



October 5, 2023

The Honorable Jason Smith Chairman House Committee on Ways and Means 1139 Longworth House Office Building Washington, DC 20515

Re: Request for Information: Improving Access to Health Care in Rural and Underserved Areas

Dear Chairman Smith,

The National Kidney Foundation (NKF) thanks the Committee on Ways and Means for the opportunity to provide comments on issues specifically relevant to patients living with kidney disease in rural and underserved areas across America. NKF commends the Committee's efforts to address geographic barriers, misaligned Medicare payment incentives, facility closures, and workforce shortages. NKF is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S.

<u>Priorities for Improving the Patient Experience with Kidney Disease</u>

"As a patient advocate, I visit numerous dialysis centers in the Midwest on a regular basis. Many home dialysis programs are hurting from lack of staff and patients interested in going home are not able to be trained. Consolidation of home dialysis facilities forces patients who want to achieve their best life with dialysis to drive long distance, or even worse, at times not be able to make the switch from in-center dialysis. When this happens, dialysis patient lives are in jeopardy." E. Ditschman, NKF Kidney Patient Advocate

People living with kidney disease have long faced systemic and structural inequities that have negatively impacted the quality of care received, particularly patients of diverse racial and ethnic backgrounds and those living in rural and underserved communities. Teri Browne, PhD, Dean of the University of South Carolina College of Social Work states "In rural areas, there is less access to primary care providers to diagnose chronic kidney disease, less access to kidney specialists to help manage it." She further states "This is problematic since patients in the early stages of kidney disease who have more access to all of that care can sometimes entirely postpone progression to kidney failure." 1

The NKF supports policy changes that close gaps in kidney healthcare, like those personally witnessed by a fervent patient advocate above. We are committed to creating a kidney health landscape that offers all Americans access to affordable, high quality, patient-centered care. Our specific comments

¹ https://www.ruralhealthinfo.org/rural-monitor/rural-kidney-health



for this Request for Information pertain to Sustainable Provider and Facility Financing, Aligning Sites of Services, the Healthcare Workforce, and Innovative Models and Technology.

Sustainable Provider and Facility Financing

Inadequate financing of providers and dialysis facilities through the Medicare End-Stage Renal Disease Prospective Payment System inhibits access to high quality kidney care in rural communities. In our recent comments on the CY 2024 ESRD PPS QIP Proposed Rule, NKF articulated how updates to the proposed base rates fall below measured growth rates and have fueled the exodus of healthcare workers to other industries and early retirement.

Further, NKF is gravely concerned about the dialysis facility closures across the country. Dialysis closures were uncommon in the past, but they are now frequent. One large provider closed 58 facilities in the final quarters of 2022, 53 facilities in 2023, and anticipates 100 additional facilities may be closed in the future. Another large dialysis organization with a significant market share has closed approximately 170 facilities within the last year due to on-going staffing shortages, supply chain disruptions, and increased costs resulting in economic constraints.

These closures inevitably impact patient care and quality of life, particularly among Black patients, individuals on Medicaid, and patients served at small facilities.² Closures are also associated with an increase in hospitalization rates within 180 days and suggestion of an increased risk of mortality.³ Dialysis center closures lead to patients travelling longer distances to receive care or apply for placements in acute care settings. A 2023 study found that the median one-way increase in distance traveled was 6.6 miles (IQR, 0–20.5) in small-town/rural areas using now outdated data from 2001-2015.⁴ This leads to decreased quality of life for patients as they are making these trips at least 6 times a week.

Aligning Sites of Service and the Health Care Workforce

There is an existing opportunity within the kidney care community to optimize the care available and provided at different settings in an effort to align sites of services. Current Kidney Disease Education (KDE) statutes and requirements prevent patients from receiving life-changing kidney disease education in environments that are most convenient to them, e.g., the nephrology office versus their local dialysis facility. NKF supports legislative efforts to expand the Medicare KDE benefit to allow physician assistants, nurse practitioners, and clinical nurse specialists to provide kidney disease

² Norouzi, S, Zhao, B, Awan, A, et al. Bundled Payment Reform and Dialysis Facility Closures in ESKD. *J Am Soc Nephrol*. 2020; 31(3): 579–590. doi: 10.1681/ASN.2019060575

³ Niu, J, Saeed, M, Winkelmayer, W, et al. Patient Health Outcomes following Dialysis Facility Closures in the United States. *J Am Soc Nephrol*. 2021; 32(10): 2613–2621. doi: 10.1681/ASN.2021020244

⁴ Niu, J, Worsley, M, Rosales, O, et al. Facility Closures and Distance Traveled to Receive Dialysis Care in the United States. *Clin J Am Soc Nephrol*. 2023; doi: 10.2215/CJN.000000000000274.





education, to allow the education to be administered within dialysis facilities, and expand the benefit to Medicare beneficiaries diagnosed with CKD stages 3b through 5. These amended policies will aid in the increased utilization of this benefit by decreasing barriers and improving access through two important vehicles for rural and underserved communities often impacted by worsened health disparities: cost and care setting. The elimination of the 20% coinsurance cost for KDE for patients for whom it is prohibitive to accessing care is vital.

Another opportunity exists to revitalize the current healthcare workforce and intentionally address nephrology workforce shortages in rural and underserved areas. In the examination of the adequacy of how graduate medical education (GME) slots are being distributed in rural America, evidence shows that fewer nephrology resident and fellowship positions are being filled. Potential candidates have reported the aforementioned low reimbursement rates, glacially slow innovation within the kidney disease space, and "perceptions of inadequate compensation and a poor work life balance" as contributing factors to their decision-making when determining their final specialty areas of practice outside of nephrology. Further, the current nephrology workforce is aging, with a large sector (approximately one-third) of active nephrologists being over the age of 55 years. This global trend is leaving a monumental gap in training and resources for future clinicians over the next ten years.

Kidney patients and advocates have raised the issue of dialysis facility closures and their impact on staff turnover rates over the last decade. In their experience, the loss of high-valued employees with specialized training has occurred because of low base rates. Employee churn negatively impacts the relationship established between patients and their care team. Staff members experiencing burnout have led to substandard quality of care and equity issues for certain sectors of the patient population. Reductions or complete elimination of the evening or 4th shift within dialysis facilities disproportionately impacts patients with limited work hour flexibility, leaving them with a fear of potential job loss. Physicians report an increased occurrence of prolonged hospitalization of patients due to the absence of available treatment slots within neighboring dialysis facilities.

NKF strongly advocates for policies that develop new providers and specialties in areas of the country where shortages are most acute. One solution to the nephrology workforce shortage is the expanded access of home dialysis to qualifying patients living with kidney disease. Home dialysis is delivered through two modalities, peritoneal dialysis (PD) and home hemodialysis (HHD). Of the over 550,000 Americans living with kidney failure who require dialysis, almost 85 percent must travel to an in-center dialysis clinic three times a week. Dialysis facility closures, a lack of home training programs, and unreliable transportation are major barriers contributing to missed treatments for patients in rural and

⁵ Lederer, E, and Lebowitz, J. Current State of the Workforce in Nephrology. *Adv Chronic Kidney Dis.* 2020; 27(4):281-290. https://doi.org/10.1053/j.ackd.2020.07.007

⁶ Sharif, M, Elsayed, M., Stack, A. The global nephrology workforce: emerging threats and potential solutions! *Clinical Kidney Journal*. 2016; 9(1): 11–22. doi: 10.1093/ckj/sfv111 ⁷ *Id*.



underserved areas, resulting in worsened physical well-being and increased psycho-emotional stress.⁸ In the examination of neighborhood-level Social Deprivation Index (SDI), of which a lack of transportation is a key domain, it was found that "White patients were more likely to dialyze at home [as the initial treatment modality] than Black or Hispanic patients" across three strata.⁹ Building upon the implementation of the 2011 Medicare ESRD Prospective Payment System provision for home dialysis training, NKF supports draft legislation, the Improving Access to Home Dialysis Act, which would provide Medicare coverage for staff-assisted home dialysis and expand patient modality education and home dialysis training. NKF calls on the Committee to advance the Improving Access to Home Dialysis Act.

Innovative Models and Technology

Innovative models and technology that improve the care of patients living with kidney disease include the expansion of telehealth policies for dialysis patients administered during the COVID-19 public health emergency (PHE) and the expansion of traditional add-on payments for novel devices and drugs into the Medicare ESRD Payment Bundle. Expanded access to telehealth and remote patient monitoring is key for patients with kidney disease, especially those dialyzing at home. During the COVID-19 PHE, the Centers for Medicare and Medicaid Services (CMS) exercised enforcement discretion on the frequency restrictions for ESRD-related clinical assessments furnished via telehealth and allowed phone-only visits in some circumstances for patients dialyzing at home. NKF echoes the sentiments of other stakeholders across the kidney care community and amplifies the message that telehealth and remote patient monitoring are exceedingly important even after the end of the PHE—both during times of relatively normal risk as well as if other infectious diseases pose a danger to this vulnerable population.

Kidney patients and advocates encourage the Committee and CMS to implement solutions that protect patients' access to the appropriate drug of their choice. We echo the sentiments of stakeholders across the kidney care community that additional resources should follow the patient in circumstances when the ESRD PPS base rate is not modified and the outlier adjustment is inadequate. Concerns remain that a sudden decrease in payments after the end of the Transitional Drug Add-on Payment Adjustment (TDAPA) period for new therapeutics could result in a decrease in access for these new renal dialysis drugs and biological products. In this spirit, we strongly suggest that the post-TDAPA payment adjustment that is applied to all ESRD PPS payments be extended past the current three-year proposed timeline and reflect the cost of the drug for patients that actually use the medication, as it does during the TDAPA period.

⁸ National Academies of Sciences, Engineering, and Medicine. 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25385.

⁹ United States Renal Data System. *2022 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States*. National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, US Department of Health and Human Services; 2022. Accessed September 1, 2023. Available from https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities





NKF continues to support the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and appreciates CMS' sustained commitment for innovative pathways to approve new technologies, equipment, and supplies within the kidney disease and dialysis space, including home dialysis. Kidney patients and advocates recognize the rigorous criteria required for TPNIES approval aids in a credible and principled approval process, however, they also recognize the importance of minor technological improvements to existing therapies in lieu of great strides in clinical novelty and substantial clinical improvement (SCI). Small improvements in safety or pain management are appreciated and valued and speak to the nuances that differentiate ESRD from other disease states. Specifically, we recommend an extension of the TPNIES eligibility period to five years and implementation of a post-TPNIES payment adjustment, an extension of the TPNIES program by one year, and an improvement to the claims and reimbursement process, as outlined in our comments on the CY 2024 ESRD PPS QIP Proposed Rule.

In closing, kidney health should be inclusive, regardless of a patient's racial or socioeconomic status. As one NKF patient advocate recently noted, "Going to your first in-center dialysis treatment should be an informative, caring, and supportive experience, however this was not our experience." NKF is firmly committed to achieving kidney equity for communities disproportionately affected by kidney diseases in partnership with the Committee.

The National Kidney Foundation again thanks Chairman Smith and members of the Ways and Means Committee for the opportunity to provide comments on this Request for Information to "aid the nationwide fight against chronic kidney disease by improving patient access to the most effective treatments, technology and innovations." We welcome the prospect of collaborating further on these pertinent issues. Please contact Ivory Harding, Director of Quality and Regulatory Affairs, at www.harding@kidney.org with any questions or concerns.

Sincerely,

Sharon Scribner Pearce

Senior Vice President, Government Relations