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Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1414-P: Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010

Dear Administrator Frizzera:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of 11,000 physicians and scientists dedicated to helping nephrologists provide the highest quality of patient care possible, thank you for the opportunity to provide comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for Calendar Year (CY) 2010.

ASN promotes excellence in the care of patients with kidney disease, promulgating innovative research related to renal disease, providing continuing medical education to enhance understanding and treatment of renal disease, and advocating for policy that improves the quality of care delivered to our patients. As such, when considering changes in policy, ASN focuses on the impact of modifications on the quality and quantity of patient care.

ASN respects and appreciates CMS' willingness to collaborate with the renal community to address the important issues and challenges facing kidney disease patients and providers in order to offer the highest-quality care. In light of the Society's overall devotion to the patients its members treat, ASN submits the following comments regarding the proposed rule.

I. Status of Consultation Codes

RE: II. Specific Coding Issues Related to Physician Fee Schedule 4. Consultation Services (p. 33551-33554)

ASN is deeply concerned that CMS has proposed to stop making payment for consultation codes, forcing providers to use existing evaluation and management (E/M) codes instead. ASN recognizes that there exists a long history of confusion and controversy regarding the appropriate use of and payment for the codes, but feels strongly that CMS should openly address the challenges rather than eliminating the consultation billing option altogether. The availability of consultations with specialty physicians is an important component in ensuring adequate patient care. Notably, the Resource-Based Relative Value Scale Update Committee (RUC) has recognized consultation services as more complex than standard medical visits and has valued them as such. Specialists often identify and administer the most appropriate, effective course of treatment—which may be unavailable in another environment—thereby promoting a high quality of care and reducing Medicare costs. Primary care physicians that lack the expertise to manage CKD and ESRD consistently refer these complex patients to nephrologists for consultations. Clearly, these consultations serve a distinct purpose from E/M interactions and thus warrant a billing option which reflects this fact.

In addition, ASN is concerned that removal of the consultation code may have a detrimental impact on the communication between referring physicians and specialists. This communication, currently facilitated by the consultation code, is an essential part of patient care coordination. Given that the impact of the code's elimination remains unclear, ASN urges CMS to delay removal of the consultation code and engage in a more thorough examination of the implications of the proposal on patient care coordination.

From an administrative perspective, ASN is concerned that a revocation of the consultation code as of January 1, 2010, would not allow sufficient time for all physicians to familiarize themselves with the protocols, generating a burdensome rise in claims denials and appeals. Furthermore, ASN is aware that the AMA CPT Editorial Panel's newly adopted definition of "transfer of care" will go into effect on January 1, 2010. As CMS noted, lack of consensus regarding the definition of "transfer" has historically been a root cause of the administrative difficulties with use of consultation codes. As such, ASN encourages the Agency to allow time to study the capacity of the new AMA CPT Editorial Panel definition to alleviate existing issues with use of the consultation codes, rather than abolishing the codes altogether.

Overall, ASN strongly recommends that CMS refrain from elimination of the consultation codes at this time. ASN encourages the Agency to work with physician specialty groups to evaluate the impact of the proposal on patient care. CMS and these groups should address the underlying documentation and payment problems associated with the codes in order to permit their use. ASN welcomes the opportunity to discuss these vital issues with CMS in greater detail.

II. Payment Proposals

RE: II. I - Provisions Related to Payment for Renal Dialysis Services Furnished by End-Stage Renal Disease (ESRD) Facilities (p. 33634-33639)

Proposed Updates to the Drug Add-On Adjustment and Composite Rate

ASN is pleased with CMS's proposed update to the composite rate and drug add-on, which reflects the MIPPA-mandated 1.0 percent increase. As ASN has previously commented, Congress' selection of the phrase "annually increase" in the Medicare Modernization Act (MMA) is clearly intended to prevent negative updates to previous years' drug add-on rates. ASN concurs with CMS that the authorizing statute intends for updates to drug add-on adjustments be a "positive increase or zero update."

Additionally, ASN supports CMS's proposal to maintain the existing case-mix adjustors. ASN believes that it will be important to maintain consistency in the current composite rate by preserving the current case-mix adjustors given the anticipated shift to a bundled payment system. The Society encourages CMS to collaborate with the renal care community to identify the most appropriate case-mix adjustors for the expanded bundle to facilitate the transition to the new payment system. Finally, ASN supports CMS's elimination of the differential between payment rates for hospital-based facilities and independent renal dialysis facilities.

However, it is imperative that any adjustment to hospital-based dialysis facility payments not be applied to pediatric hospital-based dialysis facilities. Pediatric hemodialysis units, like pediatric hospitals in general, require many more people to provide support for the child undergoing dialysis. Overall, the staffing of a pediatric unit is extensive and the cost is directly related. At present, pediatric units have exceptional rates that reflect their extensive personnel costs, and could not continue to provide care if they were paid at standard (adult) rates. As such, ASN is concerned that pediatric hemodialysis units' rates are not inadvertently negatively impacted because they are "hospital based." ASN urges CMS to specify that elimination of payment differentials will impact adult hospital-based dialysis centers only, and that these changes will not apply to hospital-based pediatric dialysis units.

Proposed Reduction to the ESRD Wage Rate Floor

In the proposed rule, CMS proposes a reduction in the wage index floor to 0.65 in CY 2010. The Agency reiterates that it intends to reassess the need for a wage floor and anticipates it "may reduce the floor gradually until full implementation of the ESRD PPS required by section 1881(b)(14) of the Act." ASN appreciates CMS's recognition that a wage index floor remains necessary to protect patient access and strongly supports the gradual pace of reduction. ASN urges CMS to consider the potential detrimental effect of elimination of the wage floor on the desirability of nephrology—particularly in light of the growing demand for the specialty nationwide—in its reassessment of the issue. CMS is encouraged to seek input from the kidney care community in its deliberations—as well as guidance should the Agency move forward with elimination—of wage floors.

III. Kidney Disease Education Services

RE: II. D. Medicare Telehealth Services (p. 33616) & II. G. Issues Related to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

10. Section 152(b): Coverage of Kidney Disease Patient Education Services (p. 33615 - 33619)

ASN has long advocated for coverage and reimbursement of educational sessions for Medicare beneficiaries with chronic kidney disease (CKD). To this end, ASN has collaborated with KCP and Members of Congress to encourage the inclusion, and the passage, of such provisions in MIPPA. Educational interventions provide individuals with CKD greater understanding of comorbidity management and uremic complication prevention, as well as the array, benefits, and risks of renal replacement therapy (RRT) options, thereby empowering them to engage in informed decision-making about their care. Further, such educational interventions may help pre-dialysis patients delay the onset of RRT, thus preserving their quality of life while reducing costs to the Medicare program.

ASN applauds CMS's inclusion of this important new benefit in a manner that incorporates many of the kidney care community's recommendations on the issue. Face-to-face sessions tailored to the needs of each patient, but emphasizing a standard curriculum of clinically appropriate topics and incorporating the opportunity for outcomes assessment, constitute a satisfactory forum for effective educational intervention. However, ASN wishes to comment on several components of the proposed implementation plan and encourages CMS to employ these recommendations to ensure the provision provides appropriate, efficient kidney dialysis educational (KDE) services for Medicare beneficiaries.

Definition of Telehealth KDE Services

ASN is pleased by CMS' decision to define KDE services as face-to-face sessions. However, the proposed rule does not clarify whether these face-to-face services may be provided through telehealth. In rural communities, telehealth services provide patients crucial access to provider expertise and consultations which may otherwise be infeasible. Notably, telehealth services have been recognized as face-to-face interactions in numerous other contexts—including the House of Representatives (*see* Fed. Reg. 79988 (December 31, 2002) *see also* H.R. 3200). Consequently, ASN encourages CMS to clarify that providers offering the KDE benefit via telehealth services are doing so in a manner that meets reimbursement requirements for KDE services.

One Payment Per Day Per KDE Beneficiary

ASN appreciates CMS's recognition of the possibility that a beneficiary may receive KDE services from more than one "qualified person." Enabling patients to interact with multiple providers possessing expertise in specific educational content areas will maximize the value of the benefit. However, in the proposed rule, CMS states that no more than one "qualified person" may receive payment on the same day for the same beneficiary where KDE services are provided. ASN is concerned about the language regarding the potential for dual-billing, as the limitations may potentially be interpreted

to encompass providers of patient care services other than KDE. Also, as currently written, the language may prevent patients from receiving two educational sessions from two different providers in the same day. For instance, it may be appropriate for a beneficiary to receive services related to dialysis modality from one provider and services related to nutrition from a second provider in the same day. As such, ASN urges CMS to clarify the limit on reimbursement to one qualified provider per day with regard to KDE services, bearing in mind the importance of preserving patient ability to tailor the benefit to meet their individual needs and schedules.

Referral Requirements for KDE Services

In the proposed rule, CMS states that a covered KDE beneficiary must “have been referred for such services by the physician managing the beneficiary’s kidney condition.” However, many patients who are diagnosed with kidney failure have not previously received care for kidney, or any other, disease by the physician who identifies it. As such, ASN is concerned that without clarification, a physician who diagnoses a patient’s need for RRT—but who was not responsible for managing the condition prior to diagnosis—will be ineligible to make the referral. ASN encourages CMS to clarify that any provider who meets the definition of a qualified provider may refer qualifying Medicare beneficiaries for KDE services.

Determination of Covered Beneficiaries for KDE Services

ASN recommends that CMS clarify that covered beneficiaries include patients who are diagnosed with *at least* Stage IV CKD and who will require dialysis or a kidney transplant. This reflects Congress’ intent to provide KDE services to Medicare beneficiaries who are diagnosed with kidney disease and must begin preparing to receive dialysis or a transplant. As it currently stands, the proposed rule would preclude individuals diagnosed with Stage V kidney failure—but who have not yet initiated dialysis or received a transplant—from receiving the education benefit. Consequently, ASN strongly encourages CMS to alter the definition of covered beneficiaries to specify that it includes patients diagnosed with “at least” Stage IV kidney disease.

Furthermore, the NKF’s KDOQI guidelines defining Stage IV kidney disease (which CMS recognizes as its clinical guideline) stipulate that they should not be used as ultimate cut-offs between stages, as the measures defining the stages are “inherently arbitrary.” As such, ASN suggests that CMS recognize that due to the variability in signs and symptoms of kidney failure, some patients between Stage IV and Stage V should be treated similarly for the purposes of qualifying for the KDE services.

Education and Experience of Qualified Providers

In response to CMS’s request for comments on the appropriate level of education, experience, training and/or certification of qualified persons for the KDE benefit, ASN suggests that CMS implement the explicit MIPPA requirements, which define qualified persons as “a physician, nurse practitioner, clinical nurse specialist, or physician assistant,” or a provider of services located in a rural area (defined as facilities located outside of a metropolitan statistical area (MSA) or defined as rural under section

1886(d)(2)(D) of the Act). In addition, ASN proposes that CMS require that these qualified persons:

- ❖ Possess current board certification in nephrology, or
- ❖ Possess, at minimum, two years of experience working primarily with patients with kidney disease

ASN also supports CMS' proposal that qualified providers be able to explain the KDE subjects specified in the proposed rule. The educational and experience requirements described above will ensure that providers of KDE possess sufficient expertise to address the complex issues of pre-dialysis kidney disease with patients in an educational session. Correspondingly, ASN supports CMS' proposal to *not* apply the "incident to" provision when implementing this important new service. Such a provision would authorize relatively inexperienced providers to assume responsibility for KDE services, thereby compromising the quality and content conveyed to patients in educational sessions. ASN strongly recommends that CMS adhere to the original intent of MIPPA and limit qualified persons to a physician, nurse practitioner, clinical nurse specialist, physician assistant, or a provider of services located in a rural area.

Contents of the KDE Curriculum

ASN is pleased with the scope and depth of CMS's proposed content for KDE services and supports all components of the topics detailed in the proposed rule. However, given that transplantation is the most successful treatment for ESRD, ASN encourages CMS to include more information specifically relating to transplantation, including preparation for transplantation, donor selection, immunosuppression, allocation policies, and lifestyle post-transplant.

ASN also recommends that CMS also include specific educational content on the most appropriate methods of dialysis access for (hemodialysis (HD) and peritoneal dialysis (PD) renal replacement therapies. As evidenced by the Fistula First program, CMS recognizes the importance of educating patients about vascular access options and increasing the number of *hemodialysis* recipients who possess arteriovenous (AV) fistulas. However, patients who select peritoneal dialysis should initiate this therapy with a healed PD catheter. Therefore, ASN urges CMS to specify that educational content include "dialysis access for both hemodialysis and peritoneal dialysis."

CMS states in the proposed rule that qualified providers must be capable of discussing nutritional and psychosocial educational content with Medicare beneficiaries. ASN appreciates CMS' recognition of the importance of these topics. Constituent with this acknowledgment, ASN suggests that CMS include nutrition and psychosocial services to the required KDE content list. ASN also recommends that CMS add to the list of proposed content information on the role of blood pressure, Calcium/Phosphate levels, and acidosis in CKD, as understanding of these factors is crucial to patient ability to properly manage their condition.

Finally ASN wishes to express appreciation for CMS' recognition that patient education needs vary by severity of disease, the age of the patient, the patient's co-morbid conditions, and other factors, and that KDE services are more effective when tailored to meet an individual beneficiary's needs. ASN also applauds CMS' effort to detail content included in reimbursable KDE services, demonstrating the wide breadth of appropriate information for KDE beneficiaries. However, ASN is concerned that potential exists that a session in which the provider addresses a topic not included on the list would not be eligible for reimbursement. In order to ensure that educational topics that are not explicitly included in CMS' list in the Final Rule—but may be appropriate for patient populations with certain severity levels, co-morbid conditions, and ages—ASN encourages CMS to include language stating that KDE services include, but are not limited to, the content as specified in Proposed 410.48(d) and permit qualified providers to include additional reasonable and necessary content at their discretion.

Development of Outcomes Assessments for KDE Services

ASN appreciates CMS's solicitation of comment from the nephrology community regarding the development and administration of the outcomes and assessments for KDE services. Additionally, ASN suggests that an outcomes assessment program for KDE services include the following:

- ❖ anemia management
- ❖ health-related quality of life
- ❖ patient education awareness
- ❖ modality selection
- ❖ vascular access

Furthermore, the assessment should have a flexible schedule for implementation that accounts for the time necessary for providers to adopt a new assessment instrument. Furthermore, CMS should consider the adoption of incentives to encourage providers to conduct long-term follow-up, and to standardize assessments to enable comparison of quality improvement. ASN would be pleased to meet with CMS to discuss the development and administration of outcomes assessments for KDE services in greater detail.

Proposed Reimbursement Amount for KDE and Comparison to the MNT Benefit

ASN supports CMS' proposal to base payment for KDE services on the medical nutrition therapy (MNT) benefit and agrees that kidney education is similar to MNT in the individual and group setting. However, ASN wishes to express concern that the proposed crosswalk does not accurately match the specified time for the two services. KDE services are to be administered in **60** minute sessions, while MNT services are provided in **15** minute sessions for individuals and **30** minutes for groups. To rectify this inconsistency, ASN recommends that CMS reimburse the 60-minute KDE session at the same level as the 15-minute MNT session, setting reimbursement amounts such that the times and total payments are equivalent for KDE and MNT services. ASN is concerned that the current language may be interpreted to suggest that that the time of a physician or other qualified person is worth just one-quarter of a nutritionist's time, potentially resulting in fractional reimbursement inadequate to incentive providers to offer these important KDE services. Therefore, ASN urges CMS to clarify the proposed times and

reimbursement rates for KDE services to provide an accurate comparison with the MNT benefit.

Additionally, ASN wishes to express concern that a large group session KDE environment may potentially compromise the quality of an individual patient's educational experience. As CMS recognizes, there is considerable variance between the stages at which patients are diagnosed with CKD. Consequently, it may be challenging for providers to present information that is appropriate for, and tailored to, all beneficiaries in attendance. Moreover, patients possess varying levels of emotional acceptance regarding their condition and different comfort levels raising questions relating to their personal health care in the presence of strangers and family members. However, ASN also recognizes that groups of the right size may be a useful format for presenting some of the KDE topics. Therefore, ASN proposes that CMS define group sessions as consisting of between 2 and 20 participants, similar to the Agency's definition of a group session for the diabetes education benefit. Moreover, ASN is particularly concerned that potential exists that all six of a beneficiary's sessions would be provided in a group format, precluding opportunity for that beneficiary to receive any education that is ideally tailored to address his or her personal needs. To ensure that KDE session formats are balanced to provide the most effective possible services for each beneficiary, ASN urges CMS to mandate that at least 2 or more of each beneficiary's 6 KDE sessions be provided a one-on-one format.

ASN welcomes the opportunity to discuss the provisions regulating this important benefit in greater detail with CMS.

IV. ESRD Inclusion in List of Eligible Telehealth Services

RE: II. D. Medicare Telehealth Services (p. 33542)

ASN applauds CMS's proposed addition of ESRD to the list of telehealth eligible services. Many ESRD patients reside in rural areas and do not possess readily available access to dialysis services. Telehealth services are an important component of ensuring the availability of high-quality kidney care in remote areas, as they facilitate patient-provider interactions which may otherwise be precluded. As such, ASN lauds and fully supports the expansion of telehealth services to include ESRD in the proposed rule.

V. Practice Expense Proposals and Rate Reduction for Vascular Access Interventions

RE: II. Provisions of the Proposed Regulation A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs) (p. 33530-33531) & Addendum B (p. 33687)

CMS indicates it will use the new Physician Practice Information Survey (PPIS), designed and implemented by the American Medical Association, as the data source for physician practice costs when determining 2010 Medicare payments. In light of PPIS findings, CMS proposes it will increase payments to primary care physicians (PCPs) by as much as 6 percent. However, ASN is deeply concerned that the agency does so by reducing payments to other health care professionals, including interventional

nephrologists. In particular, ASN is worried about the proposed 22.5 percent rate reduction to vascular access interventions for ESRD patients in freestanding vascular access centers. This proposal will have an immensely detrimental impact on access to care for kidney disease patients nationwide and will significantly compromise CMS's Fistula First Initiative. Furthermore, the rate reduction will result in reduced quality and increased costs in the vascular access environment.

CMS has long recognized the importance of increasing to increasing vascular (AV fistula) access and, through the Fistula First program, has set nationwide goals for the percentage of dialysis beneficiaries receiving this procedure. In order to achieve these goals, it is imperative that patients have readily available access to the dedicated centers where providers offer the procedure. The negative economic impact of the proposed rate reduction on vascular access centers and the providers who perform AV fistulas would result in closure or reduced capacity at many facilities. This would discourage some patients from obtaining vascular access and force many others to obtain care at more distant locations associated with a lower level of efficacy, higher costs, and lower patient satisfaction.

In order to maintain patient access to high-quality, medically necessary care and the continued success of the Fistula First program, it is crucial that CMS delay the implementation of PPIS-informed rate reductions to ensure the tool accurately represents all specialties. Further evaluation is vital, as physicians working in freestanding vascular access centers were not included in the PPIS. ASN urges the agency to postpone implementation of the proposed rate reductions. If comprehensive delay is impossible, the agency should exempt vascular access centers from the rate reduction, instead permitting them to bill using a modifier at the CY 2009 rate. This small modification would allow CMS to gain a more complete understanding of the effect of a rate reduction on kidney disease patients' access to vascular access services.

On behalf of the ASN, thank you for your willingness to consider our comments for the proposed rule for CY 2010. Our members are committed to providing the best possible care and want to ensure that physicians have the necessary resources to treat patients effectively and preserve their quality of life. We believe that our proposed recommendations will prove helpful in formulating policies that continue to promote accessible, high-quality patient care.

Again, thank you for your time and consideration. ASN looks forward to working with CMS to formulate salient solutions addressing kidney disease now and in the future. To discuss ASN's comments, please contact ASN director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,



Thomas Coffman, MD
President, ASN