Nonprofit Kidney Care Alliance

August 22, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (CMS-1768-P)

Dear Administrator Brooks-LaSure,

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments on the 2023 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule. 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 ESRD.

We appreciate the continued efforts by the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) throughout the COVID-19 pandemic to work with NKCA and its member companies as we continue to confront this virus. We offer the following comments with regard to the proposed 2023 ESRD payment rule:

Proposed Re-basing and Revising of the ESRD Market Basket

CMS proposes to use 2020 Medicare Cost Report (MCR) data from independent facilities as the new base year, supplemented with the Census Bureau's 2012 Service Annual Survey (SAS) data inflated to 2020, and May 2020 Bureau of Labor Statistics (BLS) Occupational Employment Statistics data to calculate the weights for wages, salaries, and benefits. While 2020 data is from a COVID year, which in some cases has led CMS to forgo its use, the proposed rule suggests that because in-center dialysis' typical three days per week schedule was largely uninterrupted out of necessity, it is appropriate to use. CMS details shifts in market basket cost categories. Importantly, compensation costs have increased, while pharmaceuticals as a share of costs continue to decline. CMS also breaks out certain costs heretofore categorized as Housekeeping into two categories: Housekeeping, and Operations & Maintenance.

While the use of 2020 data, including adjusting for the effects of COVID, is reasonable, the continued and deepening impact of COVID on labor inputs, changes in staffing patterns, equipment, and supply utilization (e.g., PPE) have only worsened. And, COVID's impact on clinic census is also driving up per treatment costs. Labor costs in particular are an acute problem and are unlikely to come down even if the pandemic abates.

CMS "periodically" rebases the market basket and last rebased it in the 2019 ESRD PPS final rule using 2016 data. In light of the continuing effects from the COVID pandemic, we ask that CMS closely monitor MCR data and consider rebasing sooner than the 2027 rule.

Change in Labor-Related Share

With the shift in costs from the rebasing and revising comes an increase in the labor-related share of costs from 52.3% to 55.2%. While this shift may be correct and the natural outgrowth of the other shifts in costs, it will have the effect, particularly for clinics in low wage index CBSAs, of further widening the disparity between hospitals that benefit from the *post*-adjusted/post-floor AWI as compared to ESRD clinics where AWI is based on a *pre*-adjusted/pre-floor hospital wage index data.

The ESRD PPS AWI adjustment is based on the inpatient prospective payment system (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. 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, which are 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. As one NKCA member company serving rural areas has observed, it not only effects the cost of clinical personnel, but also social services, dieticians, and biomedical engineering services. This AWI wage deficit also arises in the handful of so-called "non-rural states" in which acute care hospitals 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.

For payment year (PY) 2022, CMS is applying hospital wage data from 2019. While such data lags are not uncommon in CMS payment systems, in part due to the timing of cost reports, the potential for disparate impacts of the COVID-19 public health emergency on healthcare labor costs across markets implies this data may result in improper wage index values in certain markets and underscores 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 We, once again, urge CMS to promptly address this disparity in future rulemaking.

Cap on Wage Index Decreases

CMS proposes to limit disruption with the reduction in a provider clinic wage index that may occur when CMS adopts Census Bureau CBSA realignments to no more than 5% per year (until

a facility reaches its new wage index). While such realignments usually occur following the decennial census, there are intermediate realignments as well. This proposal—which CMS is proposing in virtually every other payment regulation—could be particularly important with the 2020 decennial CBSA realignments which will likely occur in the 2025 payment year. We support CMS' proposal and its decision to act now to create "guardrails" before they may be needed in a couple years with the decennial realignments.

Revision in Outlier Policy

Section 1881(b) provides the Secretary with authority to recognize extraordinary costs in paying dialysis providers but sets no specific amount to be allocated. Since 2011, CMS has employed a 1% set-aside out of the total base payments to pay outlier claims. Most unfortunately, CMS has overestimated what would be needed in each and every year since the bundle was expanded. The actual cost of outlier payments have ranged from a low of 0.3% to a high of 0.8% over this time. This has resulted in hundreds of millions of dollars removed from the care of dialysis patients. We, and others, have urged CMS to modify its outlier set-aside, setting a lower withhold of 0.5%. We continue to believe that a 0.5% set-aside is appropriate even with methodological changes CMS is proposing in this rule.

In this 2023 proposed rule CMS acknowledges that the methodology used thus far has not worked and proposes a change which it estimates will achieve the 1% threshold. Specifically, CMS proposes to change the manner in which it calculates the Fixed Dollar Loss (FDL) amount to a prospective calculation to take account of the three prior years' experience. We thank CMS for recognizing the continued problem and proposing a means to address this matter. Time will tell whether this proposal will succeed, but it is well worth the effort. We do, however, urge CMS to closely monitor, report publicly on the effectiveness of this change, and promptly take comment if the new methodology does not achieve its intended goal—foregoing the lengthy delay that preceded this proposal.

Defining "Oral-Only" Drugs

CMS proposes to change its definition of "oral-only" drugs by bringing them under its functional equivalence policy which it employs in assigning drugs and biologics to ESRD functional categories, which focuses on "end action," rather than the FDA's practice of looking to pharmaceutical and therapeutic equivalence. That is, in the case of a drug or biologic, if there is one that is functionally equivalent (or for which there is another means of administration) it would preclude oral-only status. This proposal, if finalized, would take effect January 1, 2025. CMS observes that drug utilization, spending, beneficiary access and cost are positively affected by inclusion of drugs and biologics in the PPS bundle, as opposed to being paid separately under Part D. For example, CMS notes that access to calcimimetics among minority populations increased as calcimimetics were covered under the Transitional Drug Add-on Payment Adjustment (TDAPA). In contrast, CMS points to the experience with phosphate binders, the only drugs remaining "oral-only," which have seen both higher utilization and costs.

These are all important factors to consider, but they do not address the additional cost pressure placed on dialysis providers when new drugs and biologics come off TDAPA and are included in the bundle. In this regard, we appreciate CMS' request for information on payment policy when a drug/biologic cycles off TDAPA coverage. Under current policy, a new drug or biologic that

falls within one of the existing ESRD functional categories, is paid the TDAPA amount for two years, after which it is paid as part of the bundle with no increase in payment.

Later in this proposed rule, in a Request for Information (RFI), CMS poses several questions on which it seeks comment regarding how it should pay for drugs and biologics which fall within a functional category as they come off TDAPA. Of these, we are commenting on the following:

1. Is an add-on payment needed for a new drug that falls within an existing functional category post TDAPA? And if so, why?

2. What criteria should CMS establish to determine which drugs or biologics should be included in the calculation?

With respect to the first question, we support CMS having the option to increase the base rate to account for a new drug or biologic, recognizing that any increase also effects beneficiary coinsurance. By providing for an increase in the base rate, developers and manufacturers will have an incentive to bring new drugs and biologics to market in a sector that has seen little innovation. And for ESRD providers it will allow them to provide new therapies to patients that can improve their health and/or wellbeing, versus the current policy which either discourages the use or new agents or promotes a two-year spike in use to take advantage of TDAPA with a fall-off thereafter. In suggesting the "option" to increase the base rate, we believe it is reasonable to expect that a new drug or biologic add value, not merely be a copycat. Much as CMS does elsewhere, CMS could require manufacturers to be able to point to at least modest, but real, improvement that a drug or biologic would represent in patient care.

Regarding question number two, we believe that it is reasonable for CMS to take into account offsetting reductions in the use of other drugs or biologics brought about by the introduction of a new drug, both to be a good steward of Medicare program resources, as well as recognizing the impact on beneficiary coinsurance. This seems to be suggested in the options CMS outlines in the RFI, i.e. a "netting" of increased vs decreased utilization. However, we do have concerns about such a policy. First, two years of TDAPA data is likely to be an incomplete basis on which to make a judgement. New drugs take some time to make their way into practice in sufficient volume to be actionable. Administering a new drug, how best to use it effectively, as well as gaining insight as to how it compares with older drugs can take more than two years. We would recommend that CMS use three years of data with which to calculate the increase (if any), as CMS did with calcimimetics in the 2021 Final Rule. Second, in deciding which drugs or biologics to take into account, we are concerned that CMS' broad application of "functional equivalence" could skew its analysis. We ask that CMS, in conducting notice and comment rulemaking, provide, in its analysis of utilization and cost data, sufficient detail to enable commenters to see distinctions, if any, when viewed between drugs under CMS functional equivalence standard vs. drugs that are pharmaceutically equivalent. Applying the broader functional equivalence standard may be appropriate, but that is something on which comment should be invited at the time.

TPNIES Policy

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 concepts 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.

We appreciate that, in the 2020 Final Rule and again in this proposed rule, CMS provides for multiple pathways by which a new renal services technology can achieve the bar of substantial clinical improvement (SCI). We do want to again caution on any reliance on large, robust clinical trials in determining substantial clinical improvement. While such trials are regarded as the "gold standard" from a statistical perspective, we urge CMS to take into account the nature of dialysis care, as well as patient profiles and how that bears on the ability to conduct large, robust clinical trials. Moreover, data from clinical trials may only become available via post-market research, which may not be completed within the three year window which CMS applies in TPNIES payment policy.

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 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. The SCI bar for TPNIES needs to strike a balance so that incremental improvements will be funded and that innovators will invest in the dialysis space but still high enough that CMS continues to be a responsible steward of limited health care resources.

Palliative-Concurrent Dialysis

We recognize that CMS does not seek comment on ESRD patients' access to hospice services in this rule, but we would be remiss if we did not, again, urge CMS to consider in future rulemaking reimbursing concurrent, (not "maintenance") dialysis services for hospice care for patients on dialysis. Currently, hospice services are available to people with a principal diagnosis of ESRD only if they completely abandon dialysis—in effect, imposing a cliff. It should not be surprising that ESRD patients, fully informed of the consequences, are reluctant to take that step. Additionally, given concerns regarding rejected claims, many hospice providers are reluctant to accept patients with a principal diagnosis of other life limiting conditions, such as severe heart failure, who also are on dialysis.

The lack of a transition off maintenance dialysis can lead to significant discomfort and pain, due to shortness of breath from fluid retention, significant and discomforting itching, confusion, and nausea from uremia. Moreover, because it can take days to organize appropriate hospice services for an individual, stopping dialysis suddenly can lead to additional pain and emotional distress at the very time when a person deserves some measure of quality and comfort at the end of life. Rather than providing "palliative care for relief of pain and symptom management" as described in CMS regulations, the denial of all dialysis services has the unintended effect of imposing pain and thwart symptom management. It also contributes to higher Medicare costs, such as hospitalization, as well as the continuing high cost of dialysis care.

As we have stated in prior comments to CMS, we recommend an alternative policy that eschews maintenance dialysis (as provided under Sec. 1881) in favor of short-term, palliative, concurrent care that employs dialysis services as one of several tools for pain and symptom management. We believe that such an approach could be provided for under the Secretary's authority at 418.202(i) that allows:

> "any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare."

"Palliative dialysis" is a compassionate path for patients with ESRD at their end of life. Rather than facing a cliff, if a patient were permitted to receive a limited number of episodes, it could provide more comfort than if that patient abruptly goes off dialysis. Those treatment episodes might be shorter and/or less frequent, but still provide palliative symptom treatment consistent with Medicare's hospice rules. Such an approach likely would not require standard dialysis blood tests and medication administration. Not only can this contribute to a more compassionate end-of-life pathway, but also reduce the patient's own financial burden, as well as the cost to the Medicare program.

QIP Measure Suppression

We support CMS's proposal to suppress the six QIP measures – including two additions since the 2022 final rule—that it identifies as significantly impacted by the COVID-19 PHE. The addition of the Kt/V Dialysis Adequacy Comprehensive Clinical Measure is particularly welcome. 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. As we commented last year when CMS suppressed the long-term catheter rate clinical measure, COVID also affected these two additional measures, both of which are related to vascular access. During the early months of the COVID pandemic, vascular access procedures (at outpatient vascular surgery and interventional radiology as well as at hospitals) were limited, and elective surgeries were deferred, i.e., not performed. This led to an inability to get new access created and an inability to get poorly functioning accesses repaired. These issues persist today, with the staffing shortfalls impacting the ability of people with kidney failure to obtain and maintain vascular access. This is a dramatic change from 2019. With any interruption in the ability to perform these procedures, it takes time to resolve a back log. This has not been possible to date, resulting in a

higher prevalence of catheters in many facilities despite the best efforts of clinicians to facilitate optimal dialysis access.

Finally, we note that continued issues related to vascular access disproportionately impacts our most vulnerable patients. These patients will be impacted by fewer locations and fewer O.R. times to place access, resulting in more bloodstream infections, hospitalizations, and mortality.

Addition of COVID -19 Vaccination Coverage among Healthcare Personnel in PY2025
The introduction of a COVID-19 vaccination measure may seem akin to the influenza measure. However, the circumstances around COVID-19, including marked regional differences in vaccination, make this very different. First, while the measure's denominator excludes those for whom there is a medical contraindication, it apparently does not exclude those for whom a religious exemption has been approved. Second, the measure is based on a "full-course" of the vaccination, the definition of which continues to evolve. Third, there is a reporting burden in terms of the required frequency—one week out of each quarter—that CMS should address. A better approach would be no more than twice yearly. Thus, while we support a *reporting* measure, we urge CMS to proceed carefully, recognizing the widely varying conditions from community to community over which ESRD providers have no control.

RFI: Home Dialysis Quality Indicators
As CMS notes, home dialysis not only supports a better quality of life, but also is associated with lower healthcare costs. Data on home dialysis patient experience remain missing. Applying the current in-center hemodialysis survey would not be appropriate, as many of the questions are not relevant. Moreover, most home patients are doing PD, whereas in-center dialysis is almost entirely HD. While some of the questions in the in-center survey, such as those on self-reported health and mobility would be appropriate, a different set of questions that focus on patient independence as well as responsiveness to requests for help from center staff and clinicians would need to be developed and tested. While one home instrument does exist, it remains unvalidated and therefore unready for use in a quality program. CMS should consider a Technical Expert Panel (TEP) to determine the most appropriate survey questions and prioritize either new development of a measure or validation and refinement of existing tools.

RFI: Potential Future Inclusion of Two Social Drivers of Health Measures
It has long been understood that addressing health disparities requires a wider lens than one focused only on health care services per se. As CMS points out, there are a number of social factors that can contribute to poor health outcomes, particularly in certain subpopulations. Poor nutrition and housing, inadequate access to transportation, and risks to personal safety, all can contribute to poor health. However, since Medicare's "reasonable and necessary" standard constrains the type of services it can provide, little has been done to screen for social drivers of health care, in part because little could be done to address them. At the same time, Medicare beneficiaries—like most people—are often reluctant to acknowledge these challenges. Others are hesitant to seek help, since doing so often means interacting with public, social service and public safety agencies with which they or family members have had negative experiences.

Dialysis providers are in a unique position because they see most of their patients three time a week and often form trusting relationships with patients. Dialysis providers already administer

numerous patient surveys, such as the KDQOL, depression screens, social work assessments and others while independent vendors administer the ICH CAHPS twice yearly. These administrations could provide a means to screen for social drivers, but with survey fatigue already an issue, CMS should consider dropping some of the existing questions before adding new ones. Even more important, as CMS knows from its Accountable Health Communities demonstration, screening for social drivers will accomplish little if there are not services to address them, either directly or from navigation and networking services to connect patients to these services. CMS also has experience with some of these services in the Medicare Advantage (MA) program, particularly Special Needs Plans and the use of MA Supplemental Benefits. In short, before CMS adds new measures around social drivers—however worthwhile—it will be critical to address the question, what's next?

Conclusion

Thank you for the opportunity to comment on the 2023 ESRD PPS proposed rule and for all that CMS is doing to make the experience of beneficiaries with kidney disease a positive one. If you have any questions, please feel free to contact me at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director