



September 10, 2023

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

Re: CMS-1784-P: CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the proposed rule for CY 2024 Payment Policies under the Physician Fee Schedule (PFS). Sustainable reimbursement for the kidney care team and other recommendations in this proposed rule are critical components of kidney care for the nearly 800,000 Americans with kidney failure, including individuals who are dependent on maintenance dialysis or a kidney transplant to live.

Kidney diseases are the ninth leading cause of death in the United States, resulting in more deaths than breast cancer, and, given the heightened risk of cardiovascular disease associated with chronic kidney disease (CKD), kidney diseases contribute to millions of additional deaths in the United States from other causes. Unfortunately, kidney diseases and kidney failure are more common among Black, Hispanic or Latinx, and Native or Indigenous Americans, Asians, Hawaiians and other Pacific Islanders, people with lower incomes, and older adults; these are populations that also have been disproportionately affected by the COVID-19 pandemic, exacerbating existing disparities.

Black Americans are 3.8 times more likely to develop kidney failure than White Americans, and Latinx Americans are 2.1 times more likely to develop kidney failure than White Americans. One out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Latinx Americans are less likely to receive a kidney transplant or initiate home dialysis when requiring dialysis for kidney failure. These and related inequities make CMS's proposals on certain health equity and social determinants of health services critically important.

ASN's comments address the following:

- CY 2024 PFS Ratesetting, Conversion Factor, and Nephrology Reimbursement
- Evaluation and Management (E/M) Visits
- Split (or Shared) Evaluation and Management Visits
- MIPS Value Pathway (MVP): Optimal Care for Kidney Health
- Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)
- Medicare Payment for Dental Services
- Medicare Diabetes Prevention Plan (MDPP)
- Telehealth Services under the PFS
- Recommendations to Increase Access to the Kidney Disease Education Benefit

CY 2024 PFS Ratesetting, Conversion Factor, and Nephrology Reimbursement

Due to statutory constraints, CMS is proposing a 1.25 percent reduction in overall payment rates with a \$1.14 (or 3.34 percent) decrease from the current CY 2023 conversion factor of \$33.89 to a conversion factor of \$32.75. In nephrology, this results in a \$1,803,000,000 (or 1 percent) payment reduction. This reduction breaks out to dialysis facility-related nephrology payments reduced by 2 percent and non-facility (E/M) nephrology payments unchanged.ⁱ

Considering the inequities and disparities in kidney diseases detailed earlier and the accompanying lack of equitable access to care for those individuals, these cuts undermine the Biden/Harris Administration's stated goals on equity. Further indicators of concern can be found in CMS' *TABLE 107: Beneficiary Service Utilization by Payment Impact Specialty Across Demographic and Equity Characteristics, CY 2022*ⁱⁱ which clearly demonstrates that nephrologists – and a handful of other specialty care clinicians – manage some of the most challenged patient groups impacted by socioeconomic factors such as Medicare/Medicaid dual eligibility and low income subsidy eligibility – in addition to high percentages of complex chronic conditions and comorbidities.

Rising prevalence and incidence of kidney diseases are being driven by concurrently increasing rates of its prime risk factors—hypertension and diabetes. At the same time, declining interest in the subspecialty—driven at least in part by newly minted physicians carrying a median educational debt of \$260,000 who are demotivated by nephrology compensation—point to troubling future potential shortages in both nephrologists and access to the specialized care only they can provide. While ASN has committed to a \$2,700,000 a Loan Mitigation Pilot Program aimed at decreasing the loan burden of those entering the field of nephrology, this program cannot by itself mitigate the negative impact of reductions in payment rates on the already severely strained nephrology workforce. .ⁱⁱⁱ

ASN applauds CMS and the Department of Health and Human Services (HHS) for prioritizing the needs of the people who are impacted by kidney diseases and are also socioeconomically disadvantaged. Recognizing the importance of CKD early detection, particularly among at-risk and socioeconomically disadvantaged populations, the United States Preventive Services Task Force (USPSTF),^{iv} is currently deliberating whether to recommend CKD screening as a preventive service. ASN eagerly awaits USPSTF's recommendation given the strong evidence that early CKD detection promotes CKD awareness and the use of evidence-based therapies. Slowing the progression of kidney diseases and increasing access for all individuals to all modalities of care including home dialysis and kidney transplantation for those with end-stage kidney disease will remain beyond our reach without this vitally important screening.

Evaluation and Management (E/M) Visits

CMS is proposing to implement a separate add-on payment for healthcare common procedure coding system (HCPCS) code G2211. CMS maintains that this add-on code will better recognize the resource costs associated with evaluation and management visits for primary care and longitudinal care of complex patients. The code will be available for all specialties to use. It is designed to recognize the inherent costs clinicians may incur, primarily in the outpatient setting, when longitudinally treating a patient's single, serious, or complex chronic condition. ASN welcomes CMS appreciation of longitudinal care of complex patients—a common denominator for nephrology patients.

In “Comparison of the Complexity of Patients Seen by Different Medical Subspecialists in a Universal Health Care System,” Tonelli and colleagues concluded that patients seen by nephrologists, infectious disease specialists, and neurologists were consistently more complex. Their methodology examined nine markers of patient complexity: number of comorbidities, presence of mental illness, number of types of physicians involved in each patient's care, number of physicians involved in each patient's care, number of prescribed medications, number of emergency department visits, rate of death, rate of hospitalization, rate of placement in a long-term care facility.^v They wrote:

“Patients seen by nephrologists had the highest mean number of comorbidities, highest mean number of prescribed medications, highest rate of death, and highest rate of placement in a long-term care facility.”^{vi}

ASN has long advocated for recognition of the responsibility placed on physicians who routinely care for complex patients. ASN notes that CMS originally finalized this policy in the CY 2021 Medicare Physician Fee Schedule final rule. However, Congress suspended the use of the add-on code by prohibiting CMS from making additional payment under the PFS for these inherently complex E/M visits before January 1, 2024.

CMS is now proposing to implement the policy in 2024. CMS writes, “If finalized, we expect that establishing payment for this add-on code would have redistributive impacts for all other CY 2024 payments, which, comparatively are less than what we initially

estimated for this policy in CY 2021, under the Medicare Physician Fee Schedule, due to statutory budget neutrality requirements.”^{vii}

ASN is pleased to see that CMS has modified its estimates on the “redistributive impacts”, but we will await final details on the actual amount paid on the add-on code and CMS’s final details on the plan for redistribution before supporting this step. ASN calls on CMS to vigorously monitor the use and impact of this code as well as provide robust information and outreach to clinicians about its proper use.

Split (or Shared) Evaluation and Management (E/M) Visits

CMS continues to propose split (or shared) E/M visits; referring to visits provided in part by physicians and in part by other practitioners in hospitals and other institutional settings. ASN believes the policy is misguided and deemphasizes the importance of medical decision making and thus the role of the physician. ASN also believes this policy is inherently counterintuitive to more recent efforts by CMS to emphasize medical decision making in justifying E/M coding.

CMS is proposing to delay the implementation of their definition of the “substantive portion” as more than half of the total time through at least December 31, 2024. Instead, CMS proposes to maintain the current definition of substantive portion for CY 2024 that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit. ASN applauds the partial delay decision, but we urge CMS to withdraw the policy altogether in the final rule.

MIPS Value Pathway (MVP): Optimal Care for Kidney Health

ASN appreciates CMS's continued commitment to the Optimal Care for Kidney Health MVP. ASN recently published the MVP development process in the Journal of the American Society of Nephrology, outlining the goals of the MVP, the measure selection process, and the collaborative development process that CMS fostered.^{viii}

CMS proposes to add six quality measures to the MVP. We support the addition of Q488: Kidney Health Evaluation to incentivize eGFR and urine albumin-to-creatinine ratio (UACR) monitoring in patients seen in nephrology clinic, such as those with diabetes and chronic kidney disease, or diabetes and resistant hypertension. ASN also supports Q493: Adult Immunization Status, in place of individual measures for influenza and pneumonia vaccination. We are also supportive of the Patient Activation Measure given its use in the Center for Medicare and Medicaid Innovation’s (CMMI) Kidney Care Choices Model, to promote alignment with the MVP and advanced alternative payment models. ASN also supports the proposed changes to the Improvement Activities measures.

ASN seeks additional clarification regarding the First Year Standardized Waitlist Ratio and Percentage of Prevalent Patients Waitlisted measures. The intent of the Optimal

Care for Kidney Health MVP is towards optimal CKD care. However, there are many existing programs and quality measures already focused on end stage renal disease (ESRD) care, and there is potential for redundancy as well as misalignment. The goal of the MVP is to optimize care for patients with CKD to slow the progression of kidney disease. Towards this goal, ASN encourages CMS to develop and implement measures that support medications such as sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy and other measures to delay CKD progression.

Finally, ASN seeks clarity on whether ESRD patients on dialysis are attributed to nephrologists in MIPS. Our understanding is that MIPS attribution of patients to clinicians primarily uses E/M codes. In contrast, the Monthly Capitated Payment for dialysis rounding uses HCPCS G-codes.

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

CMS is proposing to pay separately for Community Health Integration, Social Determinants of Health (SDOH) Risk Assessment, and Principal Illness Navigation services to account for resources when clinicians involve community health workers, care navigators, and peer support specialists in furnishing medically necessary care. While these care support staff have been able to serve as auxiliary personnel to perform covered services supporting a Medicare-enrolled billing physician or practitioner, the services described by the proposed codes are the first that are specifically designed by CMS to support services involving community health workers, care navigators, and peer support specialists.

ASN supports this proposal, as well as CMS's goal to support the utilization of community health workers, care navigators, and support specialists. These services are especially important in underserved communities, where kidney failure is most prevalent. Relatively low utilization of home dialysis in the U.S. is partially attributable to the barriers to home dialysis access for low-income communities and communities of color, which make up a significant proportion of dialysis patients. ASN strongly supports CMS' proposed steps that could increase access to home dialysis for underserved patients and those challenged by socioeconomic factors.

We believe that more individuals will be able to access important treatment modalities like home dialysis and improve individuals' quality of life if factors related to SDOH are addressed and adequate supports are given. As in previous comments to CMS, ASN urges CMS to invest in developing actionable follow-up steps for use by these members of the care team to make follow-up more meaningful and impactful for the person receiving the care.

Caregiver Training Services (CTS)

ASN also supports CMS's proposal to make payment when practitioners train and involve caregivers to support patients with certain diseases or illnesses (e.g., dementia) in carrying out a treatment plan. CMS plans to pay for these services when furnished by a physician or a non-physician practitioner (nurse practitioners, clinical nurse specialists, certified nurse-midwives, physician assistants, and clinical psychologists) or therapist (physical therapist, occupational therapist, or speech language pathologist) under an individualized treatment plan or therapy plan of care.

Since CMS solicited more general comments about payment for CTS, ASN recommends – in keeping with the totality of its recommendations in this comment letter – that CMS initiate a more expanded request for information for payment of training for other types of patients and conditions such as caregivers who assist individuals undergoing home dialysis or whose frailties due to kidney diseases do not allow them to complete all the recommendations prescribed in the plan of care.

Medicare Payment for Dental Services

ASN thanks CMS for authorizing payment for dental care prior to kidney and other organ transplant surgery. We strongly encourage CMS to finalize the proposals outlined in the CY 2024 PFS Proposed Rule to extend the policy for medically necessary dental evaluations and treatment when inextricably linked to, and substantially related and integral to, the clinical success of immunosuppressive chemotherapy for renal and other cancers.

We also urge that the payment policy be applied to medically necessary dental services clinically established to be relevant determinants of health outcomes for covered services, such as the following, for chronic kidney disease (CKD), end-stage renal disease (ESRD), and their potential infection-related complications:

CPT code 36147: AV shunt created for dialysis
CPT code 49324, 49418, Insertion of intraperitoneal catheter
CPT codes 90935, 90937, Hemodialysis procedures
CPT codes 90945, 90947: Dialysis procedure other than hemodialysis
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
CPT code 99291: Critical care services
CPT code 99490: Chronic care management
DRG code 641: Disorders of nutrition, fluids, and metabolites
DRG code 872: Septicemia or severe sepsis

Infections are the second most common cause of mortality among individuals with CKD and ESRD. Contributing to the uniquely high prevalence of infections in the population is immunosuppression associated with uremia. Other immunocompromising factors

common to individuals with kidney disease include advanced age, poorly managed diabetes, and comorbidities including autoimmune diseases requiring immunosuppressive pharmacological management.

The resulting chronic immunosuppression increases the risk of dental infections leading to potentially deadly complications including bloodstream infections, peritoneal dialysis associated peritonitis, and the exacerbation of chronic cardiovascular conditions. The danger increases with the scope and severity of dental infections.

To mitigate the risk, ASN urges CMS to extend the payment policy to include annual dental examinations, and treatment as clinically indicated, for individuals with CKD and ESRD. When established by patient-specific medical and dental parameters, dental services can be unquestionably integral to the outcome of covered medical procedures.

Medicare Diabetes Prevention Plan (MDPP)

ASN also supports CMS's proposal to extend the MDPP Expanded Model's Public Health Emergency Flexibilities for four years, which would allow all MDPP suppliers to continue to offer MDPP services virtually using distance learning delivery through December 31, 2027, if they maintain an in-person Centers for Disease Control and Prevention organization code. CMS also proposes to simplify MDPP's current performance-based payment structure by allowing fee-for-service payments for individual patient attendance.

Telehealth Services under the PFS

CMS proposes regulatory measures to implement several telehealth-related provisions of the Consolidated Appropriations Act, 2023 (CAA, 2023), provisions which ASN supported, including the temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the individual is located at the time of the telehealth service. The proposals include an individual's home; the expansion of the definition of telehealth practitioners; the continued payment for telehealth services furnished by rural health clinics (RHC) and federally qualified health centers (FQHC) using the methodology established for those telehealth services during the public health emergency (PHE); delaying the requirement for an in-person visit with the physician or practitioner within six months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and the continued coverage and payment of telehealth services included on the Medicare Telehealth Services List (as of March 15, 2020) until December 31, 2024.

ASN supports CMS's efforts to advance telehealth.

Recommendations to Increase Access to the Kidney Disease Education (KDE) Benefit

ASN appreciates CMS' recognition of the importance of the KDE benefit. ASN urges CMS to consider two steps that could make KDE more accessible to patients.

1. CMS should waive the coinsurance requirement for KDE.

Currently, Medicare beneficiaries are responsible for the 20% copay associated with KDE as a Part B benefit. For some beneficiaries, the 20% coinsurance is prohibitive to accessing these important educational services. ASN recommends that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act concerning KDE services for beneficiaries.

2. CMS should designate KDE as a preventive service.

ASN and other members of the kidney community are concerned that the coinsurance associated with KDE disincentivizes both providers and patients from taking advantage of this education. Providers are reluctant to bill patients for a service that was provided for free in the past, and patients may not have the resources to pay the coinsurance.

However, CMS has the authority to add full coverage for preventive services in Medicare through the National Coverage Determination process if the new service meets certain criteria. ASN believes that KDE meets these criteria and encourages CMS to support the inclusion of KDE as a preventive service.

Conclusion

ASN thanks CMS for its work to protect and incentivize quality care through reimbursement within the PFS. ASN urges CMS to consider the gravity of caring for the extremely vulnerable individuals impacted by kidney diseases and the true costs associated with quality care in nephrology.

To discuss the contents of this letter, please contact David L. White, ASN's Regulatory and Quality Officer, at dwhite@asn-online.org.

Sincerely,



Michelle A. Josephson, MD, FASN
President

ⁱ <https://public-inspection.federalregister.gov/2023-14624.pdf>

ⁱⁱ *Ibid.*

ⁱⁱⁱ <https://www.asn-online.org/education/training/lmp/>

^{iv} <https://www.asn-online.org/policy/webdocs/02.15.23.USPSTF.Letter.pdf>

^v JAMA Network Open. 2018;1(7):e184852. doi:10.1001/jamanetworkopen.2018.4852

^{vi} *Ibid. p.4*

^{vii} <https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-proposed-rule>

^{viii} Tummalapalli SL, Struthers SA, White DL, Beckrich A, Brahmhatt Y, Erickson KF, Garimella PS, Gould ER, Gupta N, Lentine KL, Lew SQ. Optimal care for kidney health: development of a merit-based incentive payment system (MIPS) value pathway. Journal of the American Society of Nephrology. 2023 Aug 1;34(8):1315-28.