September 27, 2019

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

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1717–P
7500 Security Boulevard
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS- 1717-P)

Dear Administrator Verma:

The Dialysis Vascular Access Coalition (DVAC) appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule with comment for the CY 2020 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (CMS- 1717-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, Azura Vascular Care, Balboa Nephrology Medical Group, Dallas Nephrology Associates, Dialysis Access Specialists, Lifeline Vascular Care, Northwest Renal Clinic, San Antonio Kidney Disease Center, and Vascular Access Centers. DVAC represents the majority of the non-hospital vascular access sector.

This letter offers comments and recommendations on the following issues:

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

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1 Federal Register, 84 FR 39398 (August 9, 2019)
CMS EXCEPTION FOR VASCULAR ACCESS FROM OFFICE-BASED DESIGNATION

Background

As noted in our comment to the CY 2020 Physician Fee Schedule Proposed Rule (attached as an addendum), 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 has 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. 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.

<table>
<thead>
<tr>
<th>Codes</th>
<th>2017 ASC Final Rule</th>
<th>2019 Proposed Rule</th>
<th>Percent Change 2017 to 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>36901</td>
<td>$370 (P2)</td>
<td>$532.59 (P3)</td>
<td>44%</td>
</tr>
<tr>
<td>36902</td>
<td>$2,983 (J8)</td>
<td>$1,125 (P3)</td>
<td>-62%</td>
</tr>
<tr>
<td>36903</td>
<td>$5,653 (J8)</td>
<td>$6,082 (J8)</td>
<td>8%</td>
</tr>
<tr>
<td>36904</td>
<td>$2,983 (J8)</td>
<td>$2,719 (J8)</td>
<td>-9%</td>
</tr>
<tr>
<td>36905</td>
<td>$5,653 (J8)</td>
<td>$2,080 (P3)</td>
<td>-63%</td>
</tr>
<tr>
<td>36906</td>
<td>$8,850 (J8)</td>
<td>$9,835 (J8)</td>
<td>11%</td>
</tr>
<tr>
<td>36907</td>
<td>N1</td>
<td>N1</td>
<td>NA</td>
</tr>
<tr>
<td>36908</td>
<td>N1</td>
<td>N1</td>
<td>NA</td>
</tr>
<tr>
<td>36909</td>
<td>N1</td>
<td>N1</td>
<td>NA</td>
</tr>
</tbody>
</table>

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

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2 83 FR 37155
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.

2020 ASC Proposed Rule exempts 36902 and 36905 from office-based designation

In the 2020 ASC Proposed Rule, CMS notes the following regarding 36902 and 36905:

- 36902. “In reviewing the CY 2018 volume and utilization data for CPT code 36902 we determined that the procedure was performed more than 50 percent of the time in physicians’ offices based on 2018 volume and utilization data. However, the office-based utilization for CPT code 36902 has fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs – from approximately 14,000 in 2017 to 38,000 in 2018. As previously stated in the CY 2019 OPPS/ASC final rule (83 FR 59036), when we believe that the available data for our review process are inadequate to make a determination that a procedure should be office-based, we either make no change to the procedure’s payment status or make the change on a temporary basis, and reevaluate our decision when more data become available for our next evaluation. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believe it may be premature to assign office-based payment status to CPT code 36902 at this time.”

- 36905. “The CY 2018 volume and utilization data for CPT code 36905 show the procedure was not performed more than 50 percent of the time in physicians’ offices. Therefore, we are not considering assigning an office-based designation for CPT code 36905 and the procedure will retain its payment indicator of “G2” – non office-based surgical procedure based on OPPS relative weights.”

We are grateful for CMS’ determinations on 36902 and 36905 and note that these approaches are consistent with several stakeholder comments made as part of the implementing regulations to the office-based designation policy that a more prudent approach to the office-based designation is for CMS to “follow trends in the sites of service for office-based procedures, and should CMS find significant and unwarranted migration of certain procedures to ASCs, implement the proposed policy at a later date.”

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

CREATION AND 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.

3 72 FR 42511
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.⁴

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

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>HOPD Volume</td>
<td>2019 Spend</td>
<td>ASC Volume</td>
<td>2019 Spend</td>
<td>Combined HOPD / ASC Spend</td>
<td></td>
</tr>
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<td></td>
</tr>
<tr>
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<td></td>
<td></td>
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<tr>
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<tr>
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<td>$6,442,237</td>
<td>182</td>
<td>$409,229</td>
<td></td>
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<tr>
<td>36821</td>
<td>28693</td>
<td>$75,793,133</td>
<td>873</td>
<td>$1,140,217</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36825</td>
<td>2010</td>
<td>$8,796,805</td>
<td>75</td>
<td>$168,638</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36830</td>
<td>18827</td>
<td>$82,396,742</td>
<td>350</td>
<td>$786,979</td>
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</tr>
<tr>
<td>Total</td>
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<td></td>
<td>$3,507,898</td>
<td></td>
<td>$233,835,952</td>
<td></td>
</tr>
</tbody>
</table>

<p>| Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting |
|-----------------------------------|-----|-------|--------|-------|-------|-----|</p>
<table>
<thead>
<tr>
<th>CPT</th>
<th>HOPD Volume</th>
<th>2019 Spend</th>
<th>ASC Volume</th>
<th>2019 Spend</th>
<th>Combined HOPD / ASC Spend</th>
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<td>2843</td>
<td>$6,392,514</td>
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<tr>
<td>36819</td>
<td>3889.5</td>
<td>$17,022,475</td>
<td>4103.5</td>
<td>$9,267,234</td>
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</table>

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.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Volume</th>
<th>2019 Spend</th>
<th>Volume</th>
<th>2019 Spend</th>
<th>Combined HOPD / ASC Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>49324</td>
<td>1472</td>
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<td>182</td>
<td>$399,459</td>
<td></td>
</tr>
<tr>
<td>49418</td>
<td>5222</td>
<td>$16,439,430</td>
<td>232</td>
<td>$319,025</td>
<td></td>
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<tr>
<td>49421</td>
<td>7779</td>
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<td>214</td>
<td>$294,273</td>
<td></td>
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<tr>
<td>Total</td>
<td></td>
<td>$48,153,169</td>
<td></td>
<td>$1,012,758</td>
<td>$49,165,927</td>
</tr>
</tbody>
</table>

Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting

<table>
<thead>
<tr>
<th>CPT</th>
<th>Volume</th>
<th>2019 Spend</th>
<th>Volume</th>
<th>2019 Spend</th>
<th>Combined HOPD / ASC Spend</th>
</tr>
</thead>
<tbody>
<tr>
<td>49324</td>
<td>736</td>
<td>$3,612,295</td>
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<td>$2,014,854</td>
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<td>49418</td>
<td>2611</td>
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<td>$12,244,574</td>
<td>4103.5</td>
<td>$5,642,764</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>$24,076,584</td>
<td></td>
<td>$11,567,056</td>
<td>$35,643,640</td>
</tr>
</tbody>
</table>

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.

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.5

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 2020 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.

5 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.”
ATTACHMENT –
DVAC COMMENT TO THE
2020 PHYSICIAN FEE SCHEDULE
PROPOSED RULE
September 27, 2019

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

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS – 1715– P
7500 Security Boulevard
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

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 2020 Physician Fee Schedule (CMS-1715-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, Azura Vascular Care, Balboa Nephrology Medical Group, Dallas Nephrology Associates, Dialysis Access Specialists, Lifeline Vascular Care, Northwest Renal Clinic, San Antonio Kidney Disease Center, and Vascular Access Centers. DVAC represents the majority of the non-hospital vascular access sector.

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

- Importance of Payment Stability for Vascular Access in the Office
- 49418 (Insertion of tunneled intraperitoneal catheter)
- E&M Changes in 2021
- Hemodialysis Access Creation Episode-Based Measure
- MIPS Value Pathways

1 Federal Register, 84 FR 40482 (August 14, 2019)
Background

As part of the Administration’s “Advancing American Kidney Health” initiative the U.S. Department of Health and Human Services (HHS) announced its vision for advancing kidney health to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and most importantly, live. The critical importance of vascular access is highlighted in the HHS report’s key findings that “infectious complications (vascular access infection, septicemia) are the most common causes of hospitalizations after the start of hemodialysis.” The report also notes that an “optimal start” reflects, among other things, initiation of hemodialysis with a functioning permanent vascular access.

Non-hospital vascular access centers (VACs) provide these 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.

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

<table>
<thead>
<tr>
<th>Sites-of-Service for Dialysis Vascular Access Services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Setting</strong></td>
</tr>
</tbody>
</table>
| 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.

Studies have shown that dedicated access centers like those operated by DVAC members provide higher quality care to Medicare beneficiaries at a lower cost than hospital outpatient departments. The largest and most rigorous study of vascular access care across sites found, 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 sepsis-related and unrelated hospitalizations than those treated in the HOPD.3

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%).4

2020 PFS Proposed Rule provides relative payment stability for vascular access services

Effective January 1, 2017, CPT established nine new bundled codes (36901 - 36909) to describe dialysis vascular access preservation services that were previously reported under separate codes. This new code set contained critical flaws, evidenced by the fact that the most common code, 36902, which is used more than 50% of the time, was cut by 39% from 2016 to 2017. An American Society of Diagnostic and Interventional Nephrology (ASDIN) survey in 2017 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. In August 2018, ASDIN updated this survey and found similar results.

The DVACs comments over the last two years have expressed ongoing concern that the Physician Fee Schedule continues to undervalue work RVUs and practice expense RVUs. In the case of work RVUs, the DVAC raised concerns regarding more appropriate crosswalks for services to better reflect the patient (i.e. a patient with a severe disease undergoing a non-elective procedure) as well as the service itself (i.e. involving a high flow artery rather than a GI procedure).5 In the case of practice expense RVUs, we urged CMS to use the industry supply quantity data collected by the DVAC to correct current inputs in the CMS database and to update clinical labor cost data

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3 El-Gamil, Audrey et al., What is the best setting for receiving dialysis vascular access repair and maintenance services?, September 2, 2017
4 Kynetec, Dialysis Patient Citizen (DPC) – 2019 Survey, September 2019
5 For example, to determine the work RVU for 36902, the RUC compared the code to 43253, an esophagogastroduodenoscopy procedure, rather than specialty recommended revascularization procedures. https://www.ama-assn.org/sites/default/files/media-browser/february-2016-ruc-recommendations.pdf
which currently undervalues clinical labor costs for vascular access services.

Significant payment disparities between sites-of-service for vascular access services also are evident (see appendix). Continued closures of non-hospital vascular access centers and migration of services to the HOPD setting would mean significant increases in Medicare spending for vascular access services as well as higher copayments for ESRD patients. Given aforementioned concerns, DVAC greatly appreciates CMS providing and proposing relative payment stability for vascular access services in 2019 and 2020 in the physician office setting.

II. 49418 (INSERTION OF TUNNELED INTRAPERITONEAL CATHETER)

As noted above, a key component of the Administration’s “Advancing American Kidney Health” initiative is to increase home dialysis rates across the country. The Administration has stated that an “optimal start” to dialysis includes initiation of renal replacement with peritoneal dialysis, which is a common home dialysis treatment option. Peritoneal dialysis (PD) uses the lining of the abdomen to remove waste from the blood through a solution known as dialysate. If the patient is appropriate for PD, there are several advantages, including patients living more independently with better health outcomes as PD better preserves remaining kidney function.6

Of course, critical to PD services is the placement of a PD catheter. In the office setting, this service is performed by VACs under the code 49418. Unfortunately, under the 2020 PFS Proposed Rule, CMS is proposing to reduce reimbursement for 49418 by 6 percent due to changes in equipment and supply pricing initiated by the 2019 StrategyGen review. Because those changes are implemented over a four-year period (2019 – 2022), we expect further significant reductions to 49418 through 2022 (in addition to the proposed cut to 49418 for 2020). Such reductions are likely to discourage the placement of PD catheters in the office setting and result in (1) slower adoption of PD services at home and (2) slower migration of PD catheter placement services from the more expensive hospital setting to the more cost-effective non-hospital (office or ASC) setting.

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

III. E&M CHANGES IN 2021

In the proposed rule, CMS proposes to implement E/M office visit coding changes with the framework adopted by the AMA CPT Editorial Panel. The policy changes for the E/M office visits would be effective for services starting January 1, 2021. The CPT coding changes will retain 5 levels of coding for established patients, reduce the number of levels to 4 for new patients (by deleting 99201), and revise the code definitions and guidelines. A new CPT code for extended office visit time will also be implemented. Based on the information provided in the proposed rule, these proposals contribute to a 5-6% redistribution between those physicians who routinely provide office visits and those physicians or other health care professionals who do not report office visits. DVAC believes this is a significant reduction to absorb into practices and urges CMS and the Congress to implement positive updates to the Medicare conversion factor to offset these increases.

Proposed Add-On Code GPC1X

In addition to the above proposals, CMS proposes to implement an add-on code for E/M office visits describing the complexity associated with visits that serve as a focal point for all medical

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Recommendation: Given the redistribution to primary care already to occur from proposed increases to E&M and the fact that we believe the proposed code GPC1X not to be well defined, we urge CMS to postpone the implementation of the GPC1X add-on code. We also urge CMS and the Congress to implement positive updates to the Medicare conversion factor to offset cuts to non-E&M services as a result of increases to E&M services and the budget neutral nature of the Physician Fee Schedule.

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: We urge 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.

V. MIPS VALUE PATHWAYS

In the proposed rule, CMS notes its intention to transform the Merit-based Incentive Payment System (MIPS) into a new MIPS Value Pathway (MVP) framework. CMS is proposing to apply the new MVP framework to future rulemaking beginning with the 2021 MIPS Performance Year. 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 notes that it has 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 requests comment on whether MVPs should be organized around “areas of practice.” DVAC believes 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.

In that light, DVAC would support MVP categories including “areas of practice” to include “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: We support MVP categories including “areas of practice” to include “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 2020 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.
### APPENDIX

#### VASCULAR ACCESS PRESERVATION SERVICES

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>2020 Physician Office Global (Proposed)</th>
<th>2020 HOPD Global (Proposed)</th>
<th>2020 ASC Global (Proposed)</th>
<th>Office as % of HOPD</th>
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*Physician Fee Schedule Nonfacility Total
H*Hospital 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, 36903, 36904, 36905, 36906

#### VASCULAR ACCESS CREATION SERVICES

<table>
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<tr>
<th>HCPCS</th>
<th>2020 Physician Office Global (Proposed)</th>
<th>2020 HOPD Global (Proposed)</th>
<th>2020 ASC Global (Proposed)</th>
<th>ASC as % of HOPD</th>
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