

KIDNEY CARE FIRST

A FRAMEWORK FOR
IMPROVING RENAL DISEASE
SUPPORT & TREATMENTS



Today, 30 million people in the United States have Chronic Kidney Disease (CKD), and kidney disease remains the ninth leading cause of death in the United States.¹ Quite simply, it is an epidemic. Kidney failure, also known as End Stage Renal Disease (ESRD), affects 726,000 people in the United States but represents only a fraction of individuals who have kidney disease. The care continuum for those with CKD includes prevention and awareness; keeping people with a CKD diagnosis healthy; preventing or slowing the progression of the disease; addressing comorbidities such as diabetes, hypertension, and cardiovascular disease; and preparing for ESRD, including access to transplant, home therapy or active medical management. Thus, the scope of CKD is significant and goes far beyond ESRD and dialysis.

Kidney Care Partners (KCP) is a coalition of 34 organizations comprised of patient advocates, kidney care professionals, care providers, researchers, and manufacturers working together to improve the quality of care for individuals with kidney disease. KCP members are committed to meeting the needs of patients at every step in the continuum of care. The community of diverse KCP members share a broad, renewed vision of what the KCP policy priorities are and how they range across the full spectrum of the disease cycle, from prevention to transplant.

For many years, KCP has developed and championed a “community bill,” legislation that addressed key priorities of the KCP membership. KCP worked to ensure the successful passage of several provisions of the community bill during the last two Congresses—e.g., allowing dialysis facilities to utilize independent third-party accreditation that will expedite the ability of new facilities to begin caring for patients, permanent reauthorization of Special Needs Plans (SNPs), and improving access to home dialysis through use of telehealth. The legislation has proven an important tool for improving care for patients and building KCP visibility and credibility on Capitol Hill. Not every priority, however, is appropriate for legislative action. Toward that end, in late 2018 and early 2019, KCP developed a policy framework document for key stakeholders, including the 116th Congress, and for other educational and advocacy priorities.

The purpose of the framework is threefold:

1. To present a robust and organized list of policy priorities across the spectrum of the Chronic Kidney Disease (CKD) care continuum;
2. To provide an ongoing opportunity for members to bring new priorities for consideration by KCP and formal endorsement by the community if approved; and
3. To provide a tool for KCP to bring awareness to the high quality care and value provided by the kidney care community and to educate policymakers and other individuals and organizations about the full scope of kidney patient needs and KCP interests and priorities.

The framework is organized around five key pillars, or broad categories of KCP policy development:

1. Awareness/Prevention;
2. Patient Empowerment;
3. Quality/Access to Quality Care;
4. Innovation; and
5. Research.

Within each pillar, multiple “policy avenues”—specific policy changes or initiatives—are set forth. These policy avenues are legislative changes, regulatory changes, or community engagement opportunities.

The sections that follow provide greater detail about each pillar and policy avenue, providing an overview of the current issue and why the policy avenue is of strategic importance to kidney patients and the entire kidney care community—specifically, why it is important, why the status quo needs to be changed, and KCP’s recommendations on how to improve it.

PILLAR 1: AWARENESS/PREVENTION

Kidney disease remains the ninth leading cause of death in the United States.² As of 2018, 30 million people in the United States had CKD, and more than 700,000 people had kidney failure or ESRD.

Progression to more advanced stages of CKD is often preventable with identification and appropriate treatment, but nine of ten people who have Stage 3 CKD and are near kidney failure do not know it. As such, KCP believes it is critical to increase public awareness of CKD to allow for early identification and intervention. Awareness can be improved by addressing four specific areas:

- ▶ Increasing overall public awareness of kidney disease and strategies to prevent it and/or slow its progression;
- ▶ Preventing progression of CKD to ESRD with appropriate interventions;
- ▶ Promoting early detection of CKD; and
- ▶ Promoting healthy lifestyles.

Increasing Public Awareness of CKD and Preventing and/or Slowing Its Progression

Treating patients under age 65 in the earlier stages of CKD is challenging because Medicare only provides coverage for this population once the disease has progressed to ESRD and a transplant or dialysis is needed to live. According to the United States Renal Data System (USRDS), 16.7 percent of CKD patients were under age 60 between 2013-2016.³ Thus KCP’s goal is to increase public awareness of kidney disease and provide education on how to prevent the disease or slow its progression that can be used in the non-Medicare population as well as older patients.

Within the Medicare population, KCP believes that legislation to expand the Medicare Kidney Disease Education (KDE) benefit is needed. The KDE benefit only allows for educational services for Medicare beneficiaries with Stage 4 CKD who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a transplant. Currently, the utilization of the KDE benefit among eligible beneficiaries is extremely low. The Centers for Medicare & Medicaid Services (CMS) has stated that the specific categories of patients eligible to receive the benefit and the providers eligible to receive payment for furnishing the benefit are limited by statute.⁴ Expanding education to beneficiaries with earlier stage CKD and with CKD Stage 5, non-dialysis, as well as expanding education efforts to target the family members who may be called upon to make treatment decisions and incorporating additional providers, such as social workers, can enhance this patient-centered effort.

Additionally, KCP believes Congress should expand the Medicare Kidney Disease Education benefit to:

1. Allow dialysis facilities to provide kidney disease education services;
2. Permit physician assistants, nurse practitioners, and clinical nurse specialists to serve as referral sources for the benefit; and
3. Provide access to these services to Medicare beneficiaries with Stage 5 CKD not on dialysis.

The community bill includes language to increase access to the Medicare KDE benefit. However, our work goes beyond the legislative changes we are seeking. KCP will continue to explore additional ways beyond that to increase education for patients with CKD. In addition to addressing limitations with the current KDE benefit, KCP supports kidney disease education that spans a broader spectrum of ages and populations, promoting efforts to enhance education regarding kidney disease and its management.

Preventing Progression of CKD to ESRD

Reaching patients in the earliest stage of CKD possible is the best way to prevent progression to kidney failure; early treatment and prevention are proven effective. KCP's goal is to reach patients in the earlier stages of CKD to educate, treat, and prevent progression to ESRD, for which the only options are transplant or active medical management. Shortcomings in the current system create barriers to achieving this goal, such as the limitations of the Medicare KDE benefit. Additionally, significantly more investment in basic research is needed to better understand the pathophysiology of kidney disease in order to prevent its progression. KCP supports greater National Institute of Health (NIH) funding for such research.

KCP also will continue to explore other ways to increase education at earlier stages, since expanding the Medicare KDE benefit to earlier stages may not be a feasible way to meet the needs of the many Americans with CKD not yet eligible for Medicare. KCP is also discussing whether education could be addressed through the regulatory process or at the Center for Medicare and Medicaid Innovation (CMMI).

Promoting Early Detection of CKD

KCP believes there is a need for improved detection of CKD and better dissemination of the importance of risk stratification among those with CKD. For example, incorporating individual patient data to assess their risk of kidney disease progression and cardiovascular disease risk is important. A kidney profile, which is two tests (blood and urine), is used to calculate an estimated Glomerular Filtration Rate (eGFR) and an albumin-to-creatinine ratio (ACR) to determine the level of kidney function and kidney damage, and provides key information assessing both



cardiovascular risk and subsequent kidney failure risk. A heatmap, based upon the current staging system for CKD that incorporates these two tests, exists but is insufficiently adopted, particularly outside the kidney community. Greater efforts need to be taken to increase awareness of testing that measures kidney function to diagnose kidney disease. Better use of diagnostic methods in the primary care setting and easy-to-use home testing kits that improve early detection would allow patients and their providers to implement a care plan at an earlier stage, potentially leading to better outcomes. In addition, ensuring that the new Application Programming Interface used by electronic health records includes CKD staging that is displayed in patients' profiles may help clinicians identify patients with kidney disease. KCP is exploring policy recommendations in this area.

Promoting Healthy Lifestyles

Promoting healthy lifestyles may help prevent and/or slow the progression of CKD. Research has shown that maintaining a healthy body weight, physical activity, quitting smoking, and monitoring blood pressure can reduce the risk of poor health outcomes related to CKD,⁵ and appropriate dietary interventions can slow the progression of kidney disease.⁶ The Department of Health and Human Services (HHS) has issued statements on dietary guidelines for those with CKD to maintain good nutritional status, slow progression, and to treat complications. KCP recommends asking HHS for additional, more granular statements on dietary guidelines for CKD. For example, the Food and Drug Administration (FDA) could include more information in food and drug labeling on the quantities of phosphorus or additive phosphorus, which has been shown to increase the risk of kidney disease.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) oversees the National Kidney Disease Education Program. One of its goals is to promote evidence-based interventions to slow progression of CKD, including educating people with CKD on how to manage their condition through nutrition. KCP urges greater promotion of the National Kidney Disease Education Program.

PILLAR 2: PATIENT EMPOWERMENT

Faced with no cure and limited options for treating kidney failure, individuals with ESRD face significant, lifestyle altering, burdensome medical treatments. Patients with ESRD who do not receive a transplant must undergo dialysis three to four times per week in a dialysis center—a time-consuming procedure that can interfere with patients' ability to work and their sense of control over their life—or perform dialysis at home. It is crucial for public policy to empower patients to have control over their care. Patients should have access to the insurance plan that is right for them and their families and should have access to the same benefits as other beneficiaries if they choose to go on Medicare.

KCP seeks to empower the patient through the following policy changes to increase patient choice:

- ▶ Expanding Medigap access for patients with ESRD;
- ▶ Expanding Medicare Secondary Payer (MSP) period;
- ▶ Promoting Charitable Premium Assistance; and

- ▶ Studying the use of palliative care for patients with CKD.

Expanding Medigap Access for Patients with ESRD

The Social Security Act guarantees that Medicare beneficiaries over the age of 65 have access to Medigap plans, recognizing the role these plans have in helping patients plan and defray the cost of Medicare services. For patients with ESRD, Medicare Part B's 20 percent cost-sharing and lack of an annual out-of-pocket maximum make affordable care extremely difficult.

Whether an individual with ESRD has access to Medigap coverage is a state decision; currently only 30 states require insurers to offer Medigap coverage to Medicare beneficiaries with ESRD under age 65. In states that do not require insurers to offer Medigap coverage, people on dialysis face significant financial stress.

KCP recommends guaranteeing access to Medigap policies to all ESRD Medicare beneficiaries, regardless of age. As Medicare is a national program, so too should Medigap policies be made available nationally. KCP's community bill would require all states to make Medigap insurance policies available to all individuals with ESRD on Medicare, regardless of age. This would solve the affordability problem for thousands of individuals on dialysis.

Expanding the Medicare Secondary Payer (MSP) Period

Under current law, patients diagnosed with ESRD are eligible for Medicare after three months and have a period of 30 months where their employer group health plan and/or COBRA is primary before Medicare becomes their primary insurance. During this time, patients are not required to enroll in Medicare, but if they do, Medicare is secondary to their employer coverage or COBRA. KCP recommends extending the period for which patients with ESRD can remain on their commercial insurance as their primary coverage.

There are numerous reasons why individuals with ESRD may want to retain their employer group health plan or COBRA insurance—they might have a plan that covers dependents; they might have a plan that offers better benefits than Medicare; or they may not be able to get Medigap in their state. Ultimately, this recommendation is about empowering patients with greater freedom to choose what works best for them and their families.

KCP supports legislation that includes a provision to extend by an additional 12 months the MSP period that allows patients with ESRD to remain on their commercial insurance, i.e., for a total of 45 months after diagnosis. Enacting this policy increases patient choice and saves Medicare dollars.

KCP also supports efforts to ensure that insurers are not in violation of federal law by limiting or reducing the MSP benefit. Our members have seen their access limited due to increased efforts by insurers to limit the number dialysis visits or not cover dialysis at all. KCP is currently working with the administration to ensure patients are protected. However, if these problems continue to grow, KCP will work with Congress to strengthen these protections.

Protecting Charitable Premium Assistance

As mentioned in the MSP policy avenue above, patients who are diagnosed with ESRD have access to their primary employer group or COBRA insurance for a period of 30 months. Even patients who have Medicare as their primary insurance often have supplemental coverage from a commercial insurer, i.e. a Medigap policy. Another option that is available to patients with ESRD is to maintain or enroll in an Affordable Care Act-compliant qualified health plan, which may be the right choice for an enrollee who lives in a state that does not guarantee Medigap access to patients with ESRD under the age of 65 or who needs a plan that covers dependents. Access to the full range of health insurance plans is critical for patients with ESRD, but some patients are unable to afford the associated high premiums. Charitable premium assistance (CPA) is needed for patients with ESRD—80 percent of whom are unable to work after going on dialysis—who cannot afford their insurance premiums.



Nonprofit organizations provide premium assistance to allow these vulnerable patients to maintain access to their group health or COBRA plans, but some insurers have sought to refuse such assistance in order to remove these sick and expensive patients from their plans. Indeed, insurers have urged the administration to ban CPA to these patients if they are eligible for Medicare or Medicaid.

KCP supports legislative efforts to ensure low-income patients with ESRD have access to CPA and opposes any action by the administration or Congress to limit such assistance. KCP urges the administration and Congress to protect patient access to CPA by curtailing insurer practices that jeopardize the coverage and care of patients with ESRD who have limited resources. KCP also supports any legislative efforts to ensure the continued ability of patients to receive CPA.

Study on Palliative Care and CKD

Palliative care is specialized medical care for people living with a serious illness. Unlike other forms of medical care, it is primarily focused on relief from symptoms and stress of a serious illness. The goal of palliative care is to improve quality of life for both the patient and the family. While the purpose of palliative care is not curative, it is often layered with curative treatment. Specially trained physicians, nurses, and other specialists work together with the patient's other doctors to provide this extra layer of support.

Palliative care can be a significant benefit to patients with CKD. It can help patients manage pain and other conditions related to CKD, assist patients with critical decisions about treatment options, including dialysis and kidney transplant, and can help patients understand what to expect

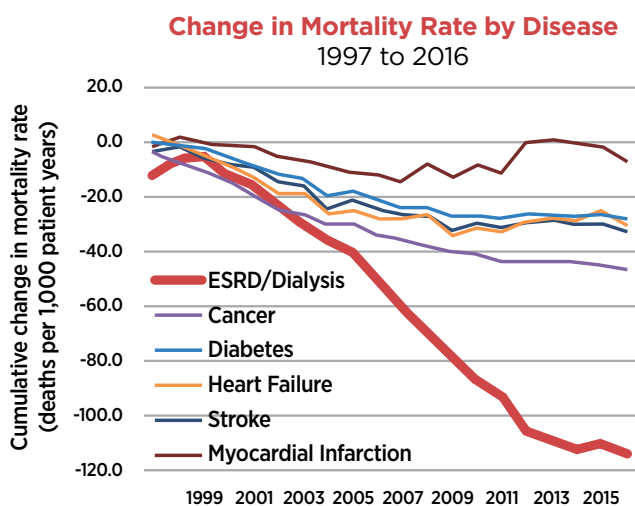
throughout the course of their illness and treatment. Finally, it can help patients deal with the stress and depression that can accompany CKD and ESRD.

More research is required to understand what kind of policy interventions would increase utilization of palliative care by patients with CKD. KCP's community bill includes legislative language that commissions a study to understand how and to what extent palliative care services are currently utilized by patients with CKD and to explore the effects of palliative care on quality of life and treatment outcomes for patients with CKD.

KCP also is supportive of studying conservative care or advanced care management. Conservative care, or advanced care management, is non-dialysis medical care for advanced CKD and kidney failure. Such a study would examine all options of care for those with advanced CKD. KCP encourages Congress to seek a study that looks at this issue.

PILLAR 3: QUALITY AND ACCESS TO QUALITY CARE

For the more than 30 million patients with CKD, and in particular for the nearly 500,000 on dialysis, data demonstrate that outcomes and quality of care have significantly improved over the past decade. Survival has improved for patients on all types of dialysis. From 2007 through 2016, mortality of Medicare patients receiving dialysis fell by 16.4 percent—more than cancer (8.5 percent), stroke (3.6 percent), or diabetes (3.4 percent). In contrast, several chronic diseases saw worsening mortality during the same timeframe, including heart failure (+1.9 percent) and myocardial infarction (+11.6 percent). From 2007-2016, hospitalization rates fell more 14 percent for patients receiving dialysis, resulting in an estimated savings to Medicare of \$775 million. In 2016, patients receiving dialysis spent an average of 2.6 to 3.4 fewer days in the hospital per year than such patients in 2007. Hospitalizations due to vascular access infection fell by 54.6 percent from 2007 to 2016.⁷



For more than a decade, KCP has provided community-wide leadership in kidney care quality. In 2005, it convened and funded the Kidney Care Quality Alliance (KCQA) to develop performance measures, worked with the CMS to harmonize like measures, and received National Quality Forum (NQF) endorsement for its measures in the areas of vascular access, influenza immunization, and patient education—with additional measures addressing fluid management and medication reconciliation receiving endorsement in subsequent years. In 2009, KCP launched a voluntary quality improvement initiative, the Performance Excellence and Accountability in Kidney Care (PEAK) Campaign, to reduce

first-year mortality. During the Campaign (2009-2012), data analyses by Brown University showed successful reduction in the first-year mortality rate for patients on dialysis by 13.6 percent and a reduction of 25 percent in the 90-day mortality rate. In 2013, KCP published *A Strategic Blueprint*

for *Advancing Kidney Care Quality*, a multi-stakeholder consensus document developed to provide a near-term roadmap on the key actions that, undertaken through collaboration and partnership, can significantly improve kidney care quality. Recognizing the importance of a more patient-centered approach to measurement, in 2017 KCQA published a multi-stakeholder consensus document identifying a framework—principles, domains and subdomains, possible priorities—related to patient-reported outcome measures for patients with ESRD.⁸

Few would argue, however, that additional improvements are needed and can be achieved. KCP believes quality and access to quality care can be significantly improved in five specific areas:

- ▶ Addressing population disparities in minority and high-risk populations;
- ▶ Addressing the shortage of health care professionals in ESRD/CKD;
- ▶ Reforming the current ESRD quality programs;
- ▶ Establishing appropriate dialysis facility measures; and
- ▶ Reducing transplant outcome measures that promote cherry-picking patients to waitlist.

Addressing Disparities

Chronic kidney disease disproportionately affects racial and ethnic minorities. Racial and ethnic minorities are significantly less likely to be treated with home dialysis and are less likely to receive a kidney transplant.^{9,10,11} Ensuring quality and access to the full range of treatment options for all patients is a high priority.

KCP has long championed the need to reduce disparities in kidney disease prevalence and access to high-quality kidney care. Toward that end we have supported, and continue to support, legislative language, which is included in our community bill, that requires the HHS Secretary to submit a report to Congress on the social, behavioral, and biological factors leading to kidney disease; efforts to slow the progression of kidney disease in minority populations that are disproportionately affected by such disease; and treatment patterns associated with providing care to minority populations that are disproportionately affected by kidney failure. KCP also recommends the Administration focus on, and Congress support, developing quality measures related to slowing the progression of kidney disease.

Addressing the Health Care Professional Shortage

As noted above, the incidence of CKD is increasing; yet the pool of specially trained health care personnel to treat patients with CKD—and especially ESRD—is shrinking. Despite an increase in the number of medical graduates, interest in nephrology among graduates is declining. From 2009 to 2016, the number of graduates entering nephrology declined by 46 percent, and the number of nephrology programs that had unfilled positions increased from 9.2 percent in 2011 to 36.8 percent in 2016.^{12,13} The national shortage of nurses, generally, is particularly acute for nephrology nurses—both nurse practitioners and RNs, with shortages particularly acute in some geographic areas (e.g., rural areas). Currently, there are slightly more than 8,400 certified nephrology nurse practitioners and RNs. A rapidly increasing emphasis on home dialysis, particularly peritoneal dialysis, intensifies the current shortage.¹⁴ The increased need for nurses will only continue to grow in the future.

The mission of the National Health Service Corps is to “build healthy communities by supporting qualified health care providers dedicated to working in areas of the United States with limited care.”

KCP believes legislation to clarify that nephrology health professionals in underserved rural and/or urban areas may participate in the National Health Service Corp loan forgiveness program can begin to address the shortage of nephrologists in some underserved areas, which also could be a driver to decrease disparities.

Reforming the Current ESRD Quality Programs

Dialysis facilities report data to the federal government under several programs. Two in particular constitute the government's primary outward-facing ESRD quality programs: The Quality Incentive Program (QIP), a penalty-based value purchasing program; and Dialysis Facility Compare/Five Star, a public reporting program. Because different measures are used (and as noted in the following section, sometimes different specifications for the same measure), the current CMS approach sows confusion for both patients and providers. For example, some four-star and five-star facilities receive penalties, while some three-star facilities do not. The plethora of measures in use, redundancy, conflicting specifications, measures where performance has topped out, lack of data from other providers in order to increase care coordination between the two programs also increases burden and diverts resources from focused quality improvement.

Even prior to the 2008 enactment of the Medicare Improvements for Patients and Providers Act that established the QIP, KCP has been a committed supporter of driving improvement in kidney care quality through value-based purchasing and public reporting. With a decade of experience at hand, however, KCP believes three specific legislative reforms would significantly enhance the QIP and Five Star programs, as follows:

- ▶ Streamline the QIP and Five Star programs to create a meaningful and parsimonious set of measures that matter.
- ▶ Require hospitals to submit discharge data to dialysis facilities in order to optimize coordination of care for dialysis patients.
- ▶ Incentivize high performers with bonus payments, as is done in other federal value-based purchasing programs (e.g., hospitals, physicians), and achieve this in a zero-sum manner by converting the pool of penalty funds to bonus payments.

Establishing Appropriate Dialysis Facility Measures

Dialysis facility performance measures are used in five ESRD programs. Measures in the QIP, Five Star, Comprehensive ESRD Care Model Survey and Certification, and Fistula First Catheter Last apply to all facilities; measures used in the ESRD Seamless Care Model apply only to those organizations participating in ESRD Seamless Care Organizations (ESCOs).

Specifications for measures matter: Precisely what data are collected, interpretation of definitions, and which patients are included or excluded affect how the measure is calculated to yield a score. In January 2018, KCP analyzed the detailed specifications and found several instances of the "same" measure using different specifications for different programs, and we also examined the impact such differences can have on facilities (e.g., being a four-star or five-star facility, yet receiving a penalty). In a similar vein, KCP has reinforced that CMS's own measure testing documents poor reliability of certain measures for small- and even medium-sized facilities. KCP also has documented concerns about the validity of measures due to under-reporting of events (e.g., the bloodstream infection measure) or due to coding changes (e.g., the Standardized Transfusion Ratio). We also

have noticed that the persistent use of measures in the QIP that are topped out (e.g., adequacy) can result in differential total performance scores despite the fact that attaining 98 percent vs. 97 percent on the measure has no clinically meaningful impact.

To date, KCP has worked to address its concerns about appropriate dialysis facility measures via regulatory advocacy, given the technical and specific nature of the subject. Currently, however, KCP believes increased Congressional oversight and a legislative approach is warranted, given that these issues have not been addressed for several years.

Reducing Transplant Outcome Measures that Promote Cherry-Picking Patients to Waitlist

KCP recognizes that transplant is the best renal replacement therapy for most patients and the need to incentivize it as a quality imperative is critical. Overall, patients who receive a kidney transplant have better survival and quality of life, as well as health care cost savings compared to patients on dialysis. In fall 2018, USRDS reports that 81,418 people were on the kidney transplant list as of December 31, 2016.¹⁵

One way to incentivize transplant is through performance measurement. Currently, performance measures exist to incentivize dialysis facilities to improve the percentage of its population on a transplant waitlist, but transplant centers, which control who is waitlisted, focus on successful outcomes. Importantly, no standardized criteria for waitlist placement exists, and criteria for who may be waitlisted vary broadly by transplant center, which could result in cherry-picking only those patients most likely to have a successful outcome. Of note, while some progress has been made in reducing race and ethnicity disparities associated with kidney transplantation, disparities by race and ethnicity persist.^{16,17}

KCP believes that the opportunity for a patient with ESRD to get on the transplant waitlist should be the same regardless of where a patient is referred and not dependent on different criteria at different transplant centers. Different criteria raise the potential for selective placement on a waitlist because the measures for facilities versus transplant centers are not directionally aligned. To promote equity, Congress could commission a study to assess the disconnect between performance measurement at dialysis facilities and transplant centers.

PILLAR 4: INNOVATION AND PAYMENT SYSTEM STABILIZATION

Currently, more than 700,000 Americans are living with kidney failure.¹⁸ Nearly 500,000 of these individuals rely on dialysis treatments to survive.¹⁹ Individuals living with kidney failure often have multiple chronic conditions, requiring their carefully coordinated care. These individuals also are unique because Congress made a commitment to them several decades ago that they would be eligible to enroll in Medicare, if they wanted to do so, based upon their diagnosis of kidney failure rather than solely on their age. Today, roughly 85 percent of dialysis patients rely on Medicare to fund their care.

While the Medicare benefit has assisted hundreds of thousands of patients, the current payment policies have become barriers to individuals with kidney failure being able to access the care they need. These same policies also threaten to stifle innovation in therapies and new treatment options.

KCP remains deeply concerned about the long-term viability of the Medicare dialysis program. Simply put, the Medicare rates are inadequate to cover the cost of providing services. For example, the Medicare Payment Advisory Commission (MedPAC) in its most recent analysis estimated that the margin is -1.0 percent for 2017 and projected only a -0.4 percent margin for 2019.²⁰

While already low, this estimate does not account for additional revenue reductions, such as the Network Fee that reduces each payment by \$0.50 and the substantial amount of unrecovered bad debt. If just these two amounts were taken into account, the average margin would be several points negative. Using CMS data, The Moran Company estimates that 55 percent of facilities have negative margins—their revenues do not cover the cost of providing services already.

Addressing the chronic underfunding of the Medicare ESRD payment is critically important to support ongoing improvements in the quality of care for dialysis patients, as well as to establish a pathway for incentivizing innovation in an area that has seen very little.

But the ESRD prospective payment system (PPS) is not the only aspect of promoting innovation. KCP also supports the efforts to modernize the ESRD program through new payment models, breaking down artificial silos that create barriers to care, and incentivizing innovation in the treatment of ESRD. Moreover, KCP urges CMS to address the underlying barriers to home dialysis and transplant—the vast majority of which lie outside of the traditional dialysis facility setting.

To achieve these goals, KCP believes that the payment system should be improved in the following ways:

- ▶ Promoting innovative clinical care models, drugs, and devices
- ▶ Removing payment barriers to innovating patient care
- ▶ Stabilizing the Medicare ESRD PPS and improving dialysis payment
- ▶ Improving access to transplant

Promoting Innovative Care Models and Research by Supporting Innovative Care Models, Drugs, and Devices

KCP supports the efforts to develop innovative treatment models in kidney care, particularly to address the delivery of dialysis. As discussed in more detail below, KCP also agrees that more can be done to increase the number of patients receiving home dialysis or transplant, but to achieve these goals it is important to address the underlying sociological and economic barriers patients face. It also will be critical to establish consistent transplant waitlist criteria and align transplant center facilities to these criteria so that every dialysis patient has the opportunity seek a transplant. We support efforts to test a variety of models to allow providers to participate in such models regardless of size, location, and affiliation.

Another critical aspect of promoting innovation in kidney care focuses on research. The historic underfunding of the ESRD payment system has created disincentives for the development of new drugs, biologicals, devices, and innovative treatment options. As noted below, the current payment policies for new drugs has only made this problem worse. While we commend the efforts of

KidneyX and support greater funding for this effort, it will be difficult, if not impossible, to translate research supported by KidneyX into actual patient care if there is not a viable payment pathway that recognizes the need for additional funding in the PPS.

In addition, KCP continues to work to identify and try to remove other barriers to innovation in the area of kidney care. One such barrier is the lack of access to hospice care for dialysis patients. It is important that federal policy recognizes the continuum of care that patients living with kidney care require. To that end, dialysis patients who wish should be allowed to receive hospice care.

Stabilizing the Medicare ESRD PPS and Improving Dialysis Payment

Eighty-five percent of patients with ESRD rely on Medicare to pay for dialysis. Given the oversized role Medicare has in covering this population, it is critical that the Medicare bundled payment adequately and fairly reimburses the cost of providing care. KCP continues to prioritize stabilizing the Medicare ESRD PPS and establishing a payment system with appropriate incentives to promote patient care. Specifically, CMS should fix unresolved problems with the current method for calculating the PPS bundled payment amount. These fixes include:

- ▶ Eliminating application of comorbid case-mix adjusters;
- ▶ Eliminating the outlier adjustment;
- ▶ Requiring HHS use the age adjustor from CY15;
- ▶ Requiring CMS to reassess the weight adjusters;
- ▶ Mandating an update to the standardization factor based on the most recently available data;
- ▶ Restoring the requirement that CMS consider reasonable costs before finalizing the bundled rate to ensure that rate covers the cost of providing services;
- ▶ Requiring CMS to include the Network Fee as an allowable cost or offset to revenue in the ESRD cost report;
- ▶ Eliminating bad debt restriction on composite rate items and services; and
- ▶ Establishing ESRD-specific productivity rate and, in the short-term, at least limit the amount of the adjustment, if margins are below a defined percentage.

MedPAC also has called for CMS to address the methodological problems, particularly both the patient-level and facility-level adjusters.²¹ Taken together, these provisions would make the bundled payment rate more accurate and stop funding designated for dialysis payment from being inappropriately removed from the system.

Given the lack of drug and device therapeutic innovations during the last 25 years, it is also important that the payment system establish the necessary incentives for investors to return to drug, biological, and device development for patients with kidney failure. Simply adding new products to a bundle without addressing any potential increase in the costs of adding these products creates will not work. Independent analyses, like those of MedPAC, have consistently shown that the bundle is underfunded. Dialysis patients deserve better; Medicare payment rates should not be a barrier to accessing innovative therapies. KCP is committed to working with federal policymakers to develop a responsible pathway for new products to be added to the ESRD PPS and, when appropriate, new dollars must be added as well.

As the ESRD PPS enters its second decade, KCP also hopes to work with federal policymakers to ensure its future viability as well. This includes engaging in a data-driven approach to rebasing and re-calibrating the ESRD, when such actions are appropriate. While cost containment is important, the priority of these tasks should be to make sure that the ESRD PPS rates cover the cost of providing high quality dialysis services and incentivizes innovation and improvements in care.

KCP continues to support developing innovative payment models, but until comprehensive reform can take place, it is critically important to ensure the integrity of the ESRD PPS so that patients not enrolled in such models remains a strong and viable option.

Improving Access to Transplant

While dialysis is an important, life-sustaining option for individuals living with kidney failure, so is a kidney transplant. KCP is committed to working with others in the transplant community to:

- 1. Improve access living kidney donor organs and deceased donor organs.** One aspect of increasing access to transplant is creating a sufficient number of kidneys available for transplant. To that end, KCP supports the “Living Donor Protection Act,” which protects the rights of living organ donors.

Similarly, KCP welcomes the opportunity to work with transplant organizations and federal decision-makers to identify how changes in quality measures could improve access to deceased organs. We also look forward to working in collaboration with the transplant community to identify other ways to increase the number of organs available for transplant.

- 2. Address reimbursement barriers to transplant with MA plans.** KCP is pleased that Congress has recognized that starting in 2021 dialysis patients should be able to select and enroll in Medicare managed care options, even if they qualify for Medicare because of disease status and not age. As patients select this option, it is equally important that MA reimbursement policies support getting these patients to transplant.

- 3. Standardizing waitlist criteria and requiring United Network for Organ Sharing (UNOS) to share data/listing of patients on transplant list with dialysis facilities.** Currently, each transplant center has the authority to establish its own criteria for patients seeking a kidney transplant to be added to its waitlist. Numerous inconsistencies across centers make it difficult for patients to identify when they are a candidate. Some of these criteria are so restrictive that they seem to cherry-pick only a handful of potential recipients, eliminating access for the vast majority of dialysis patients. KCP supports efforts to standardize and align the waitlist criteria.

In addition to standardizing waitlist criteria, it is important to establish greater transparency. While dialysis facilities do not control the waitlist, it would be helpful if they were informed which of their patients are on the waitlist so facilities, who may see patients as much as thrice weekly, can assist them in maximizing their health readiness for a transplant. Currently, facilities must rely on patients to let them know and that information is not always as accurate or current as it could be. Improving transparency would be an important step forward.

- 4. Improving Medicare immunosuppressant drug coverage.** For transplants to succeed, recipients must maintain a strict immunosuppressive drug treatment regimen. For recipients who are younger than 65 years old, their coverage for these drugs is limited. The entire kidney care community has supported legislation during the last several Congresses to address this inequity. The time for passing it is long overdue.

PILLAR 5: RESEARCH

NIDDK leads the NIH's research on kidney diseases. A January 2017 General Accounting Office (GAO) report found that NIDDK was the largest funder of biomedical research of kidney diseases, providing 60 percent of funding for kidney research across the NIH, and was the single largest funder of kidney research conducted by the federal government, including the Department of Defense, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Department of Veterans Affairs, and Patient Centered Outcomes Research Institute.²² While NIH's budget allocation has grown since that time, it only represents 2 percent of the annual total cost of care for kidney failure.

Since the GAO study was published, the number of patients with kidney diseases and associated costs to the taxpayer also have risen. There are now more than 700,000 Americans living with kidney failure; Medicare spends \$35 billion managing kidney failure and \$114 billion managing kidney diseases, 23 percent of all Medicare spending.

Despite the immense gap between the federal government's expenditures on kidney care and its investment in kidney research, NIDDK-funded scientists have produced several major breakthroughs in the past several years that require further investment to stimulate therapeutic advancements. For example, geneticists focused on the kidney have made advances in understanding the genes that cause kidney failure, and other kidney scientists have developed an innovative method to determine if new drugs cause kidney injury before giving them to patients in clinical trials. NIDDK launched the Kidney Precision Medicine Project that will focus on targets for novel therapies—setting the stage for personalized medicine in kidney care.

Basic and clinical research is important to prevent and treat kidney diseases. For fiscal year 2019, NIDDK is funded at \$2.02 billion, a \$59 million increase from the previous year. Total Medicare spending on patients with CKD and ESRD in 2018 was more than \$114 billion. Given the overall burden of kidney disease, clearly more research dollars are needed to better prevent and detect kidney disease.

Research can be improved by addressing two specific areas:

- ▶ Ensuring adequate funding for CKD/ESRD research programs; and
- ▶ Increasing the interest in research in the field of nephrology

Ensuring Adequate Funding for Kidney Research

Greater investment in kidney research should be an urgent priority to deliver better outcomes for patients and bring greater value to the Medicare program. In March 2019, KCP supported a Congressional appropriations letter led by the American Society of Nephrology and American Society of Pediatric Nephrology and signed by 27 organizations representing patients, physicians, and providers.

The letter to House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Chairwoman Rosa DeLauro and Ranking Member Tom Cole requested that a \$2.5 billion increase for the NIH be included in the Labor/HHS (LHHS) Appropriations bill, with a robust increase for NIDDK that was at least proportional. The letter also requested Congress consider a Special Statutory Funding Program for Kidney Research at \$150 million per year over 10 years, building off the success of the Special Statutory Funding Program for Type 1 Diabetes Research. As of April 2019, a \$2 billion increase for the NIH was included in the LHHS bill.

Additionally, increased support for the Centers for Disease Control and Prevention CKD Surveillance Program is merited. Additional funding for the program to raise awareness of CKD and continue its surveillance activities would enhance prevention, which as noted in Pillar 1 is a key priority.

Increasing the Interest in Research in the Field of Nephrology

To more effectively treat CKD and facilitate improvements in patient care, we need to strengthen the nephrology workforce and increase interest in nephrology careers that include an emphasis on research. Incentivizing research training and encouraging research grant submissions by nephrologists are among the steps that could achieve this. KCP also is exploring potential legislative efforts to support a HRSA grant to support nephrology training and/or NIDDK investment in the Network of Minority Research Investigators. KCP is interested in examining the existing gaps in this area to determine what more should be done.

ENDNOTES

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