedures safely done in an office-based setting. To be clear, AV access creation services can and are being performed safely in the office. However, an analysis of publicly available 2012 CMS payment data found that the rate of AV access creation procedures in the office is only .34% of total AV access creation procedures. This is likely due to the fact that there is a great financial disincentive that limits office-based AV fistula creations: the technical fee for such services are not covered in the office. To remove this disincentive, DVAC recommends that CMS consider adjusting the reimbursement for open surgical creations done in an office-based setting.

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.

Recommendation: DVAC strongly supports coverage of pAVF in the office-based setting and 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.

IV. HEMODIALYSIS ACCESS CREATION EPISODE-BASED MEASURE

A hemodialysis access creation procedural episode-based cost measure is included in the proposed rule for the 2020 performance period and beyond. We are concerned that some of the assigned services during the 90-day post trigger window following fistula creation or graft placement may unintentionally incentivize the clinician billing the trigger code for fistula

creation to delay indicated treatments beyond 90-days to avoid a cost penalty. Dialysis catheters have high functional failure and high infection rates, hence the goal to keep the indwell time to <90 days. A mature arteriovenous fistula is the dialysis access of choice because it has the best long-term patency and lower complication rate of any form of hemodialysis access. Nevertheless, 30-60% of created fistulas do not become usable for dialysis without subsequent intervention, which is typically a fistulagram/angioplasty procedure (CPT 36901-36902).

The suitability of a fistula for dialysis is clinically evident 30-40 days after creation and the best outcome following fistula creation is a functional fistula that results in dialysis catheter removal within 90-days or sooner. A fistula that undergoes an angioplasty procedure to facilitate dialysis and catheter removal within 90 days has a better outcome than either a fistula that is treated with an angioplasty later than 90 days before it can be used or a fistula that never develops. Under this episode-based cost measure, a surgeon would be penalized for angioplasty procedures performed within the 90-day post trigger window. This may incentivize a surgeon to delay fistula evaluation and angioplasty beyond 90 days, to delay new fistula creation beyond 90 days in the event of a creation failure, or even forego fistula creation altogether by placing a graft instead unless the patient is anatomically ideal for a fistula. These practices will decrease the prevalence of functional fistulas and prolong catheter indwell times which will increase catheter-related complications including infections. Mortality is highest for incident dialysis patients during the first 90 days, in part due to catheter use. As a result, the National Quality Forum decided that 90-day catheter rates should be a quality measure for QIP and five-star ratings for dialysis clinics. Introducing financial incentives to surgeons to delay interventions during the first 90 days post fistula creation will have the unintended consequence of increasing patient mortality.

We understand that under MIPS, providers will be measured under performance categories including quality, promoting interoperability, and cost. By tying the measurement of quality to cost efficient care, the MIPS program seeks to counterbalance important concerns about quality of care that may result from implementation of cost measures. Most clinicians performing HD Access Creation trigger code procedures are not the providers that will be affected by the MIPS quality measures, so our concerns about delaying angioplasties, new fistula creation or primary graft placement and the effect on the overall quality will not be addressed. We therefore believe that an angioplasty within the 90-day post trigger window after fistula creation should not be a cost assigned to the triggering clinician.

Recommendation. In 2019, as part of its comments to the 2020 PFS Proposed Rule, DVAC urged that a fistulagram/angioplasty procedure (CPT 36901-36902) within the 90-day post trigger window after fistula creation not be a cost assigned to the triggering clinician as part of the hemodialysis access creation episode. While we do not see any changes proposed to the 2021 cost measure, we hope to follow-up with CMS in the months ahead to revisit this issue.

V. COLLECTION OF CLINICAL LABOR DATA

In the 2021 PFS Proposed Rule, CMS notes that "[S]takeholders have expressed an interest in updating the clinical labor data that we use for direct PE inputs based on current salaries and compensation for the health care workforce. We are soliciting comment regarding how we might update the clinical labor data. Historically, we have used data from the Bureau of Labor Statistics and are seeking comment to determine if this is the best data source or if there is an alternative … Stakeholders are encouraged to submit feedback as part of their public comments or, if outside the public comment process, via email at PE_Price_Input_Update@cms.hhs.gov ."

As part of our ongoing discussions with CMS, DVAC collected clinical labor data and provided it to CMS as part of our comment to the 2019 PFS Proposed Rule 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. 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

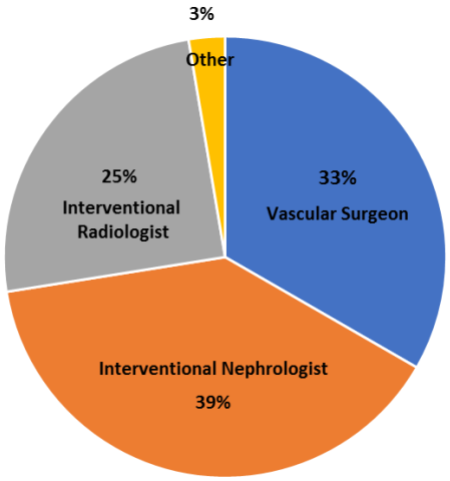
Recommendation: We ask that CMS continue its efforts to properly value vascular access services in the physician office setting, particularly through the acceptance, as appropriate, of industry-provided practice expense data.

VI. MIPS VALUE PATHWAYS

In the 2020 PFS, CMS finalized its intention to transform the Merit-based Incentive Payment System (MIPS) into a new MIPS Value Pathway (MVP) framework. Among other things, MVPs "would create a cohesive and meaningful participation experience for clinicians by moving away from siloed activities and measures and towards an aligned set of measures that are more relevant to a clinician's scope of practice." CMS also noted that it had received feedback

from stakeholders that "it is difficult for them to choose measures that are meaningful to their practice and have a direct benefit to beneficiaries."

CMS specifically requested comment on whether MVPs should be organized around "areas of practice." DVAC continues to believe such a reporting structure should be available for clinicians treating patients in centers of excellence such as dialysis vascular access centers of excellence where the majority of treatments relate to providing vascular access services to dialysis patients. As shown in the chart below, specialties treating at vascular access centers are split relatively evenly among interventional nephrologists, interventional radiologists, and vascular surgeons. It is likely that any specialty specific MVP option for one of these specialties would not contain the set of outcomes-based measures that would best meet the needs of dialysis patients served at vascular access centers of excellence.



While CMS intended to begin transitioning to MVPs during the 2021 performance year, in the 2021 PFS Proposed Rule, the agency notes its intention to delay this until at least 2022 in response to the COVID-19 pandemic. Regardless, CMS' first guiding principle for MVPs is that they should "consist of limited, connected complementary sets of measures and activities that are *meaningful* to clinicians…" In that light, DVAC would support MVP categories including "dialysis vascular access" and would look forward to working with CMS on appropriate quality measures, cost measures, and improvement activities for such an area of practice.

Recommendation. DVAC would support MVP categories including "dialysis vascular access" and would look forward to working with CMS on appropriate quality measures, cost measures, and improvement activities for such an area of practice.

CONCLUSION

DVAC's comments on the CY 2021 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 and (2)

further the important work of the Administration's "Advancing American Kidney Health" initiative, particularly as it relates to vital vascular access services for ESRD patients. 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 .

APPENDIX

VAC Outcomes

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[8] found, in 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, and
- Fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD.

Non-hospital VACs are also patient-preferred. A 2019 survey by Dialysis Patient Citizen (DPC) indicates a clear preference for vascular access services in the non-hospital setting vs. a hospital setting. The survey found the following:

- Dialysis patients prefer vascular access care in a non-hospital setting (49% to 36%), and
- Dialysis patients prefer one site-of-service for all vascular access services (87%). [9]

VAC Code Compare of Dialysis Vascular Access Repair Codes

HCPCS	2021 Physician Office Global (Proposed) *	2021 HOPD Global (Proposed) ǂ	2021 ASC Global (Proposed) ¥	Office as % of HOPD	Office as a % of ASC
36901	$711	$1,562	$704	46%	101%
36902	$1,281	$5,274	$2,391	24%	54%
36903	$4,897	$10,518	$6,822	47%	72%
36904	$1,882	$5,394	$3,271	35%	58%
36905	$2,413	$10,639	$4,689	23%	51%
36906	$6,130	$16,828	$11,248	36%	54%
36907	$653	NA	NA	NA	NA
36908	$1,801	NA	NA	NA	NA
36909	$2,047	NA	NA	NA	NA
**Physician Fee Schedule Nonfacility Total*					
ǂHospital Outpatient PPS Payment Rate + PFS Facility Total					
¥Ambulatory Surgical Center PPS Payment Rate + PFS Facility Total					
Note: 36907-36909 are add-on codes used in conjunction with 36901, 36902					

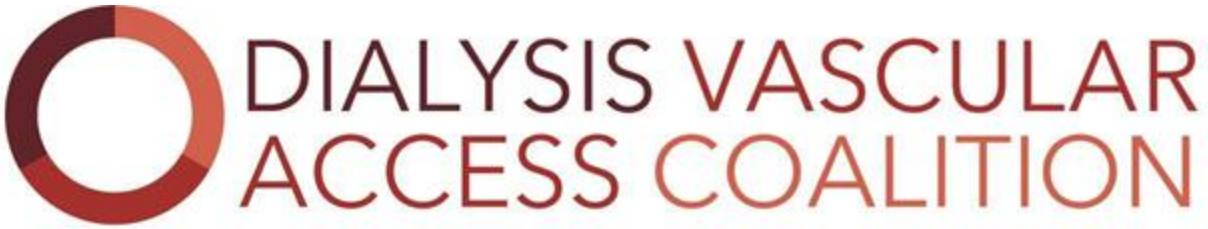
[8] El-Gamil, Audrey et al., What is the best setting for receiving dialysis vascular access repair and maintenance services?, September 2, 2017

[9] Kynetec, Dialysis Patient Citizen (DPC) – 2019 Survey, September 2019

VAC Code Compare of Dialysis Vascular Access PD Catheter Code

HCPCS	2021 Physician Office Global (Final) *	2021 HOPD Global (Final) ǂ	2021 ASC Global (Final) ¥	Office as % of HOPD	Office as % of ASC
49418	$1,103	$3,436	$1,602	32%	69%
**Physician Fee Schedule Nonfacility Total*					
ǂHospital Outpatient PPS Payment Rate + PFS Facility Total					
¥Ambulatory Surgical Center PPS Payment Rate + PFS Facility Total					

ATTACHMENT –
DVAC COMMENT TO THE
2021 ASC FEE SCHEDULE
PROPOSED RULE



October 5, 2020

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

The Honorable Seema Verma Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1736–P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2021 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule

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 2021 Ambulatory Surgical Center Fee Schedule Proposed Rule (CMS-1736-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 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, San Antonio Kidney Disease Center, and Vascular Access Centers. 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

[1] Federal Register, 85 FR 48772 (August 12, 2020)

access centers provide placement services for peritoneal dialysis (PD) catheters (special tubes inserted in a patient's abdominal cavity to allow for home dialysis). In other words, non-hospital VACs are a cornerstone of the Administration's efforts to advance American kidney health.

DVAC appreciates this opportunity to comment on the proposed regulation.

This letter offers comments and recommendations on the following issues:

- CMS Exception for Vascular Access from Office-Based Designation
- Maintaining Integrity of Current APCs
- Change in APC for G2170
- Creation and PD Catheter Placement Services in Non-Hospital VACs
- CMS Should Calculate ASC Device-Intensive Outside of C-APC Method

I. CMS EXCEPTION FOR VASCULAR ACCESS FROM OFFICE-BASED DESIGNATION

Background

As noted in our comment to the CY 2020 Physician Fee Schedule Proposed Rule, the reduction to the key vascular access code (36902) in 2017 was 39% and resulted in significant center closures in the non-hospital setting. Since the release of the 2017 ASC Final Rule, reimbursement for vascular access preservation codes (36901 – 36909) in the ASC setting also had undergone several important changes to status indicators which are largely responsible for the significant payment volatility between 2018 and 2019 proposed and final ASC reimbursement rates. These changes – relating to office-based designations and device-intensive classifications – have resulted in variability to vascular access preservation codes of roughly 62% (office-based designations) and 20% (device-intensive classifications).

In particular, in the CY 2019 ASC Proposed Rule, CMS noted it was reducing the reimbursement rate for 36902 and 36905 due to the office-based designation.[2] This proposal would have resulted in significant cuts to 36902 and 36905 as well as huge differentials between the hospital and non-hospital reimbursement rates, as shown in the table below.

Codes	2017 ASC Final Rule	2019 Proposed Rule	Percent Change 2017 to 2019
36901	$370 (P2)	$532.59 (P3)	44%
36902	$2,983 (J8)	$1,125 (P3)	-62%
36903	$5,653 (J8)	$6,082 (J8)	8%
36904	$2,983 (J8)	$2,719 (J8)	-9%
36905	$5,653 (J8)	$2,080 (P3)	-63%
36906	$8,850 (J8)	$9,835 (J8)	11%
36907	N1	N1	NA

[2] 83 FR 37155

36908	N1	N1	NA
36909	N1	N1	NA

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

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

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

P3 = Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs..

N1 = Packaged service/item; no separate payment made.

DVAC noted for the 2019 ASC Proposed Rule that non-hospital vascular access centers already were closing and that CMS' proposed office-based designation would (1) incentivize inappropriate migration of services from the non-hospital setting to the hospital setting, (2) increase the site-of-service reimbursement differential to the detriment of ESRD patient outcomes, and (3) mean significant increases in spending for vascular access services under the Medicare program as well as higher copayments for ESRD patients. We also noted that in the case of vascular access preservation add-on codes (36907 – 36909) that the interaction of the office-based policy with packaging policies in the ASC fee schedule would have resulted in reimbursement rates for many complex procedures actually being paid less in the ASC than the office. DVAC noted as well that there was precedent for CMS not implementing the office-based policy for vascular access services given 2011/2012 CMS rulemaking that exempted nuclear medicine and radiology services from the office-based designation due to equivalent concerns with the interaction of the office-based policy with ASC packaging policies.

2021 ASC Proposed Rule exempts 36902 and 36905 from office-based designation

In the 2021 ASC Proposed Rule, CMS notes the following regarding 36902 and 36905:

- **36902.** For this CY 2021 OPPS/ASC proposed rule, we reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019.
- **36905.** Similarly, CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices. Therefore, we are not proposing to designate CPT codes 36902 and 36905 as office-based procedures for CY 2021.

DVAC strongly supports CMS' decision to exempt 36902 and 36905 from the office-based designation and thanks the Agency for its determination.

We note as well that CMS is seeking comment on whether the Agency might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking. DVAC continues to believe that packaging in the ASC setting is an imperfect policy that can discourage the utilization of necessary add-on services for complex cases. Moreover, we continue to believe that the combination of (1) packaging in the ASC and (2) the office-based designation can result

in payment anomalies (as has been evidenced already by the 36901 – 36909 code family) whereby the office rates for services pay higher in the office than in the ASC setting. While we believe that the precedent of nuclear medicine and radiology services provides a precedent to exempt permanently the 39061 – 36909 family of codes, we also note that the issue now is moot for these services given the data highlighted by CMS. At the same time, DVAC looks forward to working with the Agency to explore other ways that packaging policies may be improved upon in the ASC Fee Schedule to promote optimal patient care for dialysis vascular access and other services under the Medicare program.

Recommendation: We strongly support CMS' proposal to exempt 36902 and 36905 from the office-based designation under 42 CFR 416.171(d).

II. MAINTAINING INTEGRITY OF CURRENT APCs

In the 2021 ASC Proposed Rule, CMS notes its intention to substantially add to the list of ASC covered procedures in two key ways. First, CMS proposes to eliminate the Inpatient Only (IPO) list, which lists procedures that are typically only provided in the inpatient setting, over a three-year transitional period with the list completely phased out by CY 2024. Second, CMS proposes to add 11 procedures to the ASC-covered procedures list (ASC-CPL), a list of procedures eligible for coverage and payment when furnished in an ASC. In addition, CMS proposes two alternatives to the ASC-CPL to further expand services payable in ASCs. CMS estimates 270 additional procedures would be added to the ASC covered procedures list in CY 2021.

CMS requests comment on the transition away from the IPO list as well as the proposals to further expand the ASC-CPL list. Regardless of what method CMS may choose to include in the ASC-CPL, DVAC is very concerned that CMS strive to maintain the integrity of current APCs. Shifts in APCs for key services can be result in huge swings in reimbursement and jeopardize patient access to care. This is particularly true for ASC centers of excellence, such as vascular access centers, which focus on a narrower set of services in order to optimize patient outcomes. In that light, DVAC urges that CMS create new APCs for the large list of services that the Agency plans to onboard to the ASC Fee Schedule over the next several years. Rates for the APCs can be derived directly from hospital fee schedules from which they originate. We believe such an approach would accomplish the dual goals of bringing new services to the ASC Fee Schedule even as the Agency strives to maintain payment stability for services currently being paid under the ASC Fee Schedule.

Recommendation: In order to maintain the integrity of current APCs in the ASC Fee Schedule, we recommend CMS (1) create new APCs for the large list of services that the Agency plans to onboard to the ASC Fee Schedule over the next several years and (2) derive rates for those APCs directly from hospital fee schedules from which they originate.

III. CHANGE IN APC FOR G2170

In the Proposed Rule, CMS proposes to reassign HCPCS code G2170, used for percutaneous creation of an AVF using the Ellipsys, to APC 5193, Level 3 Endovascular Procedures, while leaving G2171, for the WavelinQ procedure, in APC 5194, Level 4 Endovascular Procedures.

We urge CMS not to finalize its proposal to reassign code G2170, for percutaneous creation of percutaneous AFVs with thermal resistance energy, from APC 5194 to APC 5193. Maintaining the current assignment would result in adequate payment for facility expenses in both HOPDs and ASCs when using Ellipsys. The small number of claims, drawn from a single year, does not provide a reliable basis for making the change, and we urge CMS to maintain the current APC assignments until more adequate data can be brought to bear.

Recommendation: We urge CMS to maintain the current APC assignment for G2170 until more adequate data can be gathered for appropriate APC placement.

IV. CREATION / PD CATHETER PLACEMENT SERVICES IN NON-HOSPITAL VACs

Background

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 to promote the use of fistulas. Concurrent with the initiative, vascular access preservation services migrated to the lower cost, superior outcome non-hospital sites-of-service where fistulas are a key focus of these centers of excellence. As a result, fistula use is now well over 60% in the prevalent population.[3]

The success of the Fistula First initiative helps to highlight two important policy matters. First, the initiative underscores the need to secure the gains of Fistula First by maintaining the viability of non-hospital vascular access centers (by, among other things, not implementing the office-based policy for ***preservation*** services). Second, the initiative helps to highlight other areas where ESRD patients would be well-served by the migration of other important dialysis access services from the hospital to the non-hospital setting. These services include vascular access ***creation*** services and ***PD catheter placement services***.

Vascular Access Creation Services

Like preservation services, creation services in the non-hospital setting are significantly less costly than the HOPD. Since creation services are not payable in the office setting, the ASC is the only non-hospital site-of-service available for comprehensive vascular access services (including both creation and preservation services). It's notable, however, that the vast majority of creation services are still provided in the hospital, rather than the ASC setting. According to a 2019 Braid Forbes Health Research analysis, only 3% of vascular access creation services (36818, 36819, 36820, 36821, 36825, 36830) are done in the non-hospital setting. In this light, we believe that CMS and the vascular access sector can do for ***creation*** services what we were able to do for ***preservation*** services. That is to say, the migration of vascular access creation services to the ASC setting will strengthen comprehensive ASC vascular access centers of excellence, improve patient outcomes, and save the Medicare program and ESRD patients money. A 2019 DVAC industry analysis found that Medicare could save up to $500 million

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

over 10 years if only half of vascular access creation services moved from the hospital outpatient to the ASC setting.

Current Medicare Volume and Spend for Vascular Access Creation Services (2019)					
	HOPD		**ASC**		**Combined HOPD / ASC Spend**
CPT	**Volume**	**2019 Spend**	**Volume**	**2019 Spend**	
36818	5222	$22,854,187	232	$521,654	
36819	7779	$34,044,949	214	$481,181	
36820	1472	$6,442,237	182	$409,229	
36821	28693	$75,793,133	873	$1,140,217	
36825	2010	$8,796,805	75	$168,638	
36830	18827	$82,396,742	350	$786,979	
Total		**$230,328,055**		**$3,507,898**	**$233,835,952**

Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting					
	HOPD		**ASC**		**Combined HOPD / ASC Spend**
CPT	**Volume**	**2019 Spend**	**Volume**	**2019 Spend**	
36818	2611	$11,427,094	2843	$6,392,514	
36819	3889.5	$17,022,475	4103.5	$9,267,234	
36820	736	$3,221,119	918	$2,176,558	
36821	14346.5	$37,896,567	15219.5	$19,259,475	
36825	1005	$4,398,403	1080	$2,781,407	
36830	9413.5	$41,198,371	9763.5	$21,688,003	
Total		**$115,164,027**		**$61,565,190**	**$176,729,217**
Total Savings Potential Per Year					***$57,106,735***

PD Catheter Placements

A key component of the Administration's "Advancing American Kidney Health" initiative is to increase home dialysis rates across the country. Much as creating and preserving the best vascular accesses are critical to optimal in-center dialysis, the creation and preservation of the best PD catheters are critical to optimal home dialysis. Here again we note, however, that most

PD catheter placements services are still done in the hospital outpatient setting. According to a 2019 analysis by the Moran Company, only 6% of PD catheter placements (49418, 49421, 49324) are done in the non-hospital setting. In the case of PD catheter placements, a 2019 DVAC industry analysis found Medicare could save up to $130 million over 10 years if only half of PD catheter placement services moved from the hospital to the ASC setting.

Current Medicare Volume and Spend for PD Catheter Services (2019)					
	HOPD		**ASC**		**Combined HOPD / ASC Spend**
CPT	**Volume**	**2019 Spend**	**Volume**	**2019 Spend**	
49324	1472	$7,224,591	182	$399,459.06	
49418	5222	$16,439,430	232	$319,025.52	
49421	7779	$24,489,148	214	$294,273.54	
Total		**$48,153,169**		**$1,012,758**	**$49,165,927**

Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting					
	HOPD		ASC		**Combined HOPD / ASC Spend**
CPT	Volume	2019 Spend	Volume	2019 Spend	
49324	736	$3,612,295	918	$2,014,854	
49418	2611	$8,219,715	2843	$3,909,438	
49421	3889.5	$12,244,574	4103.5	$5,642,764	
Total		**$24,076,584**		**$11,567,056**	**$35,643,640**
Total Savings Potential Per Year					***$13,522,287***

Recommendation: We urge CMS to support policies which encourage the appropriate migration of vascular access creation services and PD catheter placement services to the more cost-effective and patient preferred non-hospital (ASC and office) settings.

V. CMS SHOULD CALCULATE ASC DEVICE-INTENSIVE OUTSIDE OF C-APC METHOD

As CMS is aware, the OPPS/ASC rule calculates the device proportion of a service in two ways. The first way is by using the comprehensive APC payment rates to develop the "device offset" amount reflected in "Addendum P" of the OPPS Proposed Rule. The second way CMS calculates the device proportion relates to the way CMS actually calculates ASC payment rates. While CMS does not provide an addendum to reflect this, the calculation is as follows:

- A. Geometric mean cost (traditional method)
- B. Geometric mean cost (traditional method) – without device costs
- C. Device cost (difference of A and B)
- **Device proportion = (C / A)**

Because the above calculation is part of the larger calculation used to set payment rates for the ASC, we believe it is entirely appropriate that CMS use the above calculation to calculate the device proportion to establish device-intensive status for services in the ASC. Furthermore, we note that this would establish consistency with the way that CMS determines the no cost/full credit and partial credit amounts for ASC procedures (i.e. which uses the traditional approach and utilizes non-comprehensive APC inputs). Under the traditional method, DVAC believes key vascular access codes would be less likely to be subject to payment anomalies, such as the 2019 anomaly by which CMS proposed to pay 36904 ($2,719) significantly more than 36905 ($2,080) under the ASC fee schedule even though 36905 is the more complex procedure.[4]

Recommendation: We urge CMS to utilize the traditional (without comprehensive) methodology to calculate the device percentage for purposes of designating device intensive status in the ASC reimbursement system as it is more consistent with the overall payment system of the ASC.

Conclusion

DVAC's comments on the CY 2021 ASC 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 and (2) further the important work of the Administration's "Advancing American Kidney Health" initiative, particularly as it relates to vital vascular access services for ESRD patients. 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 .

[4] The AMA's "CPT, 2018 Professional" describes 36905 as follows: "Code 36905 includes the services in 36904 *plus* transluminal balloon angioplasty in the peripheral segment of the dialysis circuit."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