



September 11, 2017

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1676-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1676-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose 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. We are writing to provide comments on the 2018 Medicare Fee Schedule Proposed Rule.

We are focusing our comments on the following areas:

- Valuation of the Dialysis Circuit Code Family of Services
- Proposed Refinements to the Therapeutic Apheresis Services
- CMS' Proposal for Reporting of Patient Relationship Codes Using Modifiers

Valuation of the Dialysis Circuit Code Family of Services

In the proposed rule, CMS seeks additional comment regarding the potentially misvalued work relative value units (RVUs) for CPT codes 36901 through 36909 (the dialysis vascular access codes newly created in 2017, also known as the dialysis circuit codes). CMS specifically notes stakeholder concern pertaining to the typical patient for these procedures, and states that it is considering alternate work valuations for CY 2018, such as the RVUs recommended by the AMA's Relative Value Update Committee (RUC) for the CY 2017 fee schedule rule.

RPA strongly believes that the current work values derived from the use of an inaccurate typical patient vignette substantially undervalue the physician work associated with creating and maintaining dialysis vascular access. As noted in RPA's comments on the 2017 fee schedule, the vignette developed by CPT does not accurately reflect the typical ESRD patient, since

according to the United States Renal Data System (USRDS) and other published data, the typical ESRD patient is >65 years old – not 45 years old (the CPT vignette incorrectly described the typical ESRD patient as 45 years old). Additionally, ESRD patients have multiple co-morbid medical problems, chronic debilitation, and are taking an average of 6-10 medications each day. The frail, elderly ESRD patient requires careful pre- and post-operative physician evaluation and management not captured by the inaccurate CPT vignette. Finally, the chronically ill ESRD patient is always included among American Society of Anesthesiology (ASA) class 3 or 4 when undergoing procedures. This is very different than the less complex ASA 1-2 classification of patients who undergo elective colonoscopy and other GI procedures in the CPT code crosswalks that CMS chose.

When developing its recommendations for crosswalk codes for the dialysis circuit code family, the RUC accounted for not only the urgent nature of this care but also the severity of illness reflective of the co-morbidity, chronic illness and pharmacologic load and ASA class of 65-year old ESRD patients as described above. By contrast, as noted the crosswalk codes selected by CMS are for elective colonoscopy and other GI services provided to patients with a substantially lesser disease burden. In short, RPA believes that the 2017 RUC recommendations for the dialysis circuit code family, developed through a rigorous and representative stakeholder process that identified crosswalk codes closely reflective of the patient acuity and physician work associated with vascular access care, are significantly more accurate than the values assigned by CMS to this family of services.

RPA strongly recommends that CMS utilize the 2017 RUC recommended work values for the Dialysis Circuit Code family (CPT codes 36901-36907).

Proposed Refinements to the Therapeutic Apheresis Services

In the proposed rule CMS outlines its plans to use the RUC-recommended work values for all six codes in the therapeutic apheresis code family (CPT codes 36511-36522), as well as the RUC-recommended direct practice expense (PE) inputs for these codes, without refinement. Given the thorough vetting that these codes were subjected to through the RUC process, RPA believes this is appropriate and supports CMS' decision in this regard.

However, the Agency does state in the rule that

“we considered refining the clinical labor time for the “Prepare room, equipment, supplies” activity from 20 minutes to 10 minutes for CPT codes 36514 and 36522, and from 30 minutes to 10 minutes for CPT code 36516. We also considered refining the clinical labor for the “Prepare and position patient/monitor patient/set up IV” activity from 15 minutes to 10 minutes for these same three codes. In both cases, we considered maintaining the current clinical labor time for CPT codes 36514 and 36516, and adjusting the clinical labor time for CPT code 36522 to match the other two codes in the family. We have concerns about the lack of a rationale provided for these changes in clinical labor time, and whether these clinical labor tasks would typically require this additional time.”

However, the RUC recommendation for these codes did include the following rationale for the clinical labor times:

The Subcommittee discussed the significant time needed to prepare the room, equipment, and supplies. The specialties explained that the clinical staff time hadn't been accurately accounted for when it was last reviewed in 2004. The PE Subcommittee also discussed that much of the time requested in the post-service time was duplicative of the monitoring time and removed most of that time while maintaining the specialty recommended 10 minutes for monitoring in the service period.

Thus, the RUC did provide a rationale for the setting the clinical labor times at the recommended levels, with that rationale indicating the degree of review was such that most of the post-service time was removed from that figure. Further, compelling evidence was provided noting that previous review of these codes did not include all of the specialties providing the majority of these services, accounting for previous clinical staff times that were artificially low. RPA therefore believes that this issue was given an appropriate level of consideration by the RUC, and that CMS should maintain the clinical staff times at the recommended levels.

Finally, RPA joins the College of American Pathology (CAP) in noting that a critical practice expense equipment component was mistakenly left off the RUC recommendation that was submitted to the Agency. Specifically, a Cell Separator System (EQ084) was left off the RUC recommendation for CPT code 36516. RPA concurs with CAP's recommendation that CMS add this piece of equipment (EQ084) to 36516 with 324 minutes of use. This particular equipment item is critical for all of the Therapeutic Apheresis services. CPT code 36516 also uses a piece of equipment (Liposorber - EQ174) that attaches to this missing equipment item.

RPA supports CMS' decision to use the RUC-recommended work values and direct practice expense (PE) inputs for all six codes in the therapeutic apheresis code family, and urges the Agency to maintain the clinical labor times for CPT codes 36514, 36516, and 36522 at the RUC- recommended figures. RPA also supports the CAP recommendation to add the Cell Separator System (EQ084) with 324 minutes of use to the practice expense inputs for CPT code 36516.

CMS' Proposal for Reporting of Patient Relationship Codes Using Modifiers

CMS seeks comment in the proposed rule on the Medicare Access and CHIP Reauthorization ACT (MACRA) mandated provision to require that patient relationship be included on Medicare claims. The Agency notes in the rule that it anticipates "a learning curve with the use of the modifiers to report patient relationships", and as a result proposes to make the reporting of the patient relationship modifiers voluntary for the time being and not a condition of payment, so that claims would be paid regardless of whether and how the modifiers are included.

First, RPA strongly supports CMS' decision to make reporting of the modifiers voluntary for now, and not have reporting be a determining factor in claims payment. Required reporting of the modifiers would at best not contribute to optimal patient care, and worse would be disruptive to patient care. We concur with CMS that there will be a substantial learning curve at the

physician practice level to incorporate this change, so the Agency's decision in this regard is sensible and appropriate. RPA pledges to assist CMS in provider educational efforts related to the need to report to patient relationship codes in the future if and when reporting requirements in this area are progressively increased.

Secondly, much more detail and clarity will be necessary to implement this proposal in a workable way. The Agency should provide specific definitions of terms such as continuous/broad services, continuous/focused services, episodic/broad services, and episodic/focused services, as patients may fall into all of these categories at some point in their care journey. Additionally, CMS needs to specifically address situations such as when physicians other than the patient's primary provider (i.e., a visiting physician or a surgical resident) will order a procedure or series of lab tests on that patient; how those tests would be reflected in the patient relationship codes, and even how a physician's National Provider Identifier (NPI) number would be captured at the point of care, should be accounted for in future rulemaking.

Thirdly, RPA commends CMS' ongoing efforts to address these issues through the CPT Editorial Panel, as the rigorous and open nature of that process will help ensure that the patient relationship modifiers are put in place in a practical manner.

RPA supports CMS' decision to make reporting of the patient relationship modifiers voluntary and not a condition for claims payment. We urge the Agency to provide substantially more clarity on this proposal, and support CMS maintaining its plans to pursue development of the patient modifier proposal through the CPT Panel process as that venue will offer the appropriate degree of scrutiny as this mandated change proceeds.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work on the Medicare Fee Schedule. 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 being the most prominent.

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