September 15, 2025

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

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1834-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CY 2026 Ambulatory Surgical Center Prospective Payment Proposed Rule

Dear Administrator Oz:

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 2026 Ambulatory Surgical Center Fee Schedule Proposed Rule (CMS- 1834-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 societies, including the American Society of Nephrology, American Society of Diagnostic and Interventional Nephrology (ASDIN) and the Renal Physicians Association (RPA); as well as industry providers, including Arizona Kidney Disease and Hypertension Centers, Austin Kidney Associates, Azura Vascular Care, Balboa Nephrology Medical Group, Dallas Nephrology Associates, Dialysis Access Specialists, Lifeline Vascular Care, Nephrology Associates of Delaware, Nephrology Associates of Northern Illinois and Indiana, and Northwest Renal Clinic. DVAC represents the majority of the non-hospital vascular access sector.[2]

This letter offers comments and recommendations on the following issues:

- Value of Non-Hospital Dialysis Vascular Access
- Reimbursement Pressures Facing Non-Hospital Dialysis Vascular Access are Concurrent with Rise in Catheter Rates
- Annual Update Payment Policy
- Vulnerability of Specialty-Focused ASCs

[1] Federal Register, 90 FR 33476, 17 July 2025
[2] For more information about the DVAC, please see https://www.dialysisvascularaccess.org/

- ASC Complexity Adjustment / Other Packaged Services
- Quality Measures Update
- Changes to ASC Exclusion Criteria

I. VALUE OF NON-HOSPITAL DIALYSIS VASCULAR ACCESS

Non-hospital vascular access centers (VACs) provide a wide variety of lifesaving, critical vascular access services for ESRD patients on dialysis. To access the patient's bloodstream, different vascular access options exist, including permanent access via surgical and percutaneous creation of fistulas and grafts (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) that has poor higher infection rates, hospitalizations and increased mortality. 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) and perform interventions to help mature and maintain fistulas.

Studies have shown that dedicated access centers like those operated by DVAC members provide higher quality care to Medicare beneficiaries at a lower than hospital outpatient departments. A 2017 study of vascular access care across sites found, by comparison to patients treated in hospital outpatient departments (HOPDs), patients treated in freestanding office-based vascular access centers were found to have lower all-cause mortality and fewer infections.[3] DVAC has recently updated its site-of-service analysis to include both office-based vascular access centers and ambulatory surgical centers (collectively freestanding outpatient centers, or FOCs) during the pandemic years period.

DVAC's updated study used propensity score matching to analyze data from the United States Renal Data System (USRDS) on Medicare beneficiaries for 2019 and 2020. A total of 82,498 patients who received ≥80% of their access-related care at a FOC were individually matched to 66,188 patients who received ≥80% of their access-related care at a HOPD. The study reviewed 930,803 patient encounters for vascular access repair and maintenance during the 2-year period.

Annual mortality was significantly lower in those treated at a FOC than in those treated at a HOPD (16.55 versus 18.11%; difference = -1.55%; $p<0.001$). Those treated at a FOC also experienced fewer infections (0.33 versus 0.89 per person-year; difference = -0.57; $p<0001$). Access type varied by the site of service as well with patients treated at a FOC having more AV Fistulas (71.0% versus 62.9% per person-year; difference = +7.9%; $p<0.001$) and 9.8% fewer Central Venous Catheters (CVCs) in the FOC (10.3%) compared with HOPD (20.2%) which was significant. Monthly costs for those treated at a FOC were $835.55 lower than those treated at a HOPD (7,081.75 versus 7,917.30, respectively; $p<0.001$) for annual savings in the FOC setting of $10,020 when compared with the HOPD setting. The outcomes were improved and the cost of non-hospital based vascular access care significantly less, which provides great value to the patients on dialysis in the U.S. in 2025.

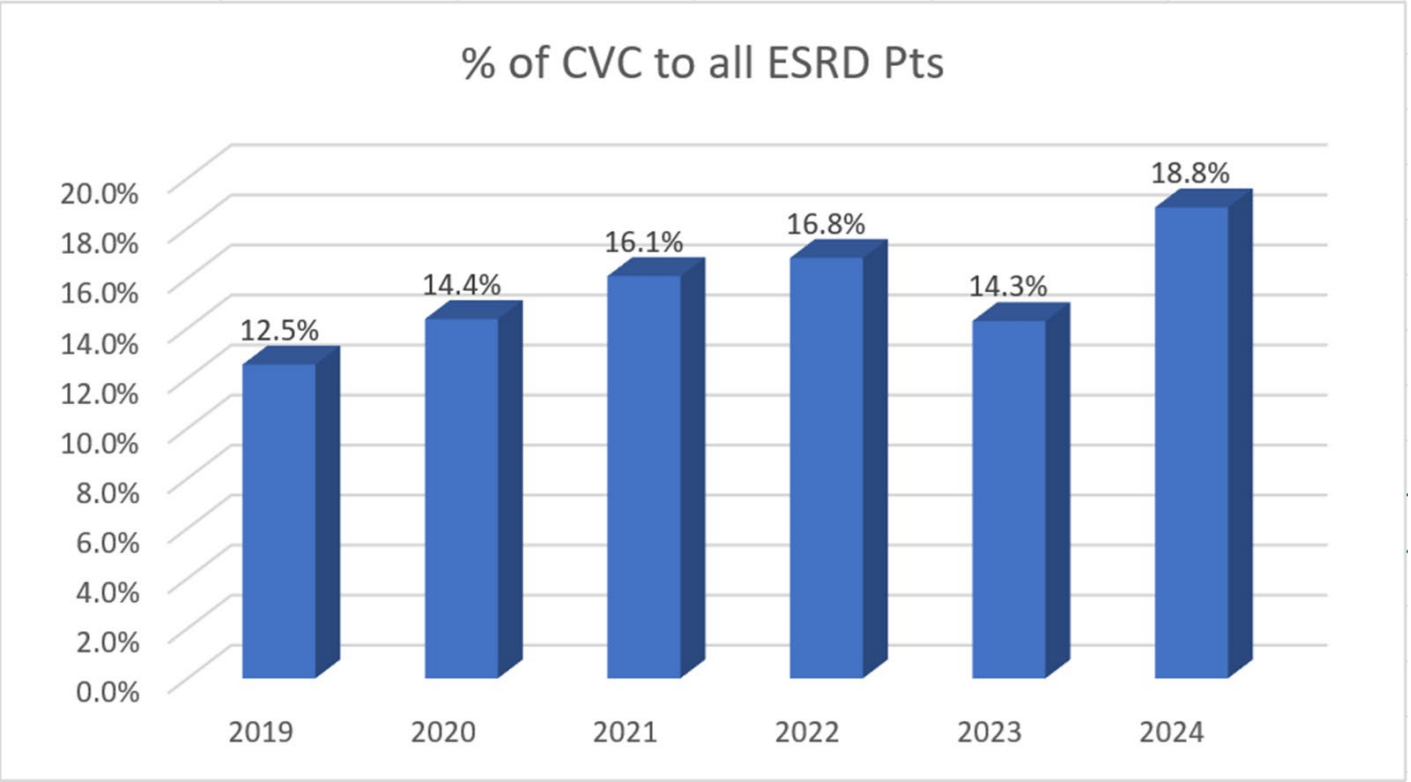
[3] El-Gamil, Audrey et al., *What is the best setting for receiving dialysis vascular access repair and maintenance services?*, September 2, 2017

In summary, patients receiving access-related care predominantly at a FOC had greater AVF use with a lower use of CVCs, fewer infections, and a lower mortality rate than those receiving care at a HOPD. These outcomes were achieved at substantially lower cost. The study has been submitted for publication and provides additional evidence of the value of non-hospital based vascular access for (1) patients on dialysis and (2) the Medicare program as a whole.

II. REIMBURSEMENT PRESSURES FACING NON-HOSPITAL DIALYSIS VASCULAR ACCESS ARE CONCURRENT WITH RISE IN CATHETER RATES

Notwithstanding the value and important of dialysis vascular access to ESRD patients and keeping Medicare costs low, Central Venous Catheter (CVC) rate rose 30% during the Biden Administration (from 14.4% in 2020 to 18.8% in 2024).[4] This rise in catheter rates is shown in Chart I below.

CHART I



These findings are consistent with the 2024 United States Renal Data System (USRDS) report which found the following:

- The overall percentage initiating dialysis with a functioning permanent access decreased from a peak of 20.0% in 2017 to 15.3% in 2022.[5]

[4] Vasc-Alert year end summaries of ESRD Patients. https://www.dialysisvascularaccess.org/reducing-catheter-rates
[5] United States Renal Data System. 2024 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024

- There are substantial differences by race with higher percentages of White (16.3%) and Asian (19.3%) new patients initiating dialysis with a functioning permanent access compared with Black (15.0%), Native American (13.9%), and Hispanic (12.4%) individuals.[6]

The correlation between reimbursement pressures facing non-hospital dialysis vascular access and the rise in catheter rates also is explicitly noted in the 2024 USRDS report as follows:

- The landscape of vascular access in the U.S., although perhaps marginally improved in some respects in 2022 relative to 2021, is discouraging [and is] likely a combination of at least two factors that emerged since 2017.[7]
- The first is the COVID-19 pandemic, during which, at least initially, creation of a permanent vascular access was considered an elective procedure. The COVID-19 pandemic was undoubtedly a major factor in recent declines in fistula use because permanent access creation procedures were likely affected when hospitals and outpatient surgical centers reduced outpatient surgeries, particularly those that were deemed non-emergent.[8]
- A second factor that likely contributed to lower use of permanent vascular access is a reduction in reimbursement for vascular access procedures performed in outpatient vascular access centers resulting from a 2017 change in the Medicare Part B Physician Fee Schedule. Reimbursement, which was cut by nearly 40% for some procedures, led to closure of more than 20% of vascular access centers in 2018 according to a survey by the Dialysis Vascular Access Coalition (Dialysis Vascular Access Coalition, 2021; Litchfield, 2019). These closures may have limited capacity to perform vascular access procedures and potentially resulted in decreases to vascular access care.[9]

The USRDS concluded its 2024 chapter on Vascular Access by noting "The nephrology community needs to do a far better job on the vascular access front…There should be renewed effort to establish permanent access prior to starting HD where suitable and appropriate and to maintain that access throughout the course of dialysis."

III. ANNUAL PAYMENT UPDATE POLICIES

CMS aligned the ASC payment system to the OPPS in 2008 to encourage high-quality, efficient care in the most appropriate outpatient setting and align payment policies to eliminate payment incentives favoring one care setting over another. However, siloed payment policies have led to increasingly disparate reimbursements. The ASC community has long urged CMS to adopt the same update factor for both the ASC and OPPS payments, and we were gratified that the first Trump administration took this necessary step toward better alignment of the payment systems by piloting the use of the hospital market basket for ASCs beginning in 2019.

[6] Ibid
[7] Ibid
[8] Ibid
[9] Ibid

Further research is needed, but there are promising signs of migration from the higher-cost HOPD setting to ASCs. When analyzing surgical volume across three outpatient settings (HOPDs, ASCs and physician offices), ASCs increased their fee-for-service (FFS) market share 0.3 percent between 2021 and 2023, while at the same time HOPD volume declined a commensurate 0.3 percent.

That said, further payment policy reform (such as elimination of the ASC weight scalar and expansion of the ASC-CPL) is necessary to hasten migration of appropriate procedures to the lower-cost surgery center setting.

REQUEST: DVAC supports CMS' continued use of the hospital market basket as the annual update mechanism for ASC payments.

IV. VULNERABILITY OF SPECIALTY-FOCUSED ASCs

Because Dialysis Vascular Access Centers are specialized centers focusing on vascular access, they are vulnerable to APC payment instability. In fact, while specialization in a healthcare service is inherently beneficial for patient outcomes and Medicare cost containment, it makes any such non-hospital center inherently vulnerable to the vagaries of Medicare payment systems. In contrast, a typical hospital may diversify across service lines and the Hospital Outpatient Prospective Payment System is set up to pay according to the average.

It is in this light that policymakers should understand that the dialysis vascular access repair family currently reside in a 4-level endovascular APC family with two key codes in the family, 36902 and 36905, reside at the bottom of their APCs, namely, APC 5192 and 5193, respectively. In the 2018 Hospital Outpatient Prospective Payment System, CMS considered stakeholder suggestions to expand the current endovascular APC family to a 5 or 6 APC family.[10] Given the new lower extremity revascularization code set effective January 1, 2026 (which significantly expands the number of endovascular codes), as well as proposed policies in the 2026 HOPPS Proposed Rule to eliminate the inpatient only (IPO) list over a 3 year period, future rulemaking could disrupt the APC treatment of dialysis vascular access procedures. Given these trends, DVAC intends to study the feasibility and potential benefits of a new dialysis vascular access APC that would provide additional reimbursement stability to these services over time.

REQUEST: DVAC will undertake a review of the potential for a dialysis vascular APC to provide long-term stability for dialysis patients. If there are significant disruptions to the 4-tier Endovascular APCs (e.g. expanding the Endovascular APC family from 4 to 5 or 4 to 6), DVAC would request that CMS work with stakeholders to consider a new dialysis vascular access APC family.

V. ASC COMPLEXITY ADJUSTMENT / OTHER PACKAGED SERVICES

Aside from inherent vulnerabilities of the current endovascular APC family, packaging in the ASC setting further disincentives the use of critical services that improve patient outcomes,

[10] Federal Register, 82 FR 52433, 13 November 2017

particularly for complex patients. The current dialysis vascular access repair services are treated as follows in the ASC payment system:

- 36901 (P3) – Diagnostic evaluation of the dialysis vascular access
- 36902 (G2) – Balloon angioplasty repair of the dialysis vascular access
- 36903 (J8) – Balloon angioplasty repair of the dialysis vascular access plus stent
- 36904 (J8) – Removal or dissolution of a clot in a dialysis vascular access
- 36905 (J8) – Balloon angioplasty repair of a dialysis vascular access plus angioplasty
- 36906 (J8) – Stent placement in a dialysis vascular access plus angioplasty and stent
- 36907 (N1) – Used w/36901 - 36906 for balloon angioplasty of central vein *
- 36908 (N1) – Used w/36901 – 36906 for balloon angioplasty of central vein plus stent *
- 36909 (N1) – Used w/36901 – Dialysis circuit permanent embolization or occlusion *

[* Note: N1 = packaged service/item; no separate payment made]

Since the implementation of the new dialysis vascular access family code set in the 2017 OPPS / ASC fee schedule, there have been concerns with the packaging of the 36907 – 36909 add-on codes. Said CMS in the rule:

- Comment: One commenter agreed with the proposed APC assignments for CPT codes 36902, 36903, 36905, and 36906, and requested that CMS finalize the proposal. However, this commenter disagreed with the proposed APC assignment for CPT code 36904 and the proposed status indicator assignment for CPT codes 36907, 36908, and 36909. In particular, the commenter believed that the proposed assignment of APC 5192 fails to reflect the clinical complexity and resource costs associated with performing the procedure described by CPT code 36904. The commenter recommended that CMS assign CPT code 36904 to APC 5193 based on its clinical and resource homogeneity to the other procedures in this APC. In addition, the commenter disagreed with the packaging of payment for services described by CPT codes 36907, 36908, and 36909 because these procedures involve substantial device costs. As an interim measure, the commenter recommended that the procedure codes be assigned to New Technology APC 1564 (New Technology - Level 27 ($4501-$5000), with a status indicator of "S" (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment.), until sufficient claims data is available on which to base assignment of the new codes to a more appropriate clinical APC. If CMS continued to believe that the New Technology APC assignment is inappropriate, the commenter urged CMS to create a composite APC for the dialysis circuit CPT codes.
- Response: We appreciate the commenter's support for the proposed APC assignments for CPT codes 36902, 36903, 36905, and 36906. We are finalizing our proposal for these codes. However, with respect to the proposed assignment of CPT code 36904, we believe that, based on its similarity to the other procedures in APC 5192, and a comparison to other codes in this series we believe that APC 5192 is the most appropriate APC for this procedure. In addition, because CPT codes 36907, 36908, and 36909 are add-on codes, we assigned these codes to a status indicator that indicates packaged payment status. Because of our packaging policy for add-on codes, we would not consider these codes for a composite APC. We note that since January 1, 2014, payment for services described by

add-on codes have been packaged under the hospital OPPS. As we do every year for all items and services under OPPS, we will reevaluate the APC assignments for these services in the CY 2018 OPPS rulemaking.

In the 2023 OPPS / ASC Proposed Rule, CMS indicated an interest in dealing with add-on codes that are not properly reimbursed under the ASC payment system as follows:

- Our current policy does not include additional payments for services corresponding to add-on codes …. these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS still represent more complex and costly versions of the service, and we believe that providers not receiving additional payments under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting which could result in barriers to beneficiary access. In order to address this issue, we propose a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary source. Under the new policy, combinations of a primary and add-on codes that are eligible for a complexity adjustment under Addendum J of the OPPS also are eligible for the new ASC complexity adjustment.

ASC Complexity Adjustment Policy Has Several Shortcomings Overall

Unfortunately, DVAC has found the ASC complexity adjustment policy has several shortcomings overall. First, complexity codes combinations have been decreasing. For 2026, CMS identified 42 complexity adjustment code combinations for codes that are payable in the ASC setting and would be eligible for a complexity adjustment if the procedure were performed in an HOPD. This is down from 47 in 2024 and 55 in 2023. One complexity code critical to dialysis vascular access in C7530 (36902/36908) was removed in the 2025 OPPS / ASC Rule. Second, the complexity adjustment policy is opaque. An independent analysis of the 2022 OPPS Medicare claims data by Braid-Forbes Health Research revealed that the volume of claims with 1 J1 code and an add-on code for certain codes may be significantly greater than the volume CMS evaluated for CY 2024 complexity adjustments, as reflected in Addendum J of the CY 2024 OPPS Proposed Rule.

ASC Complexity Adjustment Policy Does Not Properly Account for Complex Vascular Access Patients

As it relates to the complexity adjustment policy's treatment of dialysis vascular access services, there are two main concerns. First, the ASC complexity adjustment policy does not properly account for innovative technologies. For example, C7514 should be accounting for covered stents and drug coated balloons with a total cost of $4,444 (i.e. cost of a covered stent plus

weighted average of DCBs and regular balloons) rather than the current reimbursement amount of $1,626.[11][12]

- Covered Stent (SD254): $3,931 vs Bare Metal Stent (SA103): $804
  - Covered Stent is the standard of care[13]
- Drug Coated Balloons (SD382) $2,343 vs Regular Balloon (SD152): $190
  - Drug Coated Balloons are used in 15% of cases[14]

Addendum AA -- Proposed ASC Covered Surgical Procedures for CY 2026

HCPCS Code	Short Descriptor	Proposed CY 2026 Payment Rate	Crosswalk	CPT Code Combination	2026 Rate without Complexity Adjustor	Increase in Payment with Complexity Adjustor
C7513	Cath/angio dialcir w/aplasty	$1,626	→	36901/36907	$564.61	$1,061.12
C7514	Cath/angio dial cir w/stents	$1,626	→	36901/36908	$564.61	$1,061.12
C7515	Cath/angio dial cir w/embol	$1,626	→	36901/36909	$564.61	$1,061.12

Second, many other important add-on code combinations are not captured by complexity adjustment at all, including:

- 36902 / 36907, 36902 / 36908, 36902 / 36909
- 36903 / 36907, 36903 / 36908, 36903 / 36909
- 36904 / 36907, 36904 / 36908, 36904 / 36909
- 36905 / 36907, 36905 / 36908, 36905 / 36909
- 36906 / 36907, 36906 / 36908, 36906 / 36909

REQUEST: DVAC requests CMS address longstanding concerns with packaging and complexity adjustment policy.

VI. QUALITY MEASURES UPDATE

Regarding the ASC Quality Reporting (ASCQR) Program, CMS is proposing to remove the following measures and DVAC is very appreciative of these changes that reduce the administrative burdens facing ASCs:

1. *ASC-20: COVID-19 Vaccination Coverage Among Health Care Personnel* (HCP) beginning with the CY 2024 reporting period/CY 2026 payment determination

[11] Because supply costs are not shown in the OPPS fee schedule, supply costs data here is based on 2026 PFS Proposed.
[12] Covered stents and drug-coated balloons once received Transitional Pass-Through (TPT) payments, but now are packaged (Covered stent – C1874, Drug-coated balloon – C2623).
[13] KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update.
[14] DePietro DM, Trerotola SO. Choosing the right treatment for the right lesion, Part II: a narrative review of drug-coated balloon angioplasty and its evolving role in dialysis access maintenance. Cardiovasc Diagn Ther. 2023 Feb 28;13(1):233-259

2. *ASC-22: Screening for Social Drivers of Health* (SDOH) and *ASC-23: Screen Positive Rate for SDOH*, which were previously finalized to be mandatory with CY 2026 data collection/CY 2028 payment determinations

3. *ASC-24: Facility Commitment to Health Equity*, which was previously finalized to be mandatory with the CY 2025 reporting period/CY 2027 payment determination

REQUEST: DVAC requests CMS finalize the proposal to remove these measures in the 2026 ASC Final Rule.

VII. CHANGES TO ASC EXCLUSION CRITERIA

For CY 2026, CMS propose to revise its regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC CPL, similar to changes finalized in the CY 2021 OPPS/ASC final rule with comment period. Specifically, CMS proposes to revise its regulatory criteria by removing certain general standard and general exclusion criteria at 42 CFR 416.166(b) and (c), and moving them to a new section as nonbinding physician considerations for patient safety. Under the revised criteria, CMS propose to add certain surgical procedures to the ASC CPL, beginning in CY 2026, in order to expand access, while maintaining the safety for Medicare beneficiaries through the nonbinding physician considerations for patient safety. The relevant proposed changes are listed here:

- (c) General exclusions effective January 1, 2008, through December 31, 2025. Notwithstanding paragraph (b)(1) of this section, covered surgical procedures do not include those surgical procedures that:
    - (1) Generally result in extensive blood loss;
    - (2) Require major or prolonged invasion of body cavities;
    - (3) Directly involve major blood vessels;
    - (4) Are generally emergent or lifethreatening in nature;
    - (5) Commonly require systemic thrombolytic therapy;
    - (6) Are designated as requiring inpatient care under § 419.22(n) of this subchapter;
    - (7) Can only be reported using a CPT unlisted surgical procedure code; or
    - (8) Are otherwise excluded under § 411.15 of this chapter.
- (d) Physician considerations beginning January 1, 2026. Physicians consider the following safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure. The covered procedure:
    - (1) Is not expected to pose a significant safety risk when performed in an ASC;
    - (2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to required active medical monitoring and care at midnight following the procedure;
    - (3) Generally results in extensive blood loss;
    - (4) Requires major or prolonged invasion of body cavities;
    - (5) Directly involves major blood vessels;
    - (6) Is generally emergent or lifethreatening in nature; and

- (7) commonly requires systemic thrombolytic therapy.

REQUEST: DVAC believes these changes at 42 CFR 416.166 properly reflect advances in clinical care and safety protocols outside of the hospital. Consequently, DVAC requests CMS finalize the proposal to update ASC exclusion criteria in the 2026 PFS Final Rule.

CONCLUSION

DVAC's comments on the CY 2026 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 .

DIALYSIS VASCULAR ACCESS COALITION

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