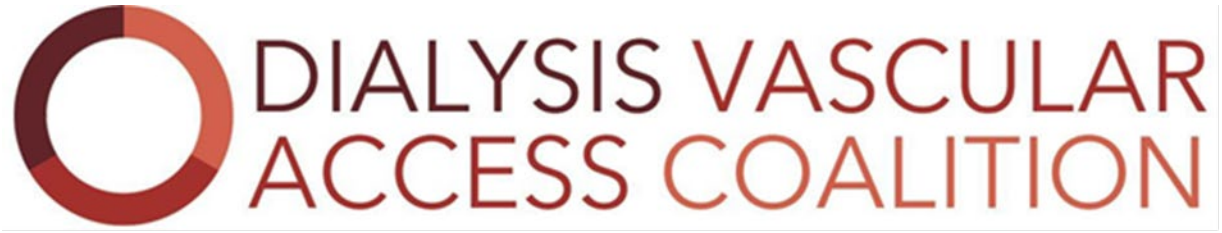

September 17, 2021

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

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS–1753–P
7500 Security Boulevard
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CY 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems 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 Ambulatory Surgical Center Fee Schedule Proposed Rule (CMS-1753-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

[1] 86 FR 42018, 4 August 2021

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

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

- The IPO List and the Importance to Specialty ASCs of Maintaining APC Integrity
- CMS Proposal to Change Determination of Device-Intensive in the ASC Setting

I. IPO List and the Importance to Specialty ASCs of Maintaining APC Integrity

Non-Hospital Specialty Providers Can Achieve Superior Patient Outcomes

Non-hospital specialty providers which focus on particular service lines – such as dialysis vascular access – can achieve superior patient outcomes than typical hospital outpatient departments. 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[2] of vascular access care across sites found, by comparison to patients treated in hospital outpatient departments (HOPDs), patients treated in freestanding vascular access centers were found to have:

- Lower all-cause mortality
- Fewer infections
- Fewer septicemia-related and unrelated hospitalizations than those treated in the HOPD.

Non-Hospital Specialty Providers Are More Vulnerable to Reimbursement Volatility

However, while non-hospital specialization is positive for Medicare beneficiaries and total program costs, it also makes such provider groups vulnerable to significant volatility in reimbursement rates for those services lines in which they specialize given that they cannot broadly diversity their services as a typical hospital might. This was evidenced clearly in the case of the huge 39 percent reduction to the key dialysis vascular access code (36902) in the 2017 Physician Fee Schedule which 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.[3]

Since 2017, dialysis vascular access centers specialty ASCs also have been subject to significant reimbursement volatility relating primarily to the "office-based designation" policy which

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

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

threatened to cut 36902 by 62 percent. While DVAC is grateful that CMS decided not to finalize the office-based policy, the 2021 CMS IPO list proposal threatened *yet another* huge (39 percent) reduction to 36902. This was due to the fact that – under current CMS policies – the IPO list proposal would have meant an estimated 25 new IPO codes would have been added to the current vascular and endovascular APCs and necessitated a new "Level 5" to both the vascular and endovascular APC families. As a result, several key dialysis vascular access codes, including 36902, would have dropped to lower APCs.

Given the history of significant reimbursement volatility in the ASC Fee Schedule, DVAC was very concerned when, in the 2021 OPPS/ASC Final Rule, CMS finalized its proposal 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 being completely phased out by CY 2024. In response, DVAC raised strong concerns regarding the impact that moving over 1,700 services to the outpatient setting might have on the integrity of *current* APCs and the potential for significant reimbursement volatility as a result. Conversely, DVAC was encouraged to see in the 2022 OPPS/ASC Proposed Rule that CMS proposes to halt the elimination of the IPO list and put the 298 codes removed from the IPO list for 2021 back on the IPO list for 2022. DVAC supports this halt in the elimination of the IPO list and CMS' proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

Recommendation: DVAC support the halt in the elimination of the IPO list and CMS' proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

II. CMS Proposal to Change Determination of Device-Intensive in the ASC Setting

Since 2017, dialysis vascular access specialty ASCs also have been subject to significant payment volatility due to CMS device-intensive policies. Specifically, because CMS historically has used HOPD rates, rather than ASC rates, to determine the device-intensive status for ASC services, dialysis vascular access services have been subject both to volatility and payment anomalies. For example, in 2019, CMS paid more for 36904 services than 36905 even though 36905 represents a higher level of service as evidenced in the chart below.[4]

Codes	2019 Proposed Rule	Column 1: Device % in 2019 Proposed Rule (Based on Comprehensive APCs)	Column 2: Device % Based on ASC Rate
36901	$532.59 (P3)	19.0%	19.0%
36902	$1,125 (P3)	23.7%	24.3%
36903	$6,082 (J8)	50.1%	51.4%
36904	$2,719 (J8)	30.6%	35.0%
36905	$2,080 (P3)	28.5%	**30.8%**
36906	$9,835 (J8)	48.2%	50.8%

[4] The AMA's "CPT, 2018 Professional" described 36905 as including "the services in 36904 plus transluminal balloon angioplasty in the peripheral segment of the dialysis circuit."

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

For 2022 and subsequent years, CMS is proposing to calculate the device offset percentage using ASC rates and not HOPD rates as is current practice. This means that any procedure in in which the device cost is 30 percent of the overall ASC procedure rate will receive device intensive status. Additionally, if a device receives HOPD device-intensive status, the device will also be device-intensive in the ASC setting. As a result of these new policies, for 2022 both 36904 and 36905 qualify for device-intensive status.

Recommendation: DVAC supports CMS' proposal to change the determination of device intensive status in the ASC setting.

Conclusion

DVAC's comments on the CY 2022 ASC 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 .