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RE: Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government Request for Information

On January 20, 2021, President Biden signed an executive order to advance racial equity and support underserved communities.¹ As part of this initiative, federal agencies should assess how their programs or policies address systemic barriers that affect people of color and other underserved groups. One area where the impact of systemic barriers has been prevalent is health care. People living with kidney disease (Chronic Kidney Disease or CKD) and kidney failure (End Stage Renal Disease or ESRD) are disproportionately from communities of color. As described in detail in this document, Kidney Care Partners (KCP) believes that existing federal policies in the area of kidney care could be modified to address inequities in the care provided to patients living with kidney disease and kidney failure. It specifically highlights how data (including information from quality metrics) could be used to support greater attention to equity (Area 1) and identifies barriers created by existing federal policies (Area 2) that affect the delivery of kidney care to individuals from communities of color.

KCP appreciates the opportunity to provide suggestions about how existing policies can be modified to address gaps and/or barriers in care. We are a coalition of more than 35 organizations, comprised of patient advocates, dialysis professionals, care providers, researchers, and manufacturers, dedicated to working together to improve quality of care for individuals with CKD. Our mission is to involve patient advocates, care professionals, providers and manufacturers to ensure:

- Individuals living with kidney diseases receive optimal care;
- Individuals living with kidney diseases are able to live quality lives;
- Dialysis care is readily accessible to all those in need; and
- Research and development lead to enhanced therapies and innovative products.

Specifically, KCP has identified a set of recommendation for the different stages of kidney disease and the treatment of kidney failure. In brief, we recommend:

- For early stages of the disease:
 - Remove barriers to accessing preventive and chronic disease management services, including: expanding the Kidney Disease Education benefit, and removing fraud and abuse restrictions that limit the provision of kidney disease education.
- For patients living with kidney failure and requiring transplant or dialysis:
 - Expand selection of home dialysis;

¹Executive Office of the President. Executive order 13985: Advancing racial equity and support for underserved communities through the federal government. Washington, DC: The White House, January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>. opens in new tab)

- Expand access to transplant by working with transplant centers to address disparities created by waitlist criteria;
- Remove barriers to care coordination created by fraud and abuse laws;
- Revise the Medicare ESRD prospective payment system to make sure:
 - Reimbursement policies promote innovation;
 - Funds targeted for reimbursement are not withheld for case-mix and facility-level adjusters that divert funds away from patients who need them the most; and
 - The outlier policies address the needs of high-cost patients and do not take money out of the system through inappropriate withhold amounts; and
- Revise measures used in the ESRD QIP (and Five Star) to:
 - Empower patients by providing valid and reliable performance data; and
 - Drive meaningful change.
- For purposes of testing new payment delivery models:
 - Refine the benchmark methodology;
 - Improve the scoring methodology;
 - Support early sustained growth in patient adoption of home dialysis modalities; and
 - Adjust selection methodology to protect small dialysis organizations.

I. Patients with Kidney Disease Are Disproportionately from Communities of Color and Experience Inequities in the Delivery of Health Care

Disparity in the incidence of ESRD between Blacks and Whites is striking, and progress in closing this gap has been slow. According to the USRDS 2020 Annual Data Report,² the adjusted prevalence of ESRD was 3.4 times higher in Blacks than Whites in 2018. ([USRDS Figure 1.8](#) by race) Ten years earlier, that ratio was 3.8, highlighting the slow progress in addressing the disparity in ESRD prevalence.

Likewise, ESRD prevalence in Hispanic populations was found to be more than 1.5 times higher than in non-Hispanics in 2018. ([USRDS Figure 1.8](#) by ethnicity) Additionally, Black, Asian, Native Hawaiian or Pacific Islander, and multiracial populations were more likely to be diagnosed later in the disease process. For example, compared to 58% of White patients, 74% of Blacks were diagnosed with ESRD at an eGFR of less than 10 mL/min/1.73 m². ([USRDS Figure 1.20](#) by race and by ethnicity)

Black and Hispanic patients also frequently experience barriers to receiving a transplant or being able to select home modalities.³ Black patients are less likely to initiate peritoneal dialysis (5.9%) or receive a preemptive kidney transplant (20.9%) than White patients (8.1% and 33.2%, respectively). Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years. ([USRDS Figure 6.9](#) by race) Between 2017 and 2018, the number of Black patients on the waiting list for a kidney transplant decreased 4.7%, compared to only a 1.2% decrease in White patients. The number of White patients on the waiting list with active status increased 0.5% between 2017 and 2018, compared to a 1.0% decrease in Black patients. In 2018, the prevalence of preemptive wait-listing was 5.0% among White patients and 3.9% among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7% in White patients and 10.3% in Black patients. The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent during the past 3-4 years, whereas a large disparity in the living donor transplant rate remains and accounts for the difference in overall

² United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. Chap. 1. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

³*Id.* at Chap. 6.

transplantation rates between Black and White individuals in 2018. Hispanic or Latino patients were also less likely to receive a preemptive transplant (1.75%) than non-Hispanic patients (2.56%).⁴

Dialysis patients are often poorer and sicker than other Medicare beneficiaries and rely on federal and state subsidies and welfare programs, such as Medicaid. In 2018, ESRD beneficiaries made up about 1% of total Medicare enrollment and 2.5% of dual-eligible enrollment.⁵ The dual-eligible population may also have different social risks, with associated implications for health outcomes and service use. Dually eligible beneficiaries with ESRD are more often people of color and have higher costs compared to non-duals, despite similar utilization patterns to their non-dual-eligible counterparts.⁶ The systemic barriers to accessing basic healthcare likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure; for example, Medicare–Medicaid dual eligibility status has been found to correlate with a lower likelihood of pre-ESRD nephrology care.⁷

II. Early Stages of the Disease

The systemic barriers to accessing basic health care likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure. The leading causes of CKD and ESRD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.⁸ We know from several years of research that people of color have more difficulties accessing preventive care and chronic disease management services.⁹ It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in their diseases not being fully managed, which led to the development of kidney disease.

There are very limited comprehensive disease management programs for individuals at-risk of developing kidney disease. Other than six educational sessions for a small number of existing Medicare beneficiaries, Medicare does not offer benefits specific to CKD to help patients manage and slow the progression of their disease.¹⁰ The program that does exist is not widely utilized.

The KDE education benefit is one way to help patients prepare for dialysis by sharing their options. However, the program should be expanded to allow patients to access it earlier in the disease state and to allow more providers to be able to provide their services. Legislation introduced in the Senate and soon to be in the House would: (1) allow dialysis facilities to provide kidney disease education services; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage V CKD not yet on dialysis.

Such programs can be rare in commercial insurance as well. Because Medicare provides a safety net of coverage for ESRD patients, many commercial plans include provisions in their plan designs that essentially

⁴*Id.*

⁵Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

⁶ Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

⁷ Nee R et al. Impact of poverty and race on pre-end-stage renal disease care among dialysis patients in the United States. *Clin Kidney J.* 2017;10(1):55-61.

⁸ Richard V. Reeves & Faith Smith. “Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System.” *Brookings*. <https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/> Aug. 7, 2020). accessed June 28, 2021.

⁹Kenneth E. Thorpe, Kathy Ko Chin, Yarira Cruz, et al. “The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases.” *Health Affairs* (Aug. 17, 2017) <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full/>. accessed June 20, 2021.

¹⁰As discussed below, Medicare through its demonstration programs has tested and plans to test additional health care delivery models to better manage CKD. To date, none of these programs has resulted in changes to the fee-for-service benefit in which the vast majority (xx%) of ESRD patients are enrolled.

push their enrollees into Medicare before the individuals are legally required to give up their commercial coverage. KCP and its members have documented multiple examples of this type of behavior and raised concerns about the ongoing practice for the last several years. Given that these plans can avoid the cost of dialysis and/or transplant, they have little to no incentive to spend resources and time trying to prevent the progression of kidney disease to kidney failure.

Another early patient decision points in Stage III or IV can be modality selection. During the last several years, KCP has sought to work with the federal government to remove barriers that make it more difficult for patients who want to select home dialysis to do so. Thus, KCP is pleased that the Administration has prioritized encouraging more Medicare beneficiaries who require dialysis to select home dialysis modalities. As the GAO has noted, there are many reasons that patients may not select these modalities, most of which center around socio-economic issues. However, we recognize that there are steps the federal government can take to help expand education and incentives. With this goal in mind, we encourage CMS to adopt the following policies:

- Expand the Medicare Kidney Disease Education program, as noted above, to: (1) allow dialysis facilities to provide kidney disease education services under certain circumstances; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage 5 Chronic Kidney Disease (CKD) not yet on dialysis.
- Remove fraud and abuse barriers by allowing ESRD facilities to provide education of CKD patients;
- Support collaboration among providers by waiving fraud and abuse restrictions so that:
 - Health care providers are allowed to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression; and
 - Licensed health care professionals should be allowed to provide education on all modalities to a hospitalized patient with kidney failure at the request of the patient's care team, including discussion of in-center and home dialysis modalities, management of kidney failure without dialysis, and kidney transplantation. The decision regarding modality choice should be the result of a shared decision-making process between the patient and the nephrologist.
- Collect social determinant of health data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about these barriers and develop policies to overcome them and to be able to set target rates of home dialysis adoption.

Additionally, we encourage OMB to work with the community to support funding for screening individuals for kidney disease on regular basis. There are treatment options and steps individuals with the disease can take to slow its progression, but they must be aware of the condition first. Along these lines, KCP also supports legislation introduced in the Senate that would add kidney disease screening to the Welcome to Medicare visit.¹¹

As an organization that represents patients, physicians, nurses, other health care professionals, manufacturers, and dialysis facilities from more than 30 different kidney care organizations throughout

¹¹S. 1971, "Chronic Kidney Disease Improvement in Research and Treatment Act."

America, we have focused on helping the federal government maintain its strong and unique commitment to Americans living with kidney disease. As the Administration continues to seek ways to address health disparities, we encourage CMS to work with KCP on the recommendations identified in this letter to align the payment system with this goal.

III. Patients with Kidney Failure

After an individual develops kidney failure, they are uniquely able to access Medicare benefits. Medicare's ESRD benefit provides coverage to dialysis services beginning three months after a person's initial diagnosis with kidney failure. However, once an individual with kidney failure begins dialysis as a Medicare beneficiary, he/she face another set of systemic barriers.

A. Patient Choice

1. Modality Choice

First, a significant number of individuals who present with kidney failure did not even know they had kidney disease. As a result, they often must rely upon a catheter to initiate dialysis. Catheters have been shown to increase infection and lead to other complications. Infections not only create immediate health concerns, but also erect another barrier to transplant. Many transplant centers refuse to waitlist patients based on their infection rates.

Second, the vast majority of individuals with kidney failure present with multiple comorbidities that make managing kidney disease more difficult as well. For the most part, these comorbidities do not affect the cost of providing dialysis treatments, they do result in many individuals not being listed on transplant waitlists because of overly restrictive transplant waitlist criteria.

KCP has consistently called on the Department of Health and Human Services (HHS) to remove the barrier that overly restrictive transplant waitlist criteria create for individuals in need of a kidney transplant. As noted below, these criteria disproportionately affect people of color, which is shown by the lower number of racial and ethnic minority patients who receive transplants.

Third, once in the Medicare ESRD benefit, these individuals have little to no access to care coordination. Federal fraud and abuse laws prohibit providers from working together in many cases. While these laws were meant to prevent abusive practices, they need to be revised to promote care coordination activities. Specifically, KCP recommends:

- Remove fraud and abuse barriers by providing safe harbors from Stark/anti-kickback laws for providers who furnish telehealth equipment needed for home dialysis.
- Support flexibilities related to telehealth that are being provided during the pandemic, but maintain the requirement for at least one physician visit each month to be an in-person visit. These flexibilities should provide support so that socio-economic barriers can be eliminated for patients who seek telehealth visits.
- Create incentive payments for nephrologists and facilities linked to home dialysis adoption.
 - Increase the physician payment for home training from \$500 (which has been the rate for more than 30 years) to \$1750, which is the \$500 amount updated for current dollars. The initial \$500 could be paid at the outset, while the increase of \$1250 could be paid out after a patient has completed six months of successful home dialysis treatments.

- Establish bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for peritoneal dialysis (PD) catheter placement in line with AV Fistula reimbursement.
- Eliminate barriers created by ESRD QIP and DFC/Five Star measures to allow for more transparency for patients seeking home dialysis performance information.
 - Eliminate the pooled adequacy of dialysis measure and replace it with the four individual dialysis quality measures to allow patients to see facility performance on home and pediatric dialysis, rather than have them rolled up in a single measure that disincentivizes the use of home dialysis. Addressing the problem of small numbers for pediatric facilities should not be resolved in a manner that eliminates transparency related to home dialysis care.
 - Expedite the process for establishing a home dialysis CAHPS, as well as a pediatric CAHPS.
- Affirm that physicians have the ability to prescribe the dialysis dose that is medically necessary for their patients and to preserve the flexibilities that Medicare Administrative Contractors (MACs) have to reimburse for more than three treatments per week with medical justification.

2. Coverage Choice

In addition, some patients who are diagnosed with kidney failure and requiring dialysis prefer to enroll in Medicare Advantage (MA) plans. These plans can provide the wrap around services that traditional Medicare does not provide. For example, dialysis patients seeking a transplant often face barriers because they do not have access to dental services. Twenty of the States do not allow Medicare beneficiaries under 65 years old to access Medigap plans.¹² Other patients seek the care coordination services that so many MA plans offer, but traditional Medicare restricts.

However, just at the time the Congress expanded access to MA plans for the patients, the previous Administration eliminated dialysis services – including facilities and nephrologists – from the Network Adequacy Requirements. KCP remains concerned that without this requirement, some plans will remove dialysis facilities and nephrologists from their networks, reducing the availability of MA plans for dialysis patients.

Similarly, some commercial plans have sought to discourage dialysis patients from maintaining their commercial insurance plan after they have been diagnosed with ESRD. For these patients, commercial plans may support additional services, require lower coinsurance obligations, or provide important coverage for their family members. Sometimes these plans include provisions in their plan design that increase cost-sharing obligations or impose other penalties that incentivize patients to enroll in the Medicare program and drop their commercial coverage. Other plans may reject charitable assistance provided by third parties that provide patients with limited funds to offset the cost of their premiums. More than 60% of the recipients of charitable premium assistance grants were dialysis patients and kidney transplant patients from communities of color. In 2020, 1 in 14 kidney transplant recipients were able to get a transplant because a charity paid for their health insurance.¹³ When insurers reject payments from charities, insurers disproportionately reduce the number of people of color from their health insurance rolls.

¹²CMS. “When Can I Buy Medigap?” <https://www.medicare.gov/supplements-other-insurance/when-can-i-buy-medigap> (2021) accessed 29 June 2021.

¹³American Kidney Fund. “Charitable Premium Assistance: A Lifeline for Low-Income People with Chronic Conditions.” <https://www.kidneyfund.org/advocacy/third-party/charitable-premium-assistance-one-pager.pdf> (2021) accessed 29 June 2021.

These policies that restrict patient coverage choice, which is inconsistent with the intent of the Affordable Care Act and the Congress in expanding access to MA plans, disproportionately affects dialysis patients, who as noted are primarily from communities of color.

B. Challenges Created by the ESRD PPS

In addition to these factors, the ESRD prospective payment system (PPS) includes policies that also create inequities in the health care services that dialysis patients receive.

1. Creating a Pathway for Innovation

Individuals living with kidney disease, especially kidney failure, have not experienced the same level of medical innovation that others living with conditions like cardiac disease or cancer have been able to access during the last 30 years. The work HHS and CMS have done to remove barriers to adopting innovative products and services for kidney care is an important starting point to incentivize innovation and innovative treatment options. Fostering innovation in kidney care generally is also central to the Administration's goals of reducing inequities in health care.

The Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and Transitional Drug Add-on Payment Adjustment (TDAPA) have been a positive step toward removing the barriers created by the ESRD PPS. Yet, as currently designed, these policies do not address the need for long-term stability because they do not include policies to adjust the base rate, even in an incremental way, when new certain new products are added to the bundle. As noted elsewhere in this letter, even if the KCP-recommended changes to the TDAPA and TPNIES were adopted, it is time to modernize the ESRD PPS to support innovative care options, promote patient choice, and eliminate barriers to care coordination.

TDAPA provides a two-year transition payment for certain new products that are renal dialysis services, but currently CMS only allows for adjustment to the bundled rate incrementally when these drugs or biologicals are added to the PPS bundle in limited circumstances. The current policy is that CMS will not adjust the base rate when new innovative drugs and biologicals that would be within existing ESRD functional categories are added into the bundle. We also ask that CMS return to the original policy that the TDAPA period would be two to three years and reimbursed at ASP+6%. This would allow CMS to collect at least two full calendar years of data to determine the utilization before folding the product into the ESRD bundle.

While we understand that there may be challenges to establishing a TPNIES for capital-related asset devices more generally, these challenges should not be allowed to create a barrier to incentivizing the adoption of truly innovative capital-related assets generally. In addition, we recommend that CMS also apply TPNIES for three years to allow it to assess the effect of adding the devices to the PPS bundle and evaluate the base rate to determine if an incremental adjustment would be necessary to support ongoing access to the device. We support structuring TPNIES to help bring innovative products to all kidney care patients.

Adjusting the base rate for truly innovative products is essential to expanding innovation to those living with kidney disease. The statute establishing the payment system anticipated such adjustments,¹⁴ so there is sufficient authority to provide for these incentives.

In addition, we ask that CMS coordinate the policy with the Medicare Advantage (MA) program, so that the additional funding for these products is also incorporated into the reimbursement MA program. We ask CMS to take steps¹⁵ to ensure that there is adequate funding for innovative products in the MA program as well.

¹⁴42 U.S.C. § 1395rr(b)(14).

¹⁵See, 42 C.F.R. §422.109.

2. Payment Adjusters

Second, the ESRD PPS contains adjusters that misallocate dollars in a way that harms all patients. CMS and its contractor designed these adjusters with the best of intentions to direct dollars toward caring for patients who require more services. However, work undertaken by The Moran Company for KCP, as well as the Medicare Payment Advisory Committee's (MedPAC) analysis, show that the adjusters are not appropriately targeting high-cost patients. This means that the money withheld to fund the adjusters remains unspent in the Medicare program and does not go to patient care. Even if some facilities claimed these adjusters, the inaccurate targeting means that there are patients for whom the reimbursement rates are lower than they should be. Lower rates of reimbursement can jeopardize access to individual services, types of health care professionals, or even dialysis itself.

Age. Age is one of the patient characteristics for which CMS has the discretionary authority to establish an adjuster.¹⁶ The current age categories and payment modifiers do not align with clinical experience. When CMS adopted the current age adjusters groups, The Moran Company raised concerns with the contractor's methodology that selected the 70-79 group as a reference with no adjustment appears to be a requirement of the statistical method and is not based on actual cost variation with age. The age groups identified as "higher cost" do not incur greater costs of care than their counterparts. In contrast, there is a significant distinction in the cost of caring for a pediatric patient versus an adult patient. The lack of correctly targeting higher costs patients means that the age adjusters randomly provide more money for some patients than others. It would be more appropriate to ensure that dialysis facilities receive adequate reimbursement for all dialysis patients who are 18 or older to support their care.

Reducing the reimbursement rate for younger dialysis patients in favor of older patients perpetuates an inequity in the delivery of health care. Blacks are on average younger (58.1 vs. 64.5 years).¹⁷ This misallocation of funds is significant because the value of the age adjuster was evaluated to be as much as \$20.00 per treatment, nearly 8% of the total base rate. Put in context, the annual inflationary update CMS applies is valued around 2% each year, which equals about \$5.00 per treatment. When CMS increased the value of the age adjusters, it did so without identifying the rationale or data supporting the substantial increase, which was 159% over the historic value of the adjusters. The Moran Company and MedPAC suggested at the time that a problem with the regression analysis led to the faulty outcome. The data publicly available indicated that the age distribution of the dialysis population had changed very little when comparing the 2009 age mix (which was used to finalize the 2011 base rate) to that in 2013. Similarly, there was very little difference in separately billed services by age category in 2013 data, reflecting the decrease in use of ESAs and some other drugs since 2011. There were no concerns expressed about limited access to dialysis services for any of the age groupings. Thus, it was unclear and in fact appears inappropriate to have modified the age adjuster. Since that time, KCP has not been able to identify any data suggesting that this modified age adjuster is appropriately targeted more costly patients. It seems to remain the result of a flawed analytical process.

While the adjusters may be claimed because it is easy to indicate a patient's age on a claim form, it does not mean that the reduction in the base rate for other patients is appropriate. Establishing the simple age adjusters of <18 years old and ≥18 years old would address this problem. Making sure that facilities have sufficient funds to care for dialysis patients is a step in the direction of making sure health care is equitably delivered.

¹⁶SSA § 1881(b)(14)(D)(i).

¹⁷Lauren M. Kucirka, Sc.M., Morgan E. Grams, M.D., M.H.S., Justin Lessler, Ph.D.(3), *et al.* "Age and Racial Disparities in Dialysis Survival." JAMA. 2011 August 10; 306(6): 620–626. doi:10.1001/jama.2011.1127.

Weight. Body Mass Index (BMI) is also one of the patient characteristics for which CMS has the discretionary authority to establish an adjuster.¹⁸ Clinicians agree that patient weight can lead to higher costs in managing the patient. They rely on BMI for adjusting patient treatments.

The ESRD PPS includes not only a BMI adjuster, but also a Body Surface Area (BSA) adjuster. BMI and BSA are both variables for the same patient characteristic. As such, they are highly correlated and should not function as independent variables in a regression analysis because they essentially measure the same thing. Patients who are underweight and qualify for a positive adjuster for low BMI are also subject to a BSA adjuster, which applies to all patients, including those with a low BMI. The BSA adjuster for low BMI patients is negative and offsets almost all of the benefit of the positive low BMI adjuster. According to an analysis by The Moran Company, the vast majority of patients with low BMI receive reduced payments because the BSA adjuster eliminates the value of the BMI adjuster. Only the very small number of patients with low BMI are eligible for any net positive adjustment.

Lower BMI is associated with a significantly higher mortality risk during the first year of dialysis therapy.¹⁹ The relative incidence of kidney failure among blacks is 2.7 times higher than among whites.²⁰ Peer reviewed studies have shown that Blacks under the age of 50 are at substantially increased risk of death on dialysis.²¹ While there are many factors that affect these outcomes, it would still be beneficial to eliminate a policy that cancels out additional funds that could otherwise be used to help these patients.

The weight adjusters are important, and we urge CMS to focus the BMI adjuster on overweight and underweight patients, eliminating the BSA adjuster. Clinicians have indicated the characteristics of overweight and underweight do require more staff time and that different supplies or equipment may also be necessary. Because the BSA adjuster applies to all patients, it does not meet the policy goal of recognizing the point at which body size results in higher staffing costs or specialized equipment. Refocusing the BMI adjuster to target the higher cost patients would ensure that the increase in reimbursement rate is targeted appropriately to the higher cost patients and is constructed using a clinical metric that is meaningful to physicians and patients.

Case-Mix Adjusters. The comorbid case-mix adjusters are patient characteristics for which CMS has the discretionary authority to establish an adjuster; the statute does not mandate their creation or application.²² Access concerns related to patients with these comorbid conditions may have arisen in 2010 because some of these conditions often require greater amounts of ESAs. The Agency noted in the CY 2011 final ESRD PPS rule that “[o]ur analysis has identified certain co-morbidity diagnostic categories that have shown higher use of separately billed renal dialysis items and services, which are recognized for a payment adjustment under the ESRD PPS.”²³ CMS has acknowledged that “the costs were identified with increased utilization of ESAs and other services.”²⁴ Clinical practice has changed significantly since the data used to establish these comorbid case-mix adjusters were collected and analyzed.

Recent work by CMS contractors during 2019 and 2020 suggests that there is little to no variation in cost in dialysis patients based on these comorbidities. There is no indication that patients with any of these comorbid conditions have difficulty accessing care. Yet, they are burdensome on patients and providers. “The

¹⁸SSA § 1881(b)(14)(D)(i).

¹⁹ Polinder-Bos, H.A., Diepen, M.v., Dekker, F.W. et al. Lower body mass index and mortality in older adults starting dialysis. *Sci Rep* 8, 12858 (2018). <https://doi.org/10.1038/s41598-018-30952-2>.

²⁰USRDS. *Annual Report*. (2020). <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>. accessed June 12, 2021.

²¹Kucirka, *supra* note 15.

²²SSA § 1881(b)(14)(D)(i).

²³*Id.* at 49100.

²⁴CMS, “Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Proposed Rules.” 80 *Fed. Reg.* 37808, 37817 (July 1, 2015); *see also* CMS, “Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule and Proposed Rules.” 75 *Fed. Reg.* 49030, 49099 (April 12, 2010).

inclusion of adjustment factors for comorbid conditions that are poorly identified on dialysis facility claims may cause undue burden on patients undergoing additional diagnostic procedures in order to meet documentation requirements, and reflect differences only in the cost of formerly separately billable services.”²⁵

The documentation requirements outlined in the Benefits Policy Manual for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome create the same overly burdensome requirements that CMS has recognized for bacterial pneumonia and monoclonal gammopathy when it eliminated these adjusters. The burden on facilities and, in some instances, patients make the cost of documenting the requirements greater than any potential benefit a facility might receive from claiming the adjuster. As described below, clinician can account for these conditions in ways that do not require additional, expensive tests that require patients to seek additional health care visits and shoulder the additional coinsurance costs associated with them. The next few paragraphs provide the real-world example of how patients with these conditions are examined and treated, without increasing the cost of providing services to them.

Pericarditis. Pericarditis is the inflammation or swelling of the thin sac-like membrane surrounding the heart. This condition is one that can occur suddenly and rarely lasts long. Only a small number of patients receiving dialysis experience this condition. While patients may report atypical chest pain and nephrologists may listen to the patient’s heart for the pericardial friction rub, nephrologists rarely require patients to incur the cost of having an electrocardiogram before simply treating the condition based upon the patient’s report and listening to the patient’s heart.

Yet, to document this condition, the Benefits Policy Manual requires “suggestive electrocardiogram changes (e.g., widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported” in addition to listening for the pericardial friction rub. Thus, as with the bacterial pneumonia, the documentation requirements are inconsistent with current diagnostic practices. Because of this fact and the small number of patients with the condition and its short duration, KCP recommends that CMS eliminate the pericarditis comorbid case-mix adjuster and allow facilities to rely upon the outlier policy for those patients who may incur higher costs because of this condition.

Gastrointestinal (GI) Tract Bleeding with Hemorrhage. While GI tract bleeding may account for the greater use of some drugs or biologicals, the cost of meeting the current documentation requirements exceeds any potential benefit that this adjuster might provide. In speaking with nephrologists, it is clear that while many patients may experience GI bleeds, the treatment protocol is to treat to the condition rather than require patients to receive one of the expensive tests the Benefits Policy Manual sets forth. Few dialysis patients obtain an endoscopy, colonoscopy, adionuclide scan, or radionuclide imaging, and/or angiography to confirm the condition. Even if a patient does undergo one of these procedures, it can be difficult to identify the actual clumping of the arteries that cause the bleed. Additionally, once a patient has had one of these procedures, it is unlikely that a nephrologist would order a second or third one simply to confirm what he/she already knows has likely occurred again. Thus, for the same reasons that CMS proposes to remove the monoclonal gammopathy comorbid case-mix adjuster (documenting it requires patients to undergo procedures they otherwise would not), CMS should eliminate the GI bleeding comorbid case-mix adjuster. Facilities that experience higher costs related to patients with this condition can instead rely upon the outlier policy.

Hereditary Hemolytic or Sickle Cell Anemia. In the CY 2011 Final Rule, CMS included hereditary hemolytic anemias (including sickle cell anemia) as a case mix adjuster, citing analyses showing higher ESA usage for dialysis patients with anemia of chronic kidney disease that also have hereditary hemolytic anemias. While some studies have shown that hereditary hemolytic or sickle cell anemia in ESRD patients with anemia of CKD is associated with higher ESA utilization, this condition is present in a small percentage of the ESRD

²⁵MedPAC, Comment Letter on the ESRD PPS CY 2017 (2016).

population²⁶ and the current documentation requirements do not align with clinical practice. Nephrologists monitor patient hemoglobin levels to determine the dosing of ESAs. While it may be of interest to know definitively whether a patient has hereditary hemolytic or sickle cell anemia, the fact that a patient requires more ESA to maintain target hemoglobin levels is independent of the specific diagnosis. Thus, rather than require patients who do not already know their status to undergo one of the tests outlined in the Benefits Policy Manual, nephrologists focus on managing the patient's anemia. Thus, it becomes extremely difficult, if not impossible, for facilities to meet the documentation requirements for this condition. An approach that is more consistent with clinical practice would be to rely upon the outlier policy to address the higher costs.

Myelodysplastic Syndrome. The extremely few dialysis patients with myelodysplastic syndrome (MDS) are battling not only kidney failure, but also a potentially fatal blood cancer. In caring for these patients, nephrologists focus on keeping them from being uremic. Given the small number of dialysis patients with MDS and the difficulties in documenting the disease, we recommend that CMS eliminate the comorbid case-mix adjuster and instead rely upon the outlier policy.

When these adjusters remain in effect and are not claimed, dollars meant for patient care are removed from the system. These dollars could be directed to help address patient needs, such as improving patient education about home modalities, helping patients navigate the transplant process, improving the placement of fistulas, receiving adequate dialysis doses (including treatment compliance), and achieving targeted hemoglobin levels. All of these metrics are associated with decreased dialysis survival and which Blacks are less likely to receive.²⁷

Low Volume/Rural Adjusters. In addition to the case-mix adjusters that remove dollars inappropriately from patient care, the facility level adjusters for low-volume and rural facilities result are also not targeted. The inequitable results lead to fewer resources in facilities not designated as rural, as well as those low-volume facilities that do not make the "cut" to receive the current LVPA. While the low-volume adjuster is mandatory, a rural adjuster is discretionary.²⁸

The solution that MedPAC has proposed is similar to the recommendations KCP and others in the kidney care community have made during the last several years. We propose that CMS eliminate the overlap between the rural and low-volume adjuster by relying upon a two-tiered low-volume adjuster policy, with the current low-volume adjuster being the first tier and the second tier applying to facilities with 4,001-6,000 treatments per year.

Making sure that facilities with fewer patients over which they can spread their fixed costs will protect access to dialysis patients who rely on those facilities. A rural adjuster focuses on facilities in certain ZIP codes and assumes there is low-volume in those areas. It is a blunt instrument that does not match the specific problem it seeks to solve. That problem is increasing the reimbursement rate for dialysis facilities who have fewer patients over which to spread their fixed costs. The government has an interest in keeping these facilities open to serve patients who otherwise would not have access to a local facility. In contrast, the low-volume adjuster specifically addresses this problem. It also includes a mechanism to eliminate the potential for gaming.

MedPAC has recognized this interest that:

A key objective of rural payment adjusters is to maintain access to care. Areas with low population density may have only one small, low-volume provider. In these cases, costs may

²⁶Vimal K. Derebail, Eduardo K. Lacson, Jr., Abhijit V. Kshirsagar *et al.*, "Sickle Trait in African-American Hemodialysis Patients and Higher Erythropoiesis-Stimulating Agent Dose" *J. Am. Soc. Neph.* (Jan. 23, 2014)(published online).

²⁷Kucirka, *supra* note 15.

²⁸SSA § 1881(b)(14)(D)(iii) & (iv).

be above traditional PPS rates because the low population density prevents economies of scale, and the low volume and high costs may be beyond the providers' control. Special payments by federal or local sources may be needed to maintain access to care in these communities.²⁹

In its *Report to the Congress*, MedPAC raised concerns about rural adjusters as often being too broad and recommended a more targeted approach: "Payment adjusters should be targeted to providers that are necessary to preserve beneficiaries' access to care."³⁰ Of particular interest to the Commission is the use of low-volume adjusters. Maintaining specific distance requirements, which CMS has established for the ESRD low-volume facility adjuster, is a critical component of MedPAC's recommendation.³¹ In evaluating the then current rural adjusters, MedPAC noted:

In general, most adjusters succeed in increasing payments to rural providers, which is important for keeping access to care in certain isolated areas (Medicare Payment Advisory Commission 2005). However, the programs are rarely targeted to isolated providers, and in some cases the magnitude of the payment is not empirically justified.³²

MedPAC has also expressed concern about the overlapping nature of the ESRD low-volume and rural adjusters in its most recent Commission meetings. In the April 2019 meeting, the staff presented an "illustrative example" of a single low-volume and isolated (LVI) facility adjuster that would better target payments. As that [analysis](#) demonstrates, the rural adjuster allows larger facilities to receive the adjustment, even though they do not have the same challenges as the facilities with fewer patients. The tiered low-volume adjuster KCP recommends and that MedPAC suggests would better target the adjustment to those facilities with fewer patients and that are isolated.

We believe that the 4,001-6,000 range is appropriate based upon an analysis prepared by The Moran Company. While it is not possible to replicate the geographic isolation criteria, The Moran Company was able to perform an analysis of cost report data to show the distribution of low treatment volumes in relation to facilities' margins. Based upon this analysis, it is clear that facilities with 4,001-6,000 treatments per year also experience significantly negative margins per treatment and rural facilities with more than 6,000 treatments generally exhibited normal Medicare margins, making it inappropriate to provide them with a low-volume adjustment. This second-tier low-volume adjuster would allow CMS to target the dollars directly to those facilities that struggle because of a smaller patient base.

Additionally, the revised low-volume adjuster recognizes that some isolated facilities are in urban areas, not only rural. These areas tend to serve Black and Hispanic patients who are also facing socio-economic barriers that impact their health care. Better targeting funding to isolated facilities that are essential to the communities they serve will help those facilities provide high quality care to these otherwise marginalized patients.

3. Outlier

Since the beginning of the ESRD PPS, the outlier pool has not paid out the full amount withheld each year. As described below, now that calcimimetics qualify for outlier payments, there may be a significant shift of the patients who qualify for outlier payments. It is important to address both the longstanding issue that outlier thresholds are consistently set too high, resulting in underpayment of the outlier pool, and to address the emerging issue of significant shifts in outlier eligibility when new therapies become eligible for outlier

²⁹MedPAC, *Report to the Congress*, 154 (June 2012).

³⁰*Id.*

³¹*See id.* at 155.

³²*Id.*

reimbursement to protect access to such therapies by ensuring that outlier payment is available for higher-cost cases. Any year when the outlier pool retains dollars that are not paid out, KCP recommends that CMS reallocate those dollars to support reducing the barriers that create inequities in the care dialysis patients receive. These funds could be used to support educational programs, support pilot programs related to improving specific health care outcomes (such as nutrition), or simply returned to the system as an increase in the base rate. We appreciate that some of these ideas may need to be addressed with legislation, but we also believe that it is important to consider creative solutions to this long-standing problem that can help those patients most in need.

As CMS has explained each year, the dollars withheld for the pool have never been paid out in a manner that reaches the 1.0% withhold. This has meant that dollars intended to reimburse the costs associated with more expensive patients have not been distributed and are lost to the system. Historically, KCP and others in the kidney care community have recommended that CMS reduce the outlier pool withhold to less than 1% and, in some years, even to zero. We continue to believe this approach would be consistent with the intent of the Congress. When it authorized the pool, the Congress did not set a minimum percentage. We reiterate this recommendation.

With the inclusion of the calcimimetics in the ERSD PPS, there could be new challenges with regard to the outlier pool. First, CMS is projecting substantial increases to outlier thresholds, both the FDL and MAP amounts. As described below, this could further exacerbate the longstanding issue of the outlier pool being underpaid. In addition, the proposed substantially higher thresholds will require greater losses before the outlier pool will be triggered.

Second, The Moran Company has found that the cases qualifying for outlier payment could shift. The proportion of the outlier payments associated with patients receiving any new drug could increase substantially. They also found that many patients whose treatments historically qualified for outlier payments would no longer qualify under the current policy due to the significant increase in the outlier threshold. Any new product that qualifies for the outlier pool and has a significant cost associated with it will lead to higher threshold amounts. This will make it more difficult for the outlier pool to support the costs associated with other products, because those costs alone may no longer meet the higher threshold. This situation could lead to the outlier pool being primarily consumed by a single group of services.

There are likely different ways to address this issue. KCP would like to work with CMS on developing a long-term solution to ensure outlier availability to mitigate losses incurred by facilities that treat patients with higher-than-average costs and to apply the outlier payments to a variety of high-cost patients.

C. ESRD Quality Programs (QIP and Five Star)

KCP continues to support efforts to assess and account for social risk³³ factors in the ESRD QIP Program and other quality programs through adjusters and other mechanisms, but recognize that the right balance must be struck to ensure that disparities are identified without inadvertently disincentivizing the provision of care to more medically complex patients. We have asked CMS to examine measures used in the ESRD QIP and other federal accountability programs to determine how social risk might impact performance and whether risk adjustment for such factors might improve the ability to differentiate true differences in performance between facilities. In addition, some of the measures currently in the ESRD QIP and Five Star programs do nothing to address disparities in care and, in some cases, perpetuate the current problems. As

³³ Borrowing from the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) definition from its 2016 *Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*, "social risk" factors include dual enrollment in Medicare and Medicaid as a marker for low income, residence in a low-income area, Black race, Hispanic ethnicity, and residence in a rural area.

described below, KCP asks that CMS eliminate or revise these measures to promote health equity and allow the ESRD quality programs to truly empower patients and their care partners.

Standardized Transfusion Ratio (STrR). KCP has asked CMS to eliminate the use of the STrR measure and adopt in its place an outcomes-based measure for anemia management measure, such as Hgb <10 g/dL.³⁴ The STrR is based on transfusion information to which dialysis facilities do not have access because it is maintained by hospitals or outpatient departments that refuse to provide the information to dialysis facilities even when asked. This fact makes the measure something that facilities cannot act on to improve. As a result, the measure does nothing to improve patients' hemoglobin levels, which has a significant impact on their quality of life. Lower hemoglobin levels are associated with the following symptoms including:

- Fatigue or tiredness;
- shortness of breath;
- unusually pale skin;
- weakness;
- body aches;
- chest pain;
- dizziness;
- fainting;
- fast or irregular heartbeat;
- headaches;
- sleep problems; and
- trouble concentrating.³⁵

Because Black patients often have more difficulty maintaining higher hemoglobin levels, the STrR's lack of actionability can perpetuate the disparity between Black and White patients.

A measure of Hgb < 10 g/dL is preferable. It is actionable and targets the very patients who need help. Hemoglobin values less than 10 g/dL are more prevalent in Blacks, afflicting 27.2% and 30.6% of Black hemodialysis and peritoneal dialysis patients, respectively, compared to 23.8% and 22.7% in Whites.³⁶ While transfusions may be more prevalent in Black dialysis patients, the differences are smaller and result from decisions made in the hospital rather than the dialysis facility. For example, 23.4% of Black dialysis patients received one or more transfusion(s) in 2018, compared to 22.9% of Whites.³⁷

There is both historic and current higher ESA use among Black and Asian patients on home dialysis, while the differences for hemodialysis patients are small. ([USRDS Figure 2.2](#) by race). For instance, 61% of Black and 63% of Asian patients on peritoneal dialysis were administered ESA each month during 2018, compared with 52% of White patients.³⁸ However, irrespective of modality, the mean hemoglobin values among patients treated with an ESA were lower for Blacks than Whites, 10.33 compared to 10.43 mg/dL, respectively, in hemodialysis patients and 10.13 versus 10.32 mg/dL in peritoneal dialysis patients. ([USRDS Figure 2.3](#) by race).

These data points demonstrate that a measure focused on better management of anemia in the dialysis facility will more likely lead to improved patient outcomes than a measure directed at transfusions, which are

³⁴ United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

³⁵ NIDDK. "Anemia in Chronic Kidney Disease." <https://www.niddk.nih.gov/health-information/kidney-disease/anemia#complications> (accessed June 22, 2021).

³⁶ United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. Chap. 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

³⁷ *Id.*

³⁸ *Id.*

one or more steps removed from the dialysis setting. Doing so could help improve the outcomes of Black patients.

Standardized Hospitalization Ratio (SHR) and Standardized Readmission Ratio (SRR). The QIP should use true risk-standardized rate measures, as the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. CMS could use the underlying hospitalization and readmission rates and appropriately risk adjust them using race and ethnicity, as is done with the Standardized Mortality Ratio (SMR). It should also build off of its prior contracted work with NQF and develop socio-demographic adjusters and submit the new measures to NQF for endorsement consideration.

Given the burden that hospitalizations and readmissions have on patients, having a metric that accurately represents the performance of facilities is critically important to empower patients. In 2018, the adjusted rates of overall hospitalizations among Medicare ESRD beneficiaries were fairly high among all patients:

- White: 1,771 hospitalizations per 1,000 patients
- Black/African American: 1,758 hospitalizations per 1,000 patients
- American Indian/Native Alaska Native: 1,572 hospitalizations per 1,000 patients
- Asian: 1,183 hospitalizations per 1,000
- Native Hawaiian/Pacific Islander: 1,512 hospitalizations per 1,000 patients³⁹

When compared with the general Medicare population, these rates are extremely high. One study looking at 2016 data found that there were 243.2 hospitalizations per 1,000 patients in traditional Medicare and 185.4 hospitalizations per 1,000 patients in Medicare Advantage plans.⁴⁰ The Kaiser Family Foundation reports there were 240 hospitalizations per 1,000 Medicare beneficiaries in 2018.⁴¹ Clearly, hospitalizations and the related readmissions rates are areas where there could be substantial improvement for all patients, but especially patients from communities of color.

In addition to not accurately reflecting facility performance because of the use of a ratio rather than a rate and the lack of being risk adjuster, the SHR and SRR measures are not reliable, with overall inter-unit reliability (IUR) of 0.35 and 0.55, respectively. (Statistical literature traditionally interprets a reliability statistic of 0.50-0.60 as “poor”.⁴²) Importantly, reliability statistics were not stratified by facility size when the measures were most recently submitted to NQF for endorsement maintenance.

Prior trends reported by CMS indicate that smaller facilities will likely have IURs significantly lower than the global statistics presented above, such that the scores received by smaller facilities can be expected to be largely attributable to random noise and not signal. Such facilities, many of which treat small rural or low-income communities, will be disproportionately impacted, resulting in random and specious penalties being imposed on the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.

³⁹ *Id.* at ESRD Ref. G. Hospitalizations G.2.1.

⁴⁰ Robert Graham Center. “Understanding the Impact of Medicare Advantage on Hospitalization Rates.” (2016) https://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/BMA_Report_2016.pdf (accessed June 22, 2021).

⁴¹ Kaiser Family Foundation. “Medicare Service Use: Hospital Inpatient Services.” (2021) <https://www.kff.org/medicare/state-indicator/medicare-service-use-hospital-inpatient-services/?currentTimeframe=1&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (accessed June 22, 2021).

⁴² Adams JL. *The Reliability of Provider Profiling: A Tutorial*. Santa Monica, California: RAND Corporation. TR-653-NCQA, 2009.

Moreover, patients residing in such areas, already shouldering significant social risk-related disparities, cannot trust the measures as a valid representation of performance to help inform their decision-making. KCP believes ensuring performance measures addressing these critical clinical topics provide reliable information is vital to improve outcomes and necessary to reduce facility and patient burden and confusion, and that it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size.

Percentage of Prevalent Patients Waitlisted (PPPW). KCP remains concerned about the use of the PPPW in the ESRD QIP. The NQF has formally rejected this measure, concluding that it lacks validity. Lacking validity means that the PPPW measure does not accurately measure its facility performance. Part of the problem is that the measure fails to measure actions taken by dialysis facilities. “Fair and accurate attribution is essential to the success of value-based purchasing and alternative payment models.”⁴³ If patients or other stakeholders were to use it to make medical decisions, they would be using invalid information.

An invalid measure will only perpetuate the substantial health disparity that exists when it comes to accessing transplants. The disparities in wait-listing are pervasive and well-documented:

- Black patients are less likely to receive a preemptive kidney transplant (20.9%) than White patients (33.2%).
- Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years.
- The number of White patients on the waiting list with active status increased 0.5% between 2017 and 2018, compared to a 1.0% decrease in Black patients.
- In 2018, the prevalence of preemptive wait-listing was 5.0% among White patients and 3.9% among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7% in White patients and 10.3% in Black patients.
- The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent over the past 3-4 years, whereas a large disparity in living donor transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018.⁴⁴

Transplant centers assess a myriad of demographic factors—*e.g.*, family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, among others. Use of these types of sociodemographic factors only reinforces that those who face sociodemographic barriers when it comes to health care generally will now also experience them when it comes to trying to access a kidney or other organ transplant.

Recognizing the importance of developing a measure that is actionable and reflects the work dialysis facilities undertake to help patients be added to waitlists, KCP through the Kidney Care Quality Alliance (KCQA) is convening a group of transplant and kidney care experts to develop a measure that will be submitted to NQF for consideration. We encourage CMS to work with the community in this process. Until a valid measure is developed, we ask that CMS not perpetuate the inequities in the transplant system by using a measure that will penalize facilities treating the patients most in need of resources to address their health needs.

Standardized Fistula Rate and Long-Term Catheter Rate. KCP supports the use of the standardized fistula rate and long-term catheter rate measures in the ESRD QIP. However, CMS should consider adjusting or stratifying both vascular access measures for age, race and ethnicity, and insurance status prior to dialysis

⁴³NQF, “NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services” 13 (March 1, 2019).

⁴⁴United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. Chap. 6. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

initiation. Vascular access discrepancies have been consistent for both incident and prevalent over the past decade. Most recently:

- In 2018, highest catheter use at hemodialysis initiation was observed in adults aged 18-44 years (86.5% versus 63-65% in other age groups), patients of Hispanic or Latino ethnicity (84.7% versus 80.0%), and those with dual eligibility for Medicare and Medicaid (85.7% versus 79.5% in patients with Medicare as a secondary payer, for instance).
- In prevalent patients that same year, catheter use was much higher in women than men (19.9% versus 15.8%), in Whites (18.3% versus 14-17% in other race groups). Distribution of vascular access was similar among those with Medicare fee-for-service and those in Medicare Advantage plans.⁴⁵

Stratifying the quality measures will allow health care providers and other stakeholders to identify and prioritize differences in care, outcomes, and experiences across the different racial and ethnic groups. They will be able to develop and implement equity-focused practices to address disparities and better understand the experiences of patients from communities of color.⁴⁶ Thus, we encourage CMS to stratify these measures to help address the clear gaps that exist in the area of vascular and home dialysis access placements.

Patient Satisfaction Measure. In the ESRD QIP and Five Star programs, the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) serves as the patient satisfaction metric. KCP believes it is important to include the ICH CAHPS in the ESRD quality programs, but the fielding of the current measure has created such a high level of patient burn-out with completing the lengthy survey twice a year that the measure is no longer valid. CMS's own data show that response rates are low and continue to drop, threatening the validity of ICH-CAHPS as an accountability measure. Response rates are currently approximately 35%, raising concern for possible underrepresentation of patient groups. For instance, in a cross-sectional analysis of survey administration to 11,055 eligible in-center hemodialysis patients across the U.S., Dad et al.⁴⁷ reported in 2018 that non-responders (6,541 [59%]) significantly differed from responders, broadly spanning individuals with fewer socioeconomic advantages and greater illness burden, raising limitations in interpreting facility survey results. Non-responders were more likely to be men, non-white, younger, single, dual Medicare/Medicaid eligible, less educated, non-English speaking, and not active on the transplant list.

Understanding the patient's perspective and incorporating it into health care decision-making is critical. Rather than be a barrier to the Administration's goal of achieving that outcome, ICH-CAHPS should be administered to patients once a year (not twice) to reduce burdens on patients. When asking patients to complete the survey, the contractor should divide the survey into the three validated section and field each one. Then, while a facility would be surveyed on the complete tool, any one patient would have to complete only one-third of the questions. CMS should exclude the homeless to whom the survey cannot be distributed, given that facilities are not allowed to provide the survey directly to patients.

In addition, we reiterate our outstanding request that the survey be revised to include home dialysis patients and that CMS obtain NQF endorsement of the new measure, which MedPAC and others in the community also have consistently requested. We appreciate that CMS has completed some work on the tool, but given the Administration's strong desire to incentivize home dialysis, having an in-center only tool seems to contradict that position.

⁴⁵*Id.* at Chap. 3.

⁴⁶See Advancing Health Equity. "Using Data to Reduce Disparities and Improve Quality." <https://www.solvingdisparities.org/sites/default/files/Using%20Data%20Strategy%20Overview%20Oct.%202020.pdf> (accessed June 22, 2021).

⁴⁷ Dad T et al. Evaluation of non-response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. *BMC Health Services Research*. 2018;18:790.

Finally, it is important that CMS allow facilities and patients to use the ICH-CAHPS survey results to improve care. Patients and physicians participating in the recent TEP on patient-outcomes measures raised concerns multiple times that the fact that facilities never see the results and cannot communicate with patients about the results leaves patients feeling as if they had wasted their time completing the survey. Patients want to be heard. As currently administered, ICH-CAHPS has the opposite effect. Given that the majority of dialysis patients are from communities of color, the administration of the ICH-CAHPS survey does them a great disservice by further marginalizing their voices.

Kt/V Comprehensive Clinical Measure. To promote transparency in dialysis performance, KCP recommends that CMS use the distinct adult hemodialysis and peritoneal dialysis adequacy adult and pediatric measures endorsed by the NQF. A pooled measure approach results in all patients from the four dialysis populations (adult and pediatric/peritoneal and hemodialysis) being combined into a single denominator and scores being calculated as would be done for a single measure. While the vast majority of patients do receive adequate dialysis (urea clearance),⁴⁸ this pooled approach to reporting eliminates the ability to determine performance on any specific patient population or dialysis modality and perhaps masks social disparities in this aspect of care. Patients need to understand a facility's actual performance on the different modality types to make informed decisions about modality choice; the pooled measure hides this information from patients.

NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure. KCP remains deeply concerned about the reliability and validity of the measure. Research conducted by the CDC (the measure developer) and others, including CMS, show that the measure is not a valid representation of the care provided. CMS data shows that as many as 60-80% of dialysis events may be under-reported with the NHSN BSI measure.⁴⁹ In a follow-up TEP, CMS and other HHS agency officials indicated that the percentage was slightly lower, but TEP members remained concerned that the percentage is still unacceptably high. The measure in many instances may incorrectly report that a facility has a low number of blood stream infections when the opposite may in fact be true.

Given the understandable importance that patients place on a facility's ability to manage blood stream infections, a measure that fails to accurately represent the facility's performance deprives patients of their ability to make informed healthcare decisions and may obscure social disparities. It also unfairly penalizes facilities that diligently pursue and report the hospital infection data necessary for a full picture of infection rates. Simply put, the measure is not reporting accurate data to patients or providers. Knowing the importance of this measure, KCP through the KCQA plans to develop a BSI measure to replace the flawed one in the ESRD QIP. We encourage CMS to avoid misinforming patients by eliminating the NHSN BSI measure and relying upon the NHSN Dialysis Event Reporting Measure while KCQA develops a more appropriate measure.

IV. Testing New Payment Delivery Models

KCP supports the new ESRD Treatment Choices Model and the Kidney Care Choices Models. We agree that structural changes in the way care is delivered can help address barriers individuals living with kidney failure face when deciding which modality to select. More also needs to be done to make sure that all patients, especially those who are Black or Hispanic, have access to organ transplants. To help avoid the ETC Model in particular from unintentionally reinforcing the current disparities, KCP has asked CMMI for additional rulemaking to refine the structure of the model and suggests a few modifications.

According to an analysis by Discern Health, the current ETC structure creates "permanent" winners and losers, which eliminates the value of the incentives. We support using incentives to expand home dialysis

⁴⁸ United States Renal Data System. [2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States](#). National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

⁴⁹81 Fed. Reg. 77834, 77879.

choice, but such policies need to allow for low performer to be recognized for improvement and have the ability to achieve the higher tier incentives. Discern Health found that 4.3% of dialysis facilities have a home dialysis rate of greater than 90%. This concentration of home dialysis volume “pulls” benchmarks upwards introducing a Home Dialysis Measure anomaly. For the significant number of facilities with home dialysis rates less than 5%, this places higher program scores out of reach. Conversely, facilities with home dialysis rates greater than 90% are virtually guaranteed a positive adjustment as a result of ETC design. Current scoring and benchmarking approaches create an inequity in the system that unfairly disadvantages the very participants who should be incentivized.

First, KCP recommends that CMS adopt a population-weighted benchmark would avoid cherry-picking and lemon-dropping of more complex patients who are often Black or Hispanic. Instead of setting benchmarks at the 90th percentile of aggregated units, benchmarks could be set at the 90th percentile of patients within those aggregated units. KCP supports using subregulatory guidance to make this change. This approach would align with Physician Compare, which use patient-weighted percentile to set benchmarks.

Second, KCP asks that the Model recognize improvement against such facilities’ own historic performance in the top scoring tier and across the life of the Model. We suggest adding a 2-point option at 15% improvement in the top tier and scoring on improvement throughout Model period to reward continuous growth. This approach would be consistent with the scoring methodology the Congress established for the ESRD Quality Incentive Program (QIP) that relies on improvement as well as attainment.

Third, we suggest that the Model support early sustained growth in patients’ adoption of home dialysis modalities. CMMI could use the compound annual growth rate (CAGR) as part of its scoring methodology. When growth is “faster” than the CAGR rate, participants would score better under the CAGR Improvement Score. When growth is “slower” than the CAGR rate, participants will score better under the existing Improvement Score. This approach would allow for variation in adoption of home dialysis and maintain the value of the incentives over the life of the Model.

Finally, we also ask that small dialysis organizations serving communities in HRRs have 50% or more of their facilities and patients subject to the Model be allowed to reduce their participation in keeping with the national 30% threshold. The current selection criteria has resulted in facilities that are more concentrated in certain geographic areas, such as the boroughs of New York City. Such a large “sampling” places the facilities at a higher risk and could result in their organizations closing because of penalty phase of the Model. KCP recommends that in keeping with the 30% threshold for the Model participation over all that CMMI further refine facility selection criteria to ensure that small chain dialysis providers are not disproportionately selected into the ETC Model.

In addition, KCP has convened the KCQA to develop meaningful home dialysis and transplant measures that could be used to help facilities, nephrologists, patients, and care partners to understand how the steps taken by facilities are working or not under the Model. We hope to have measures for testing and review in the coming months.

V. Conclusion

KCP appreciates the focus on identifying and reducing barriers that create disparities in health care. Because people from communities of color are disproportionately affected by kidney disease and kidney failure, we ask that the Administration prioritize addressing the problems we have identified in this letter as a starting point for helping achieve health equality for this population. We also commit to working across the various agencies to support policies that will improve access to health care, as well as other social services and programs to eliminate barriers created by social determinants of health. Please feel free to contact our counsel in Washington, DC, Kathy Lester with any questions. She can be reached at klester@lesterhealthlaw.com or 202.534.1773.

Sincerely,



John Butler
Chairman

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
American Society of Nephrology
AstraZeneca
Atlantic Dialysis
BBraun
Cara Therapeutics
Centers for Dialysis Care
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Nephrology Nursing Certification Commission
Renal Physicians Association
Renal Healthcare Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma