September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1807-P: CY2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed "CY2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies". Currently, more than 800,000 Americans are diagnosed with kidney failure or End Stage Renal Disease (ESRD), including more than 550,000 receiving dialysis and more than 200,000 living with a kidney transplant. The high prevalence of kidney failure is partly attributable to the increase of diabetes and hypertension, increasingly pervasive chronic diseases that are the leading risk factors for kidney diseases.

Kidney diseases represent the eighth leading cause of death in the United States, resulting in more deaths than breast cancer. These deaths occur in part to increased risk of cardiovascular disease (CVD) associated with chronic kidney disease (CKD), as well as progression to kidney failure. Unfortunately, kidney diseases and kidney failure disproportionally impact historically marginalized populations including Black, Hispanic or Latinx, and Native or Indigenous Americans, Asians, Hawaiians and Other Pacific Islanders, people with lower incomes, and older adults, underlying and exacerbating existing disparities. Black Americans are 3.7 times more likely to develop kidney failure than White Americans, and Latinx Americans are 1.5 times more likely to develop kidney failure than non-Hispanic or non-Latinx Americans. Remarkably one out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Latinx Americans have a lower likelihood of receiving a kidney transplant or initiating home dialysis to treat kidney failure.

Overall Concerns Regarding the Medicare Physician Fee Schedule (MPFS)

The MPFS proposed rule includes a 2.8% reduction to the MPFS conversion factor (CF). Reductions to the CF impact every single clinician providing care to Medicare patients.

At the same time, clinicians continue to face ongoing financial challenges operating their practices since the Medicare payment system has failed to keep pace with inflation. In 2025, the proposed 2.8% payment reduction will coincide with an expected 3.6% increase in medical practice cost inflation, as measured by the Medicare Economic Index (MEI). Nephrology will experience an overall 2.2 percent cut for 2025. When adjusted for inflation, Medicare physician payments have declined by 29% from 2001 to 2024.[i] This is clearly not a sustainable trajectory.

Since 2020, Congress has mitigated but not eliminated reductions caused by the application of Medicare's budget-neutrality adjustment, which statutorily prohibits any net increase in cost to the federal government when adjustments to the MPFS exceed $20 million. Most recently, in the Consolidated Appropriations Act, 2024, Congress provided 2.93% of relief to help offset 2024's payment cut, once again mitigating but not eliminating the reduction and failing to keep up with medical inflation for 2024. Unfortunately, the additional 2.93% expires at the end of 2024, which is the main contributor to the proposed 2.8% reduction for 2025.

The MPFS is the only payment system within Medicare lacking an annual inflationary update, even though clinicians — many of whom are small business owners — contend with a wide range of shifting economic factors, such as increasing administrative burdens, staff salaries, building rent, and purchase of essential technology when determining their ability to provide care to Medicare patients. The absence of an annual inflationary update, combined with statutory budget neutrality requirements, further compounds the difficulties nephrologists face in managing resources to continue caring for patients in their communities.

ASN beseeches the Biden-Harris Administration to work directly with Congress and across HHS to find solutions to a collapsing payment system.

Specific Issues in the CY 2025 MPFS Proposed Rule

ASN specifically addresses the following topics in this comment letter.

I. Expanding Caregiver Training Services (CTS) to include home dialysis training services for caregivers
II. Expanding Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Disease (HCPCS code GIDXX) to include nephrologists
III. Expanding coverage for dental services for ESRD beneficiaries
IV. Incorporating certain Advanced Primary Care Management (APCM) services into the traditional Medicare program to support individuals with CKD.

V. Expanding coverage of compounded immunosuppressive drugs
VI. Increasing uptake of Kidney Disease Education
VII. Expanding audio-only coverage, additions to the telehealth list, lifting of frequency limits
VIII. Incorporating New MIPS Quality Measures Proposed for the CY2025 Performance Period/2027 MIPS Payment Year and Future Years

I. ASN urges CMS to incorporate home dialysis training for caregivers into the proposed Caregiver Training Services (CTS) codes

ASN commends CMS for proposing new coding and payment for caregiver training services related to direct and support care. ASN believes that caregiver training is essential for improving patient outcomes and overall care quality. Therefore, ASN requests that CMS extend these caregiver training codes to include home dialysis training for caregivers. This addition would support CMS and the Biden Administration's goals of increasing home dialysis accessibility for ESRD patients by acknowledging the crucial role of caregiver support in achieving successful home treatment. Currently, patients with cognitive and physical limitations have limited home dialysis options without caregiver assistance, typically from a family member, due to the lack of home health care benefits for this type of service. Expanding these codes would enable more resources to be allocated toward training caregivers, such as family members or friends, enhancing support for home dialysis patients. This would incentivize dialysis providers to offer home dialysis for patients with more complex needs, who often fare better at home with appropriate support but require more extensive training. Expanding patient choice in dialysis location should remain a key objective of the payment system.

II. ASN urges CMS to expand Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-on for Infectious Disease (HCPCS code GIDXX) to include nephrologists

ASN applauds CMS' effort to recognize the additional effort and complexity of care that is required of specialty providers in the inpatient setting. Cognitive, non-procedural time-consuming medical services such as infectious disease (ID), nephrology, neurology, rheumatology, and endocrinology are undervalued in the current inpatient reimbursement structure. In the present healthcare environment, where physicians are often hospital employed or contracted, undervaluing these services has the unintended effect of leading to lack of services for Medicare beneficiaries because hospital systems limit investments in recruiting and retaining lower paid specialists such as nephrologists and ID clinicians.

ASN urges CMS to recognize that managing infectious diseases is a complex task that extends beyond the specialty of infectious disease alone. In nephrology, nephrologists frequently handle the treatment of complex infections in ESRD and transplant patients, as they are most equipped to address the challenges posed by kidney failure, dialysis procedures, and interactions with immunosuppressive medications. Infection control

and treatment involve coordination between hospital care and dialysis centers. Nephrologists play a crucial role in bridging these settings due to the fact that only nephrologists are equipped to facilitate an ongoing treatment plan from a hospital to a facility.

ASN proposes that this code be expanded beyond infectious disease specialists to include nephrologists in the care of ESRD and kidney transplant patients with infectious complications. Alternatively, a different, new add on code could be developed for nephrologists alone to recognize the complexity of management of infectious disease in kidney failure and kidney transplantation. This modification will better recognize the additional expertise and effort that nephrologists bring to the management of infectious disease in the hospital setting.

III. ASN supports CMS's proposal to expand coverage for dental services for ESRD beneficiaries.

ASN thanks CMS for proposing to make necessary oral and dental care available for co-morbidities frequently associated with kidney failure. In so doing, CMS will significantly reduce the risk of medical complications currently faced by individuals with kidney failure and avoid the costly interventions now borne by Medicare, beneficiaries, and taxpayers. ASN has long supported the expansion of Medicare coverage to include dental services.

In February 2024, ASN and the National Kidney Foundation (NKF) jointly urged CMS to use its existing authority or its broad waiver authority to allow Medicare payment for diagnostic and therapeutic dental services for Medicare ESRD beneficiaries receiving dialysis when, because of immunosuppression, poorly controlled diabetes, heart disease, malnutrition, and/or other relevant comorbidities, dental treatment can be integral and substantially related to the clinical success of such covered nephrology-related medical services as:

CPT codes 36901-36906: Dialysis circuit procedures
CPT codes 90935, 90937, 90940: Hemodialysis procedures
CPT code 90961: Physician or other qualified healthcare professional visits for ESRD
CPT codes 90989-90999: Other dialysis procedures
CPT codes 99212-99215: Evaluation and Management (E/M) Services
DRG code 872: Hospitalization for septicemia or severe sepsis

Identifying and resolving dental infections can be similarly integral and related to the clinical success of other covered medical services for co-morbidities frequently associated with kidney failure. Currently, many individuals covered under the ESRD benefit lack access to these essential services due to inadequate Medicare coverage. Notably, 61% of individuals with Medicare coverage with a diagnosis of kidney failure are under the age of 65, yet only 11% of these individuals have Medigap coverage, highlighting a significant gap in dental care access.

Research has consistently demonstrated that oral health can be a crucial determinant of overall health outcomes in patients with kidney failure. Treatment of dental infections risking/causing blood stream infections (BSI), poor glycemic control, and other complications can be integral and substantially related to the clinical success of medical therapies to manage ESRD.

Kidney failure patients have higher rates of decayed, missing, and filled teeth, dental plaque, loss of attachment, xerostomia, gingivitis, periodontitis, as well as mouth and jaw-bone lesions, than the general population. The consequences of poor oral health are worse for kidney failure patients due to their advanced age, diabetes, polypharmacy, and/or impaired immune function. As a result, adults with kidney failure experience more severe oral diseases compared to the general population, which can contribute to increased mortality rates.[ii]

Given these findings, the expansion of dental services in Medicare should be considered a fundamental component of standard care for all dialysis patients just as it is for patients being evaluated for a kidney transplant. Providing this coverage is essential for improving health outcomes and ensuring comprehensive care for those affected by kidney failure.

IV. ASN supports Incorporating Certain Advanced Primary Care Management (APCM) Services into Traditional Medicare

ASN supports the proposal to incorporate certain Advanced Primary Care Management (APCM) services into traditional Medicare. ASN believes this integration will be especially beneficial for individuals with chronic kidney disease (CKD). APCM services would include elements of existing care management codes, including chronic care management (CCM), transitional care management (TCM), and principal care management (PCM), as well as communication technology-based services (CTSB), including virtual check-in services. Unlike existing care management codes, CMS is proposing that the code descriptors for APCM services would not be time-based providing more latitude for their use.

The inclusion of these APCM services and corresponding reimbursement codes has previously demonstrated that improved care management can enhance communication between patients and their caregivers. This improved communication fosters better decision-making, helping patients, their caregivers, and clinicians make more informed choices regarding treatment.

Chronic kidney disease is often asymptomatic, with an estimated 23% to 63% of patients unaware they have the condition until it progresses to the point where they require emergency dialysis[iii]. Early detection of CKD is crucial because, while the disease is often not reversible, it can be treated, and its progression can often be slowed or halted if managed early. By expanding access to advanced care management

services, physicians will be better equipped to identify CKD in its earlier stages, ultimately leading to improved outcomes for patients.

V. ASN supports the proposal to include compound immunosuppressant drugs in the Part B-ID benefit

ASN joins the American Society of Pediatric Nephrology (ASPN) in supporting the proposal to include orally and enterally administered compounded formulations for immunosuppressive drugs covered under the Part B-ID benefit.

Pediatric kidney transplant recipients often require formulations of immunosuppressive drugs that can only be obtained in compounded formulas. Expanding coverage to include these formulations in the Part B-ID benefit will ensure that pediatric patients receive appropriate and high-quality care tailored to their unique medical needs.

VI. ASN urges CMS to take the necessary action needed to increase the uptake of KDE

ASN urges CMS to take the necessary actions needed to increase the uptake of Kidney Disease Education (KDE) benefit which is greatly underutilized. ASN appreciates CMS's effort, particularly the expansion of the KDE within the ESRD Treatment Choices (ETC) Model, but believe further actions are needed to improve accessibility.

a. Waiving the KDE Coinsurance Requirement

Currently, Medicare beneficiaries must pay 20% of the copay for KDE services under Part B, which can be a barrier to accessing this vital program. ASN recommends that CMS waive this coinsurance requirement to improve access. A waiver facilitating easier access and greater utilization of KDE would support CMS stated goals of increasing home dialysis, optimal starts to dialysis and reduce the risk of dialysis-related complications requiring hospitalization.[iv][v][vi]

b. KDE as a preventive service

The coinsurance associated with KDE can discourage both clinicians and patients from utilizing the service. Clinicians may be hesitant to charge for a service previously provided at no cost, and patients may struggle to afford the copay. CMS has the authority to add full coverage for preventive services in Medicare through the National Coverage Determination process if a new service meets certain criteria. ASN, along with other members of the Alliance for Home Dialysis, believe the KDE benefit qualifies as a preventive service. By increasing patient awareness of choices of modality, Medicare is aligning patient input with their care that ASN believes ultimately leads to choices more in keeping with a patient's goals and abilities. Increasing alignment is essential to improving outcomes and preventing unintended consequences. ASN encourages CMS to fully cover KDE through the National Coverage Determination process.

VII. Expanding audio-only coverage, additions to the telehealth list, lifting of frequency limits

CMS proposes a new permanent policy allowing audio-only telehealth services for services delivered to patients from their home if the physician is capable of using audio-video, but the patient does not have or does not consent to video use. This is an expansion of the policy previously adopted that allowed audio-only services for patients receiving telehealth for mental health conditions.

Through 2025, CMS also proposes to continue lifting frequency limits on telehealth for subsequent inpatient and nursing facility visits and critical care consultations, as well as to not require physicians providing telehealth to report their home address.

ASN supports this proposal.

VIII. New MIPS Quality Measures Proposed for the CY2025 Performance Period/2027 MIPS Payment Year and Future Years

CMS has proposed inclusion of the following measures in MIPS for CY2025 Performance Period. Notably, they would be included in the Optimal Care for Kidney Health MVP originally developed by ASN

- *First Year Standardized Waitlist Ratio (FYSWR)*

- *Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)*

ASN recognizes the importance of improving transplantation rates for patients with ESRD but does not support the First Year Standardized Waitlist Ratio measure or the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure. These measures are largely outside of nephrologist's ability to influence as well as outside the scope of the dialysis facility's sphere of influence. While patients can be referred, being waitlisted is under the control of the transplant center.

FYSWR

ASN is aligned with CMS' written "intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation." When the patient is healthy enough before dialysis or shortly after initiation, this is a highly desirable goal. However, the average incident ESRD patient – especially someone who "crashes" into dialysis – is often not healthy enough to be waitlisted for a transplant or to receive a living donor transplant in that first year.

ASN believes this measure does not appropriately address factors within a nephrologist's control – neither in the determination to waitlist by a transplant facility or to perform a living donor transplant as determined by a transplant surgeon. We are also concerned when CMS writes "The Pre-Rulemaking Measure Review (PRMR formerly the MAP), did not support this measure for rulemaking with the potential for mitigation to update the measure and address the concern from the Renal Standing Committee regarding the evidence base and specifications, and thus recommended this measure be resubmitted for endorsement by a CBE. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant positive correlation between the clinician activities and the addition of patients to a transplant waitlist, which are necessary for patients to receive the improved outcomes associated with kidney transplant."

In general, we do not believe this is an appropriate MIPS measure for a nephrologist.

PPPW and aPPPW

As stated above, ASN supports the objectives of these measures and notes that CMS writes "This measure and the previously proposed measure under Table A.7, the First Year Standardized Waitlist Ratio measure, work in tandem to assess initial and on-going care. This measure would assess monthly wait listing in active status of patients. It also would evaluate and encourage maintenance of patients on the waitlist." The goal of transplanting as many kidney failure patients as possible providing they are healthy enough is one ASN wholeheartedly supports. As noted above, while PRMR did not support the FYSWR, it only conditionally supported this measure and only for the PPPW. Again, leaving ASN to view these as unsupported MIPS measures for a nephrologist.

Ultimately, nephrologists play a crucial role in referring patients for transplantation; however, they have no influence over the selection process for waitlisting. Most nephrologists are unable to access and navigate the transplant center's waitlist even for patients they referred. Furthermore, it is unfair to tie physician practices success to a patient's active status when they lack any control or input regarding a patient's status as active or inactive, as reflected in the new IOTA and organ offer metrics. Active or inactive status is completely controlled by the transplant center – not the practicing nephrologist.

Additionally, there is substantial variability in listing rates among transplant centers, with standardized waitlisting rates differing widely, which further undermines the validity of this measure[vii]. The FYSWR, PPPW, and aPPPW measure in their current proposed forms underscore the need for measures that align incentives across the entire continuum of care. ASN believes the current proposed measures fall short of achieving

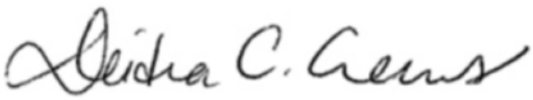
this alignment. ASN urges CMS to implement measures that more accurately reflect the role of nephrologists in the transplantation process and promote high-quality care for patients.

Conclusion

ASN stands ready to work with CMS to realize the full potential of the nephrologist's role along the entire spectrum of care for individuals with kidney diseases. We also stand with the entire house of medicine, when we ask the Biden-Harris administration to work with Congress to address the challenges posed by the current physician fee schedule and its lack of an inflationary adjustment. For any questions regarding this letter, please contact David White, ASN Regulatory and Quality Officer at dwhite@asn-online.org.

Thank you for your consideration of these comments.

Sincerely,



Deidra C. Crews, MD, ScM, FASN

President

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[i] https://www.ama-assn.org/system/files/2024-medicare-updates-inflation-chart.pdf.

[ii] Treatment of dental infections risking/causing blood stream infections (BSI), poor glycemic control, and other complications can be integral and substantially related to the clinical success of medical therapies to manage ESRD.

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[iii] Molnar, A.O., Hiremath, S., Brown, P.A. *et al.* Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis. *Syst Rev* **5**, 117 (2016). https://doi.org/10.1186/s13643-016-0297-2

[iv] Wong et al. (2018). "Effectiveness of structured pre-dialysis education in increasing the uptake of home dialysis: A systematic review." *Kidney International*, 93(5), 1016-1027

[v] Fadem et al. (2011). "Education and ESRD: A critical look at optimal patient outcomes." *American Journal of Kidney Diseases*, 58(2), 236-247.

[vi] Moist et al. (2008). "Relation between dialysis modality and risk of bacteremia in chronic hemodialysis patients." *Clinical Journal of the American Society of Nephrology*, 3(5), 1407-1413.

[vii] Kidney transplant program waitlisting rate as a metric to assess transplant access
Paul, Sudeshna et al. American Journal of Transplantation, Volume 21, Issue 1, 314 - 321