Nonprofit Kidney Care Alliance

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1749-P
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations on the Centers for Medicare & Medicaid Services (CMS) ESRD proposed rule for fiscal year (FY) 2022. NKCA represents eight nonprofit dialysis providers: Centers for Dialysis Care; Central Florida Kidney Centers, Inc.; Dialysis Center of Lincoln, Inc.; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; Puget Sound Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 22,500 patients at more than 326 facilities in 32 states. In an effort to keep patients off dialysis, we also serve more than 10,000 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of end-stage renal disease. As nonprofit providers, approximately 85 percent of our patients are covered by Medicare, including Medicare Advantage (MA) plans.

We appreciate the continued efforts by CMS and the Department of Health and Human Services (HHS) throughout the COVID-19 pandemic to work with NKCA and its member companies to serve ESRD beneficiaries across the country as they face this virus. We offer the following comments:

Wage Index

The ESRD base rate is adjusted for several factors. The labor-related share of the base payment, currently 52.3% of the base rate, is adjusted for geographic differences in wage levels. Rather than an ESRD-specific area wage index (AWI), CMS uses the inpatient hospital prospective payment system area wage index system to adjust the wage-related share of the ESRD PPS. However, unlike the application to hospitals, the ESRD wage index is based on the *unadjusted and pre-reclassification* hospital AWI.

The dialysis-related labor market for nursing and dialysis technicians has been challenging for many years and is made worse with the pressures associated with the COVID-19 pandemic. Not only are dialysis providers at a disadvantage relative to other health care providers—particularly hospitals—but also non-health providers in some markets, where we must compete with large retail chains on wages and work-related stress.

In the 2020 ESRD proposed rule, CMS solicited comments regarding "concerns … and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS." CMS went on to say that it would take comments into

consideration in future rulemaking. **We ask that CMS, in future rulemaking, address the labor market pressure on dialysis providers, made worse by the current pandemic, which will likely reverberate well after the current public health emergency.**

The ESRD PPS AWI adjustment is based on the inpatient prospective payment (IPPS) hospital wage index. In theory, this is not unreasonable given that ESRD facilities, hospitals, and other providers compete in the same labor markets for labor, particularly nurses. However, as pointed out by commenters on the 2020 Proposed Rule, this is not how CMS applies the AWI to ESRD facilities, as CMS uses the pre-floor, pre-reclassified hospital wage data. So, while hospitals—the dominant health care provider in most markets—can reclassify to an area with a higher wage index, garnering additional financing, ESRD providers must compete with a wage deficit relative to hospitals in the same market. To make matters worse, CMS applies the wage index pre-floor, affecting rural ESRD providers as well as others where the hospital AWI rural floor can, and often does, lift the wage index of non-rural hospitals. This AWI wage deficit also arises in the handful of so-called "non-rural states" that benefit from the imputed rural floor. The statute gives the Secretary broad authority to set geographic wage adjustment policy that could be used to level the playing field in the competition for skilled health care personnel. We urge CMS to promptly address this disparity in future rulemaking in the near future.

Commenters in 2020 also expressed concern with the data lag in the ESRD PPS wage adjustment, made more acute by the growing number of states' and municipalities' increases in minimum wage requirements. For payment year (PY) 2022, CMS is applying hospital wage data from 2018—a four-year lag which will now be made worse by the extraordinary labor market pressures brought on by the COVID-19 public health emergency (PHE). While data lags are not uncommon in CMS payment systems, in part due to the timing of cost reports, this only serves to underscore the importance of creating a level playing field between hospitals and other providers such as ESRD facilities competing in the same market for health care personnel.

Outlier Policy

When the ESRD PPS bundle was adopted in 2007 and implemented in 2011, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. To account for the cost of these higher outlier payments, providers do not receive the full base rate for each treatment. Since 2011, the program has never reached the 1 percent threshold established in the implementing regulations. From 2011 through 2013, actual program experience fell well short of the 1 percent outlier target threshold (reaching only 0.3 to 0.5 percent). The closest the program came to the 1 percent threshold was 0.8 percent in 2017. In 2018, as the proposed 2020 rule acknowledged, outlier payments fell to 0.5 percent again. And, in this 2022 proposed rule, CMS reports that the outlier payments in 2020 only hit the 0.6 level—missing the 1% threshold yet again. This is a cumulative real loss to ESRD clinics and, ultimately, to their patients, resulting from an unnecessary and persistent loss to the base rate. We propose, as we have before, that CMS reduce the outlier threshold from 1 percent to 0.5 percent.

This is made all the more urgent given the cost pressures on providers due to the COVID-19 pandemic, particularly around labor costs, which, as we note above, are particularly acute.

While an outlier adjustment is required under the statute, it does not specify a particular value. We believe that a 0.5 percent outlier threshold would reduce the offset to the base payment, reducing the continued "leakage" from the base, and still provide for payment in the case of extraordinary costs. Moreover, we again ask CMS to address the operation of the outlier policy as part of its ongoing work with its contractors to review the overall functioning of the ESRD PPS and take administrative action to address its shortcomings.

Transitional Payment for New and Innovative Equipment and Supplies (TPNIES)
In the 2020 ESRD PPS, CMS codified its policy around new and innovative equipment and supplies. In 2021, CMS made a number of improvements to further focus its policy on supplies and equipment that better meet a standard of substantial clinical improvement. As we stated then, we believe that CMS should set the bar high enough to foreclose "me too" applications for transitional payment. At the same time, as we have noted previously, dialysis—whether in-center or in-home—has seen little innovation in the past several decades.

In our comments on the 2020 ESRD proposed rule, we expressed our support for CMS's proposal, subsequently adopted, to incorporate both "newness" *and* "substantial clinical improvement" as necessary to qualify for the TPNIES. In particular, we concurred with CMS's proposal to apply a test of substantial clinical improvement similar to that used in the Inpatient Prospective Payment System (IPPS) to spur innovation for products that offer more than minor, if any, real clinical improvement. In such a system, developers and manufacturers know up-front by what criteria a new product will be judged. At the same time, we noted that new equipment and supplies need not be "blockbusters" to qualify. Rather, they may:

> (i) offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;
> (ii) offer the ability to diagnose a medical condition in a patient population where that condition is currently undetectable, or diagnose a medical condition earlier in a patient population than allowed by currently available methods; or
> (iii) significantly improve clinical outcomes for a patient population as compared to currently available treatments.

We believe that by setting the bar higher than only "newness," CMS can help ensure that increased Medicare expenditures and beneficiary copayments are better justified. However, we do have concerns with how CMS proposes to apply that policy. First, in determining substantial clinical improvement, we question whether and how CMS accounts for the nature of dialysis care, as well as patient profiles and how that bears on the ability to conduct large, robust clinical trials. Second, CMS seems to be conflating its determination of whether a supply or equipment meets the twin test of newness and SCI, with what *should* be separate and distinct questions of how to pay depending on site of service and whether purchased or leased.

With respect to the determination of SCI, we urge CMS to calibrate its policy to take into account that, as the dominant payor in the dialysis field, CMS is, in effect, the primary (if not sole) gatekeeper on whether new equipment and supplies will come to market at all. With most ESRD patients covered through Medicare and/or Medicaid, CMS payment rules play a critical role in any assessment of return on investment by developers and manufacturers. Robust clinical

trials, while the gold standard from a statistical perspective, can be particularly daunting due to the nature of the ESRD population.

In the 2020 Final Rule, CMS provided for transitional payment for equipment dedicated to in-home dialysis care for a single beneficiary, provided that the equipment is owned by the dialysis facility, rather than leased. We urge CMS to revisit its decision regarding capital-related assets for in-home dialysis only if purchased outright, and not under a lease arrangement.

While we understand CMS's point about ownership and depreciation, this is more appropriately addressed in the payment methodology and level rather than by outright exclusion. This is particularly important for smaller dialysis organizations. Not all dialysis facilities have the ability to purchase new devices and may use operating leases in order to provide the benefit of new equipment for their patients. It is our understanding that the lease agreements typically account for depreciation and maintenance. CMS policies for TPNIES payment should not only offer improved equipment to patients of providers with the capital to purchase the latest equipment, but also enable all providers to use innovative and beneficial equipment for patient care.

In a similar vein, we continue to believe that the TPNIES policy should be focused on transition payment for new equipment that represents a substantial clinical improvement, and not limited by site of service. If an application for TPNIES is focused on in-home only, so be it. But the standards of newness and SCI should apply, regardless. Simply put, if CMS wants to promote innovation and improve patient care, both stated goals in prior rulemaking, then limitations based on site of service should not be employed. We urge CMS to revisit its policy in this matter in future rulemaking.

CMS received two applications for transitional payment: the Tablo system and the CloudCath system. In both cases, CMS points to limitations in the studies supporting these applications. As we note above, however, the ESRD sector does not easily lend itself to the kind of robust clinical trials that would be preferred. Moreover, one of the applications, for the Tablo system—which has been submitted previously—has shown real-world improvement in that it is easier for in-home dialysis patients to learn to use, and then be better able to use on a regular basis, compared to other similar equipment. For patients dialyzing at home, rather than in-center, this is not a minor improvement and warrants a careful and balanced review.

ESRD QIP Proposed Changes

CMS proposes several QIP-related changes, most of which are attributed to problems with the implementation of the new ESRD Quality Reporting System (EQRS) and the impact of COVID-19. We want to thank CMS for its thoughtful approach to addressing these twin challenges, creating a bridge over the immediate problems while still preserving data collection and reporting.

In November 2020, CMS merged three reporting systems into EQRS. CMS acknowledges that the implementation of the EQRS has been challenging to the point that it has compromised the submission of critical quality data. Therefore, CMS suspended submission of data, with a restart of the system on or about July 12, 2021.

CMS announced, through this rulemaking, an exception to the QIP reporting deadline to September 2021 for QIP data from September 2020 through December 2020. Accordingly, due to both the problems with EQRS and the impact of the COVID-19 PHE, CMS proposes the suspension of both the scoring and award of Total Performance Score (TPS) for any facility in 2022. We support this proposal and thank the agency for recognizing that both the EQRS and COVID-19 impacts are beyond the control of any facility and, therefore, facilities should not be at risk on their TSP score.

QIP Measure Suppression Policy

Recognizing that COVID-19 has affected delivery of care by ESRD facilities in ways beyond their control, in turn affecting their performance on QIP measures, CMS proposes a policy structure to determine which QIP measures should be suppressed for PY 2022. CMS then applies that proposed policy against the current 14 QIP measures and proposes to suppress four. We thank CMS for recognizing the significant impact of COVID on ESRD facilities' ability to achieve high-level performance on QIP measures. We ask that CMS consider suppression for the remainder of the PHE, as the effects of the pandemic have ongoing impact to our vulnerable patient population. Morbidity and mortality remain high at this time, with many geographic areas with increasing rates of COVID, including documented vaccine 'breakthrough' cases in dialysis patients with the delta variant. Hospital systems in certain areas remain overwhelmed and have cancelled procedures or do not have capacity at this time for fistula surgeries.

With respect to the four factors that CMS proposes to determine whether a QIP measure should be suppressed, we offer the following comments.

Factor 2 speaks to "clinical proximity," but this may overlook clinical impacts that may be indirect, or "downstream," but not "proximate." For example, the impact of the shutdown of non-urgent, scheduled surgery on vascular placement has reduced fistula placement. For example, surgery departments of hospitals in a county where one of our members is located did not permit elective surgery for peritoneal dialysis catheter insertion. Similarly, fistula rates have decreased, in part due to difficulty in scheduling insertion and declotting of AV fistula surgeries. Failure to declot the fistula, lead to loss of the fistula or graft. This resulted in central venous catheter (CVC) insertion rather than placement of permanent access for management of ESRD. We also saw a delay in the follow up of our patients with Stage 4 and Stage 5 CKD whereby they would not go to the hospital for pre-emptive placement of fistula in order to avoid exposure to hospital environment. We are also seeing transplant programs that have slowed the processing of pre-transplant evaluation visits and thus are limiting access to pre-emptive living donor transplantation to the point that dialysis becomes necessary rather than proceeding directly to transplant.

Factor 4 speaks only to "*national* shortages or rapid or unprecedented changes" in personnel, supplies, diagnostic tools, patient case volumes, and so on. While the current pandemic has had nationwide impacts, we have also seen state-by-state and regional impacts on personnel, patient volumes, and equipment and supplies. This would be not unlike PHEs, which are typically not national in scope, but state or regional in scope as a response to natural disasters. <u>As such, we believe that CMS should broaden its geographic factor to include "sub-national, regional, and state" in its application of Factor 4</u>.

Applying the proposed four factors, CMS proposes to suppress four (4) measures:

- Standardized Hospitalization Ratio (SHR);
- Standardized Readmission Ratio (SRR);
- ICH CAHPS Survey Administration patient experience; and,
- Long-Term Catheter Rate.

We support CMS's proposal to suppress the four measures it identifies as "severely impacted" by the COVID-19 PHE. While CMS continues to explore other, perhaps more targeted alternatives, such as updating measure specifications to isolate COVID-19's effects, we urge CMS to provide full opportunity for stakeholder review and comment on such alternatives.

In addition to the four measures CMS proposes, we recommend that CMS take another look at its data to assess the impact of COVID on two additional measures, both of which are related to vascular access—not unlike the catheter measure which CMS proposes to suppress:

- Hemodialysis Vascular Access: Standardized Fistula Rate (SFR) (Clinical Measure); and
- Kt/V Dialysis Adequacy-Comprehensive (Clinical Measure).

CMS states that its analysis of available data indicates that long-term catheter use rates have increased significantly. CMS states its concern that the COVID-19 PHE "impacted the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID-19 precautions at healthcare facilities, or due to patient reluctance to seek medical treatment because of risk of COVID-19 exposure … and that this contributed to the significant increase in long-term catheter use rates." We are puzzled that CMS is not finding a corollary, but reverse (i.e., declining) development in the rate of patient months using AVF as well as a corresponding effect on the Kt/V measure. Of note, with higher rates of dialysis catheters, by definition, patients with catheters will achieve lower clearance, which means lower 'K' (clearance) and lower Kt/V rates. Thus, it seems reasonable that if catheter rates are suppressed, so should AVF fistula and Kt/V. We ask that CMS take a second look to determine whether the data indicate a negative effect that might not rise to the level of "severely impacted," but that is still significant. The ability to achieve an adequate Kt/V depends on the flow of blood to the dialyzer. When an access (catheter or fistula) is compromised, the blood flow is reduced so a treatment (say four hours) that was sufficient for a given patient may no longer be sufficient. While that patient's treatment time might be extended, extension will often not be sufficient to achieve an adequate Kt/V until the access is repaired.

As another of our members has reported, during the months of March through June 2020, all of their vascular access centers (outpatient vascular surgery and interventional radiology) were closed and elective surgeries were deferred, ie, not performed. This led to an inability to get new access created and an inability to get poorly functioning accesses repaired. Because of the backlog this deferral created, they are still catching up on procedures to this day.

Reporting of all 14 Measures

CMS also proposes that facilities still report on all 14 measures, but then goes further to propose that it will still publicly report even those measures that are suppressed. With respect to the

former, this seems prudent so that CMS can track developments in the field. However, we are concerned that public reporting, albeit with caveats and explanatory notes, will contribute to confusion and public mistrust. We recommend that CMS publicly report all ***but*** suppressed measures. This will maintain visibility on ESRD quality with consumers, while avoiding confusion. In the interest of transparency, CMS could even identify the measures it is not reporting to the public due to the impact of the COVID-19 PHE on their validity.

Special Scoring Methodology and Payment Policy for PY 2022
Due to the EQRS operational issues and the effects of COVID-19, CMS proposes a special scoring rule for PY 2022 (which would normally be based on 2020 data). CMS proposes to still calculate performance for all 14 measures with 2020 data but would not assess achievement nor improvement points. Accordingly, CMS proposes to not award TPS for any facility, nor any payment reduction under QIP, in 2022. We agree with and thank CMS for recognizing both the EQRS issues and the impact of COVID-19. At the same time, CMS will still be using 2020 data to provide feedback to facilities so that each knows where they stand on each of the 14 measures. Again, we urge CMS not to publicly report on any suppressed measures because, notwithstanding any footnotes or caveats, this will likely lead to confusion on the part of the public. Also, depending on the impact of the PHE on CY2021, we ask CMS to consider whether calculation of the TPS would be affected and whether similar consideration should be given for not awarding TPS during CY2021/PY2023.

Request for Information - Closing the Health Equity Gap
Health disparities among patients with chronic kidney disease represent a serious challenge. Broadly speaking, causes of health disparities include limited access to early and regular care, inadequate access to good nutrition, gaps in public health education, language barriers, and discrimination in the provision of care. Approximately 50 percent of dialysis patients in the United States are Black, Latinx, Native American, or Native Hawaiian and other Pacific Islander. People of color are less likely to receive a kidney transplant compared to white patients.

Compounded by the presence of underlying disparities, factors including bias create an environment in which people of color are more likely to have negative experiences with the health care system. Among the many actions that must be taken to reduce disparities, we believe that we must be able to measure them so that we know whether we are closing the gaps, as well as gain insights on what works and what does not. As CMS notes, this means better data collection.

Therefore, we are very pleased that CMS is asking for comments on four possible initiatives that might address disparities in health care and bring greater equity in the delivery of health care in the ESRD community:

- Stratification of facility QIP measures by dual-eligible status;
- Stratification using statistical techniques that provide indirect estimation of race and ethnicity;
- Collecting social, psychological, and behavioral data for reporting; stratification of QIP measures; and other quality data; and,
- Creating and applying an ESRD Facility Equity Score.

Stratification of facility QIP measures by dual-eligible status
CMS proposes to build on its experience using dual-eligible status as a proxy for social risk factors. Both the National Academies' and the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) reports have pointed to dual-eligible status as a fair proxy for identifying beneficiaries at risk due to underlying socioeconomic factors. Knowing the dual-eligible status of ESRD patients could help create a "baseline" relative to current measures, such as catheter vs. fistula rates. From there, CMS could work with the dialysis community to identify and support the strategies and tools to address disparities and then measure progress over time. We would note that progress will not be easy, as many ESRD patients have decades of poor health prior to starting dialysis. In this regard, we strongly believe that it is essential that CMS go upstream to address disparities before the only choice is dialysis. Simply put, waiting until someone is on dialysis is a poor time to start addressing health disparities. For example, one natural place to start is with Medicare Advantage Dual-SNP plans. Also, with the new Kidney Care Choices (KCC) voluntary models, we have an ideal opportunity as a community to review and address the effects of some disparities on beneficiaries prior to starting dialysis. Understanding differences in baseline CKD care between those who are and are not dual eligible could also assist our community to consider where resources could be allocated to slow progression of kidney disease.

Stratification using statistical techniques that provide indirect estimation of race and ethnicity
CMS describes two approaches in which it has some experience with indirect estimation by which it imputes certain factors *at the population level,* for plans and facility level to estimate race and ethnicity. CMS acknowledges the limitations of this approach and notes that it would only serve as an intermediate, "stop-gap" approach. As such, it is not clear that either of the two methods CMS outlines would do much to advance the effort to narrow the equity gap, compared to the use of dual-eligible status, in the short run. If CMS decides to still propose an indirect estimation approach in a proposed rule, it may wish to address the question of whether this could divert resources, time, and energy away from the development of better methods.

Collecting social, psychological, and behavioral data for reporting; stratification of QIP measures; and other quality data
CMS indicates that it is interested in the collection and sharing of a standardized set of social, psychological, and behavioral data by ESRD facilities, including disability, race, and ethnicity. CMS also expresses an interest in collecting such data using definitions that comport with interoperable health information exchange. The proposed rule does not reference the demographic and comorbidity data currently collected on the CMS Form 2728, nor the potential to modify that form to capture additional information by expanding existing fields or adding new ones. Because the Form 2728 is used to establish patient eligibility for coverage, at initiation of dialysis, this seems the most obvious place to consider additional, one-time data collection. We would urge CMS to be economical in its expansion of data collection on the Form 2728 so as not to create unnecessary concerns on the part of patients who are going through a very difficult transition.

Creating and applying an ESRD Facility Equity Score
As intriguing as a "score" may sound, we believe that it is premature to consider boiling down a set of health equity performance measures—which *should* be reportable—into a single "score."

The focus at this time should be on establishing the right patient characteristics and contrasting them with the most meaningful clinical and consumer measures. If, having done that, it is apparent that a "score" is meaningful, then CMS should propose a methodology for how it would be computed through notice and comment rulemaking. Such a methodology will need to be sensitive to the population and community from which a facility draws its patients and their health disparities experience prior to needing dialysis. We note again our point earlier, if CMS wants to address health disparities of ESRD beneficiaries, it needs to go upstream before a beneficiary finds themselves requiring dialysis.

COVID-19 Vaccination Coverage among Healthcare Personnel Measure – Request for Information And COVID-19 Vaccination Coverage for Patients in ESRD Facilities – Request for Information

We would like to address these two RFIs together—as the right health care objective, vaccination, is so obvious. Like influenza and pneumonia, vaccination for COVID-19 is the right objective and worthy of a performance measure. The challenge that CMS needs to address in any future rulemaking is accounting for the "mixed messages" and, in some cases, outright obstruction by state and local authorities.

Patient and staff reluctance to vaccinate is not new. However, the current low vaccination rates in some areas of the country stem from other factors, such as social media and voices of authority that defy any educational efforts, or even employment mandates, that facilities may apply. If CMS institutes new measures for staff and patient vaccination, which we would support, we urge CMS to incorporate—at least for some period of time—alternative or supplementary factors that can take account of robust, good faith efforts on the part of dialysis facilities to promote vaccination, not just a numeric threshold.

ESRD Treatment Choices (ETC) Model

We appreciate CMS including an opportunity for ETC rulemaking in the ESRD PPS and would appreciate the continuation of this annually. We believe annual review and comment is beneficial so that necessary refinements and adjustments can be made. As small and regional providers, NKCA member companies have a large proportion of clinics included in this mandatory model. As the model is intended to only include 30 percent of clinics nationwide, for regional providers, some of our members face almost 100 percent of their clinics included in the model, posing different challenges than those companies that can spread out their risk.

Preemptive LDT attribution

CMS proposes to change the attribution for a preemptive LDT beneficiary to the Managing Clinician (MC) with the plurality of claims during the year prior to the transplant date, with attribution going to the latest claim of service preceding transplant if claims are the same. CMS also proposes that these beneficiaries be eligible for attribution if they have at least one eligible month during the 12-month period of the transplant. NKCA has previously raised this issue and supports this updated attribution process.

Nocturnal In-Center Dialysis

Beginning in model year 3, CMS proposes adding nocturnal in-center dialysis to the calculation of the home dialysis rate for certain ESRD facilities. We support CMS's goal to incentivize

additional alternative renal replacement modalities under the ETC model and inclusion of nocturnal in-center dialysis. However, we believe that it will still be very challenging to provide a nocturnal program from a cost burden perspective. Both associated costs and staffing challenges can be insurmountable barriers. Small providers will still face challenges under the home dialysis rate. To address these challenges, we encourage CMS to consider also giving credit to providers that refer current and prospective patients to a clinic with nocturnal in-center dialysis or home programs.

Definition of Large Dialysis Organization (LDO)
As part of its discussion of the ETC model, CMS proposes to define an LDO as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. We thank CMS for its proposal. NKCA's member companies range from 6 to 250 clinics. We have noted previously the different challenges faced by small and mid-sized dialysis organizations in the ESRD PPS, the Comprehensive ESRD Care (CEC) model, the KCC models, and now the ETC model. We have appreciated previous policies for non-LDOs to participate in models under aggregation and other minimum thresholds as well as opportunities to ease into increased risk arrangements. These policies have allowed for a more diverse provider participation, providing helpful data and expanding access to the beneficiaries we serve. Maintaining viability for small and mid-size providers is critical to maintain patient choice in many geographic areas. We support this updated definition and stand ready to help CMS continue to support smaller and mid-size dialysis organizations. Also as we noted, many of our member companies have over 75 percent of their clinics in the ETC model, which is far greater than CMS's intention of 30 percent across the country, and any additional support for their increased participation should be addressed and welcome.

Organ Supply
NKCA agrees with CMS in acknowledging the pending work being done across HHS to increase access to organs and decrease barriers to transplant. We agree with CMS that, while those policies are getting underway, it is not appropriate to hold participants accountable for deceased donor transplants. We do, however, believe this is critically important in the future and that policies should be updated as organ supply and policies to increase transplant are expanded.

Exclusion of Cancer Beneficiaries
CMS proposes to exclude ESRD beneficiaries and preemptive LDT beneficiaries who have been diagnosed with vital solid organ cancers. While we agree that cancer beneficiaries should be excluded from the model, we believe there is no reason to limit the diagnosis to solid organ cancers. NKCA believes it may be more efficient and inclusive to include a broader definition of any active cancer diagnosis.

Health Equity Incentive
CMS proposes a health equity incentive to a participant's improvement score based on dual-eligible or LIS recipients in the home dialysis and/or transplant rate. We appreciate everything CMS is doing to promote health equity among our patients and believe an incentive would be a positive step in that direction. We recommend consideration of a more tiered approach, providing increased incentive as more beneficiaries with dual-eligible and/or LIS status are provided home services or transplant. As CMS has noted, there are many socioeconomic

challenges to home dialysis, as well as transplant, that need to be managed and coordinated. NKCA members believe we should be working with all patients to increase the use of these modalities when appropriate, and incentives should exist at any level to encourage that behavior.

Data Sharing
CMS is proposing to notify and share beneficiary-identifiable data to ETC participants who sign an agreement for compliance purposes. Model and beneficiary data is hugely helpful in caring for and providing appropriate care to ESRD beneficiaries. We support CMS sharing this data to identify pertinent information for each beneficiary attributed to the model. In addition, we support CMS's proposal to make aggregate data available on performance rates in order to track and improve on the model.

KDE Telehealth Waivers
We support CMS's proposal to allow ETC participants and qualified staff to furnish kidney disease patient education services via telehealth, regardless of the beneficiary's geographic area or the site of the beneficiary, and regardless of the site of service of the practitioner. We have long believed this could assist in going upstream to address kidney disease before reaching ESRD and to educate patients earlier related to their treatment options.

We also support the Kidney Disease Patient Education services beneficiary coinsurance waiver to reduce or waive the 20 percent coinsurance requirement. Related to such waiver, CMS is also considering prohibiting any ESRD facility or other entity from providing qualified staff or the ETC pparticipant with any financial support or incentive to provide the kidney disease patient education services coinsurance patient incentive. We agree that CMS should prohibit dialysis facilities from effectively making up the financial difference the ETC participant/qualified staff would experience by waiving the patient's co-pay for Medicare-covered CKD education. In connection with the foregoing, we request a clarification in this proposed rule on "under arrangement at fair market value" (FMV) services from dialysis facilities. Dialysis facilities may provide clinical staff under a personal services or similar arrangement, in compliance with applicable Anti-Kickback Statute, Stark, and other requirements, to provide certain needed services. In such instances, the provider pays the dialysis facility a fair market amount for the use of those personnel. This often occurs where the dialysis facility maintains staff with pertinent expertise, and this expertise might include personnel with experience in educating patients as to CKD. We believe a dialysis facility providing staffing to the provider at FMV would not constitute providing financial support so long as it was done in compliance with existing requirements. Please clarify that your proposal does not prohibit these FMV arrangements.

While we do believe that waiving the coinsurance would serve to increase beneficiary adoption of CKD education services, the willingness of ETC participants and qualified staff to provide those services at a rate that does not adequately cover their costs may serve to diminish the availability of educational programs. Accordingly, we would encourage CMS to revisit its decision to not pay the kidney disease patient education services at 100 percent. Adopting a full payment model for those beneficiaries without secondary coverage would provide the best chance that education would become more widespread, with the goal of reducing beneficiaries' future care costs and better preparing beneficiaries to choose a home or self-care dialysis

modality should the need for dialysis arise. This would also help to alleviate the fraud and abuse concerns CMS notes as to financial assistance from ESRD facilities and other entities.

Conclusion

Thank you for the opportunity to comment on the 2022 ESRD PPS Proposed Rule. The NKCA appreciates the opportunity to provide input to ensure that the system continues to support quality of care to the patients we serve. As nonprofit providers, some proposed changes to the ESRD PPS can affect us much differently than others. We would be pleased to discuss these comments and suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director