

January 23, 2023

The Honorable Bill Cassidy 520 Hart Senate Office Building Washington, DC 20510

The Honorable Tim Scott 104 Hart Senate Office Building Washington, DC 20510

The Honorable John Cornyn 517 Hart Senate Office Building Washington, DC 20510 The Honorable Thomas Carper 513 Hart Senate Office Building Washington, DC 20510

The Honorable Mark Warner 703 Hart Senate Office Building Washington, DC 20510

The Honorable Robert Menendez 528 Hart Senate Office Building Washington, DC 20510

# RE: Request for Information: Improving Care for Patients Jointly Enrolled in Medicare and Medicaid

Dear Senators Cassidy, Carper, Scott, Warner, Cornyn, and Menendez,

On behalf of the 37 million adults in America with kidney disease, the National Kidney Foundation (NKF) applauds your efforts to identify and implement policy solutions to improve integration and care coordination for individuals who are dually eligible for Medicare and Medicaid (also referred to as "duals"). This issue is particularly important to duals with kidney disease, who often struggle with complex medical needs, financial challenges, low health literacy, insufficient family or community support, and other factors that lead to poor health outcomes.<sup>i</sup>

It is imperative that policy changes to improve the care of duals focus on early awareness, detection, and management of chronic kidney disease (CKD). These policies should also empower individuals with kidney failure to choose a full spectrum of high-quality treatments that align with their goals, preferences, and values for care, including expanded access to home dialysis. Finally, any policy designed to improve care for duals with kidney disease must include enhanced access to transplantation. While there are myriad approaches to accomplishing these objectives, we encourage you to incorporate the following kidney health priorities as part of any legislative solution to improve the care of dually eligible beneficiaries:

- 1. Encourage the adoption of a USPSTF Screening Recommendation for CKD.
- 2. Expand eligibility for and accessibility of the Medicare Kidney Disease Education benefit.
- 3. Expand C-SNPs to include patients with CKD Stages 4 and 5.
- 4. Support the development of more patient-centered quality measurement.
- 5. Leverage plan flexibility to expedite patient access to transplantation



## **About Kidney Disease**

More than 37 million Americans have chronic kidney disease (CKD), including nearly 800,000 with irreversible kidney failure. Another 80 million Americans are at risk for developing kidney disease from hypertension, diabetes, and other risk factors. Unfortunately, 90 percent of those with CKD have not been diagnosed. The Medicare program spends approximately \$153 billion – more than 24 percent of total spending – on patients with kidney disease. Further, kidney failure, also referred to as end stage renal disease (ESRD), affects only 1 percent of Medicare beneficiaries but accounts for 7 percent of Medicare spending.

Kidney disease is the tenth leading cause of death in the United States, causing more deaths than widely known cancers such as breast and prostate cancer. CKD stages 4 and 5 have nearly double the mortality rate of Medicare patients with CKD stage 3 and a fourfold increased rate of mortality compared with Medicare patients without CKD. Mortality rates increase with advancing CKD stage and are magnified by the co-occurrence of cardiovascular disease (CVD) and diabetes<sup>ii</sup>. CVD is the most common cause of death for CKD patients. The proportion of CKD patients who die from cardiovascular disease increases as kidney function decreases, as do deaths from infections and other causes<sup>iii</sup>.

CKD is also associated with higher prevalence of disability. Limitations in activities of daily living (ADL) have been reported in nearly 25% of patients 65 years old and older with CKD 3 and 4. Muscle wasting and diminished physical performance occur in concert with CKD, resulting in diminished physical performance<sup>iv</sup>. Impaired physical performance of the lower extremities in CKD associated with all-cause mortality. Further, lower socioeconomic status increases disability among adults with CKD. In addition to disability, advanced stages of CKD are associated with lower quality of life.<sup>v</sup> As a result, duals with kidney disease are more likely to require care for both medical and long-term services and support needs.

## **Kidney Disease and Dually Eligibility**

The kidney patient dual-eligible population is particularly complex and expensive. Per-patient annual expenditures for dual-eligible kidney patients are \$94,253, higher than expenditures for patients enrolled in Medicare Advantage plans (\$75,263) or with Medicare coverage only (\$65,817).<sup>vi</sup>

Beyond costs, differences in patient experience persist between dual and non-dual beneficiaries, especially among patients with kidney failure. An analysis of dual-eligible beneficiaries in Pennsylvania found that duals with ESRD had higher rates of negative outcomes, such as hospitalization and skilled nursing facility admissions, than Medicare-only beneficiaries but were less likely to experience positive outcomes like access to home dialysis.<sup>vii</sup>

Finally, the social determinants of health that are common among dually eligible populations often disproportionately and uniquely affect people with kidney disease. Food insecurity – inadequate access to or high cost of fresh and healthy food options -- often prompts patients to consume foods that are low in



nutritional value or contraindicated for kidney patients (e.g., canned foods that are high in sodium, phosphorous, or other preservatives) because they exacerbate hypertension, diabetes, and CKD.<sup>viii</sup> Transportation access can also inhibit good kidney care, especially among patients with kidney failure who require thrice-weekly dialysis treatment. Patients seeking home dialysis as an alternative to in-center dialysis may have housing challenges, such as insufficient room to store equipment and supplies or outdated electric outlets that prevent them from accessing that option.<sup>ix</sup> Each of these challenges can be addressed through better coordination and integration of benefits and services.

## Recommendation #1: Improve Diagnosis, Detection and Management of CKD

As noted earlier, 90 percent of individuals with CKD are *undiagnosed.* Kidney disease can be "silent" in its early stages with mild symptoms such as fatigue, dizziness, low appetite and swollen feet and ankles. Even among patients with advanced CKD, underdiagnosis is a problem. Approximately half of patients with CKD stage 3 are undiagnosed<sup>x</sup> and as a result are less likely to access guideline concordant care for delaying and managing CKD. More troubling, as many as 38 percent of patients with end-stage kidney disease learn of their diagnosis only after their kidneys have failed, requiring them to initiate dialysis in the emergency room in what as known as a "crash" start, and up to 63 percent of patients initiate dialysis in another "unplanned" fashion.<sup>xi</sup> This is not only traumatic for the patient and costly for the system, it has significant repercussions for patients' ability to access and succeed on home dialysis.

Adoption of a USPSTF screening recommendation is the lynchpin of any effort to combat and stem the burden of CKD. Since the USPSTF issued its last CKD screening recommendation in 2012, CKD has become increasingly modifiable and screening high risk individuals for CKD has become even more important. The drug class of sodium-glucose co-transporter-2 (SGLT-2) inhibitors and non-steroidal mineralocorticoid receptor antagonists show efficacy in slowing CKD progression and reducing risk of cardiovascular disease and heart failure in patients with diabetes and CKD, as well as in patients with CKD without diabetes.

Because kidney disease is a risk factor for cardiovascular disease, it is imperative that this disease be identified so appropriate therapies be initiated not only for kidney disease but also for cardiovascular disease prevention. Kidney disease does not have symptoms usually and unless patients are screened, they may never be diagnosed and treated. Screening and diagnosis of CKD will save lives.

## Recommendation #2: Expand eligibility for and accessibility of the Medicare Kidney Disease Education benefit

Kidney Disease Education (KDE) is highly effective in promoting informed dialysis selection, optimal dialysis starts, and home-dialysis use. With proper support and expansion, it could also be used to increase rates of preemptive transplantation, thereby bypassing the need for dialysis altogether. Unfortunately, less than one percent of patients with kidney failure receive Medicare KDE prior to dialysis initiation, and African American race, Hispanic ethnicity, and the presence of congestive heart failure and hypoalbuminemia are associated with significantly lower odds of receiving KDE services.<sup>xii</sup>



Current benefit design for KDE restricts qualified health care professionals from delivering services and limits coverage to specific, finite settings. The public health emergency has demonstrated that safe and effective care can be achieved by health care teams who are located outside of the same physician office setting, while also expanding beneficiary access to much needed services, in particular those beneficiaries who were limited to access because of challenges related to transportation, long commutes to physician offices, inflexible work schedules, and/or provider shortages. We encourage you to include provisions in your legislative strategy that expands the universe of patients who can access these important services and to provide greater flexibility around qualifying health care professional and settings where services can be provided.

## Recommendation # 3: Expand ESRD C-SNPS to Patients with CKD 4 and 5

While individuals with kidney failure can elect to receive their benefits through a Special Needs Plan (ESRD C-SNPs), this care model is not available to other individuals with CKD. The existing ESRD C-SNP could provide greater value to CMS and to patients by including patients with advanced CKD (CKD stages 4 and 5). At the time that a patient transitions to CKD stage 4, slowing further progression is vital. However, this presumes that CKD has been appropriately managed up to this point, which is largely not the case at the population level. Although hypertension a common risk factor for CKD, it is uncontrolled in half of U.S. CKD patients. In addition, despite demonstrated efficacy of Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) treatment in reducing progression to ESRD, renin-angiotensin-aldosterone blockade is underused and has declined over time. Statins in patients with CKD over 50 are also dramatically underutilized.<sup>xiii</sup>Specialized care for CKD patients may also increase adherence with nutritional recommendations and medication adherence, thereby contributing to opportunities to delay further CKD progression, while also better managing the complications of comorbidities and complications of CKD that contribute the inpatient utilization and readmissions and drive increased costs to payors.

# C-SNP Care Could Improve the Transition to Kidney Failure

For CKD patients whose transition to kidney failure cannot be prevented or slowed, the current transition of care is not optimal. Coordinating the transition between CKD and kidney failure by a single payor accountable for costs and quality over this period has the potential to improve patient education and support, better manage comorbidities prior to dialysis, reducing inpatient usage and mortality after the initiation of dialysis, reduce catheter usage, increase access to preemptive transplantation, and improve patient access to other treatment modalities for kidney failure including self-care or home dialysis. The consequence of the current paradigm for CKD to kidney failure transitions is care that is expensive, low quality, and not in the best interest of patients or payors. CMS has already recognized the value of coordinated care in this setting, as evidenced by CMMI's Kidney Care Choices (KCC) model.

We strongly recommend that legislative solutions include provisions to direct CMS to expand the ESRD C-SNP model to people with CKD stages 4 and 5.



## **Recommendation #4: Support more Patient-Centered Quality Measurement**

A major challenge in the care of dually eligible beneficiaries and in other domains of kidney care is the absence of comprehensive, tested, and validated quality measurement. Historically, quality measurement in nephrology has focused on dialysis. An evaluation of 60 national kidney metrics by the American Society of Nephrology (ASN) Quality Committee found that half were related to dialysis management and none pertaining to CKD. Of the evaluated measures, over half were of medium to low validity.<sup>xiv</sup> Many of the 14 measures in the Quality Incentive Program (QIP) are not patient-centered (e.g., Standardized Fistula Rate), are topped out, or fail to target meaningful outcomes for patients (e.g., Standardized Transfusion Ratio). Of particular relevance to the dually eligible population, concerns have been raised that the QIP is not driving improvement at all; rather, it is penalizing facilities that serve structurally disadvantaged populations.<sup>xv</sup>

Simultaneously, Medicare beneficiaries are transitioning to Medicare Advantage (MA) plans. The Congressional Budget Office (CBO) estimates that over 50% of Medicare beneficiaries will be enrolled in an MA plan by 2030. Quality initiatives for MA plans, namely, the Star Ratings, similarly fail to account for kidney disease, dialysis, transplantation, or palliative care.

To assure that legislative and policy solutions to improve care for duals have their desired impact, we strongly recommend that you include provisions that lead to the development of evidence-based quality measures to support clinical practice. Proposed measures and measure concepts include:

- 1. Kidney Health Evaluation for Adults with Hypertension
- 2. Delayed CKD Progression (either process or outcome)
- 3. Optimal Starts
- 4. Home Dialysis Rate
- 5. Transplant Waitlisting or Transplant Rate

# Recommendation #5: Expedite Patient Access to Kidney Transplantation:

Access to kidney transplantation is crucial for individuals diagnosed with advanced CKD. It is the optimal therapy for kidney failure, providing significant benefits to patients and the federal government. Compared to dialysis, kidney transplantation leads to better quality of life and survival outcomes and reduces costs. Annual Medicare expenditures for beneficiaries receiving hemodialysis were \$95,932 in 2020, compared to \$39,264 for beneficiaries with a kidney transplant.<sup>xvi</sup> Legislative solutions to address care for dually eligible beneficiaries with kidney failure prioritize access to transplant care, including pre-transplant testing for transplant candidacy, transplant surgery, and long-term post-transplant care.

In the United States, kidney patients must have adequate medical and prescription coverage to receive a deceased, living, or preemptive transplant. Low-income and disadvantaged populations often lack sufficient insurance to undergo required testing for transplant surgery, hindering their access to the kidney transplant



waitlist to receive a deceased or living donor kidney.<sup>xvii</sup> Patients under the age of 65 only receive Medicare benefits once they begin dialysis, completely eliminating the option for a preemptive transplant (receiving a living donor transplant before initiating dialysis).<sup>xviii</sup> Underserved communities experience varying barriers to accessing the kidney transplant waitlist. Removing insurance as a hurdle by ensuring robust coverage for kidney patients with advanced-stage CKD would be substantially advantageous for the American public and government.

While kidney transplantation is the optimal treatment for kidney failure, living kidney donation offers superior outcomes compared to deceased donation. Given the growing kidney transplant waitlist, the scarce deceased kidney pool, and the benefit living donors have on society, we encourage you to consider how dual Medicare and Medicaid coverage can provide long-term post-living donation health coverage for living kidney donors.

## Conclusion

In closing, NKF reiterates our appreciation for your leadership and commitment to the care for some of our nation's most vulnerable population. We welcome the opportunity to further discuss these recommendations and policy solutions that improve the care, outcomes, and quality of life for dually eligible beneficiaries. If you have questions or need additional information, please contact Lauren Drew, Congressional Relations Director, at Lauren.Drew@kidney.org.

Kevin Longino CEO and Transplant Patient

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Sylvia E. Rosas MD, MSCE President

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<sup>\*</sup> https://www.cms.gov/files/document/ckd-data-highlight102020-2.pdf, and

https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-016-0297-2

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