



September 14, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1695-P; Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs et al.

Dear Administrator Verma:

The Renal Physicians Association (RPA) appreciates this opportunity to submit comments to the CY 2019 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule.¹ RPA is the professional organization of nephrologists; its goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

Our comments will discuss the following issues:

- **Endovascular Procedures Ambulatory Payment Classifications (APCs) 5191-5194**
- **Device intensive designation for codes 36903, 36904 and 36906**
- **Application of ASC Office-Based Payment Policy to Newly Created Codes**

Endovascular Procedures Ambulatory Payment Classifications (APCs) 5191-5194

In the proposed rule, CMS notes that in August 2017 the Hospital Outpatient Payment (HOP) Panel recommended review of the number of APCs for endovascular procedures to determine whether additional granularity (that is, more APCs) is necessary for the endovascular APC series.

While RPA was among the stakeholder groups that offered a proposal for an additional APC (RPA's proposal called for expanding the current structure of four endovascular APCs to five APCs), we support and agree with CMS' proposal to continue with a four-level APC structure

¹ 83 Fed. Reg. 37046 (July 31, 2018).

and the proposed CPT code assignments to each of the endovascular APCs as described in the 2019 OPSS/ASC proposed rule and Addendum B.

More specifically, we agree with CMS' most recent assessment in the proposed rule that the current four level structure does not result in any 2-times violations² and "that there is sufficient granularity within the existing Endovascular Procedures C-APC structure."³ We also believe, based on CMS' most recent assessment of the updated claims data, that adding additional APCs to the endovascular series could result in some APCs containing very few procedures, which would (unless necessary to insure clinical and resource homogeneity) be contrary to the central principle of APC groupings in the OPSS.

Device intensive designation for codes 36903, 36904 and 36906

RPA also appreciates and agrees with CMS' proposal to restore device intensive status to CPT codes 36903, 36904 and 36906. These codes represent complex services that require one or more atherectomy catheters, angioplasty balloons and covered stent devices that account for a significant percentage of the overall procedure costs. The proposed device intensive status and ASC status indicator J8 appropriately recognizes the device intensive nature of these procedures and restores an appropriate ASC payment level and relativity for these three codes within the dialysis access circuit family of codes.

Application of ASC Office-Based Payment Policy to Newly Created Codes

RPA strongly believes that the proposal to apply office-based payment policies to newly created codes in the ASC payment system is problematic for several reasons, outlined below.

It is Premature for CMS to Apply the ASC Office-Based Payment Policy to the Dialysis Circuit Codes—RPA understands the rationale for the ASC office-based procedure policy and CMS' interest in site-neutral payment policies in Medicare in general. However, we strongly believe that application of the ASC office-based policy to the new dialysis access circuit family of codes in the ASC setting is premature. These CPT codes were new effective January 2017, and CY 2019 is the first year that any claims data is available for these codes.

Applying the ASC office-based payment policy to these codes at this early stage will have a highly significant detrimental impact on the ASC payment rates for two critically important services for dialysis vascular access care: CPT code 36902 (angioplasty), for which the ASC payment is proposed to be reduced by approximately 55% as compared to 2018, and CPT code 36905 (thrombectomy with angioplasty), for which the ASC payment is proposed to be reduced by approximately 54% as compared to 2018. RPA believes there currently is insufficient claims history to consider applying the office-based payment policy, which would lead to severe reductions in 2019. We believe that basing reductions in payment rates of this magnitude on less than 18 months of utilization data is inappropriate and would create a variety of highly negative unintended consequences for ESRD Medicare beneficiaries.

² *Id.* at 37095.

³ *Id.*

Furthermore, Medicare claims data suggest that the procedures described by CPT codes 36902 and 36905 are being performed at higher frequency in the ASC compared to the services described by the predecessor codes before the new codes became effective in 2017. This utilization trend of migration of these service to the ASC site of service suggests that it is likely that in future years these codes will be performed in the office setting <50% of the time by 2019 or 2020.

Statutory and Regulatory Considerations in Applying the Office-Based Payment Policy to the Dialysis Access Circuit Procedure Codes—The statutory requirements for ASC rate setting do not require CMS to set ASC rates based on the physician office rate. In fact, the only requirement is that the rate does not exceed the “the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year.”⁴ The statute also instructs the Secretary to set ASC rates so as to “take into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure.”⁵

CMS sets an alternative payment amount for an ASC covered procedure that it “determines is commonly performed in physicians’ offices.”⁶ CMS identifies office-based procedures as those performed more than 50 percent of the time in physicians’ offices, and which have a level of complexity consistent with other procedures performed routinely in physicians’ offices.

However, in the rule establishing the new ASC payment system CMS stated it was not basing the office-based designation on utilization data alone and undertook a detailed review of groups of surgical CPT codes related to procedures that are performed 50 percent or more of the time in the office setting “to determine if there was a logical correlation between procedure complexity within a group of related procedures and the frequency with which those procedures were performed in the office setting.”⁷ This evaluation of clinical complexity and relativity is important in order to avoid anomalies – i.e., more complex procedures designated as office-based while less complex related procedures are paid based on the OPPS relative weight.

As described in more detail below, assigning an office-based payment rate to 36905 while assigning a hospital-based rate to 36904 is not consistent with this policy because 36905 is a more complex procedure than 36904.

Impact of Proposed ASC Payment Rates on Dialysis Access for ESRD Patients—RPA recognizes that the ASC office-based payment policy is designed to not incentivize inappropriate migration of services from the less intensive and lower cost office site of service to the ASC. Over the past 15 years, the percutaneous dialysis vascular access procedures have moved from being performed in the hospital to predominantly in the office site of service. This change occurred because hospitals were not able to respond rapidly enough to the vascular access needs

⁴ SSA § 1833(i)(2)(E)(ii).

⁵ SSA § 1833(i)(2)(B)(i).

⁶ 42 C.F.R. § 416.171(d).

⁷ 72 Fed. Reg. 42510 (Aug. 2, 2007).

of this complex patient population and accomplish the goals of Fistula First Breakthrough Initiative to increase arteriovenous fistula prevalence and decrease catheter use. Patient outcomes and satisfaction have improved due to this initiative, and costs have been reduced. However, the open surgeries that ESRD patients need including fistula or graft placement, open revisions, and open thrombectomy cannot be performed in the office. Patients therefore continue to receive these services in the hospital.

Providing dialysis vascular access services at two separate locations, the hospital and office, is not optimal patient care. ESRD patients are on dialysis 3 days per week and typically have several other medical appointments during the week due to their multiple comorbidities. It is very important for the nephrologist to be able to accomplish patients' dialysis access in the fewest possible visits to minimize transportation and other logistical challenges that can cause significant delays in care. Dividing procedural care between the hospital and office has led to delays in obtaining initial fistula surgery, delays in obtaining open procedures when percutaneous interventions are unsuccessful, and has made it more difficult to reduce catheter time. As a result, nephrologists and dialysis facilities have not made the desired progress in reducing the percentage of patients with catheters in place more than 90 days – an important goal for patient outcomes and part of the CMS Quality Incentive Program (QIP). Additionally, dialysis patients continue to have a high rate of hospitalization, which is more likely to occur when vascular access services are provided in the higher cost hospital outpatient department.

RPA believes that the migration of dialysis vascular access services (including codes 36902 and 36905) from the hospital and office to the ASC is appropriate to optimize ESRD patient care and reduce overall costs of care for these patients. Specifically, all dialysis circuit related procedures are on the ASC list of covered procedures, including open procedures and it is critically important that it be financially feasible for ASCs to offer all those services. For example, the physician does not always know when starting a procedure, what procedure will be required (e.g., the intent may be to perform a minimally invasive procedure but it may be necessary to convert to an open procedure that cannot be performed in the office setting.) The proposed reductions in codes 36902 and 36905 resulting from application of the office-based payment policy will tremendously compromise ASC's ability to offer the complete range of dialysis access services to insure optimal dialysis access whether the patient needs an open or a percutaneous dialysis access procedure.

The ASC Office-Based Payment Policy Results in Significant Payment Anomalies Among the Dialysis Access Code Family—The proposed office-based payment reduction causes a rank-order payment anomaly affecting CPT code 36905, which would be paid substantially less in an ASC than the similar but less complex and less device intensive CPT code 36904. As proposed, ASC payment for CPT code 36904 (valued based on the OPPS relative weight) is \$2,719; ASC payment for 36905 under the office-based policy is paid \$2,080. CPT code 36904 involves performing a dialysis access thrombectomy without additional intervention, while CPT code 36905 is significantly more complex as it involves performing a dialysis access thrombectomy and angioplasty of all identified stenoses within the dialysis circuit. Despite the higher complexity and cost, CPT code 36905 would be paid less under the proposal when performed in the ASC. This result is counterintuitive and is further evidence that the dialysis access codes are

too new and have an insufficient history of claims data to warrant application of the ASC office-based payment policy.

In addition, applying the office-based payment policy to the dialysis access codes significantly underpays for base procedures combined with procedures described by add-on codes. The add-on codes in the dialysis access code family are 36907 (angioplasty, central dialysis segment), 36908 (stent, central dialysis segment), and 36909 (embolization). Because add-on codes are packaged in the OPPS and ASC, the OPPS and ASC payment rates for the base procedure reflect the additional costs of the add-on code procedures. But add-on codes are separately paid in the physician office setting. Therefore, when the ASC payment amount is set to the physician office payment amount, none of the costs of the add-on code procedures are included in the payment and there is no separate payment for in the ASC for the add-on code. Under the office-based payment policy, add-on code procedures are paid essentially \$0 (no separate payment and no accounting for the costs in the base code through packaging).

For example, central venous stenosis requiring angioplasty (36907) or stent placement (36908) is encountered 10-20% of the time during a dialysis access procedure described by 36902 or 36905. The impact of this anomaly on payment for common procedures in the two sites of service is illustrated in the following table:

Dialysis access procedure	CPT codes	2019 Proposed Office Payment	2019 Proposed ASC payment
Angiogram with peripheral PTA/central PTA	36902 + 36907	\$1,751	\$1,125
Angiogram with peripheral PTA/central stent	36902 + 36908	\$3,442	\$1,125
Thrombectomy with peripheral PTA/central PTA	36905 + 36907	\$2,707	\$2,080
Thrombectomy with peripheral PTA/central stent	36905 + 36908	\$4,398	\$2,080

In the 2011 OPPS/ASC final rule, CMS acknowledged that the MPFS non-facility PE RVU payment amounts for nuclear medicine procedures were not appropriate because the diagnostic radiopharmaceutical is separately paid in the office setting but packaged in the ASC. CMS stated that it “understand[s] the commenter’s concern about the MPFS non-facility PE RVU amounts not reflecting the diagnostic radiopharmaceutical costs.”⁸ Similarly, with CPT codes 36902 and 36905, the MPFS non-facility PE RVU amounts do not reflect the add-on code costs. Therefore, like they did for nuclear medicine procedures, CMS should base the ASC payment for 36902 and 36905 on the OPPS relative weights instead of the MPFS non-facility PE RVU amounts.

⁸ 75 Fed. Reg. 72050.

Summary and Recommendations

RPA respectfully requests that CMS not apply the ASC office-based payment policy for CPT codes 36902 and 36905 for 2019, and instead base the ASC payment rates for these codes on the OPPS relative weights. These codes should continue to be valued using the OPPS relative weights in 2019. Furthermore, RPA believes that the ASC site of service is best positioned to provide optimal outcomes and cost efficiency, and CMS should avoid disadvantaging that site of service with drastic payment reductions for two critical dialysis access procedures.

RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future work in refining reimbursement for vascular access services. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Shapiro". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael D. Shapiro, MD, MBA, FACP, CPE

RPA President