THE KIDNEY CARE COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

Via electronic submission

June 6, 2022

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Office of Management and Budget
The White House
Washington, DC 20500

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: "Independent Renal Dialysis Facility Cost Report Form" (CMS-265-11, OMB No. 0938-0236)

Dear Director Parham and Administrator Brooks-LaSure:

We write today regarding proposed changes to the "Independent Renal Dialysis Facility Cost Report Form" (CMS-265-11, OMB No. 0938-0236) under review by the Office of Management and Budget (OMB) and Centers for Medicare and Medicaid Services (CMS.)

The Kidney Care Council (KCC) members collectively provide life-sustaining dialysis treatment and kidney care to 95 percent of individuals living with kidney failure, or End Stage Renal Disease (ESRD), in the United States. KCC members[1] constitute a diverse coalition of small, medium, and large businesses, are organized as both for- and not-for-profit organizations, employ tens of thousands of dedicated health care practitioners, and deliver quality care in urban, suburban, and rural communities across the country. KCC members deliver dialysis treatments in more than 6,000 facilities; train, support, and manage the care of thousands of patients who have elected home hemodialysis or home peritoneal dialysis; and support patients waiting for a kidney transplant. Dialysis providers are responding to COVID-19 by marshalling every possible clinical and operational solution we can develop during a dynamic and evolving public health emergency.

(1) KCC supports updating the Independent Renal Dialysis Facility Cost Report, however, facilities must be afforded sufficient time to comply prior to reporting.

KCC supports improvements to the Independent Renal Dialysis Facility Cost Report (Cost Report) that will streamline cost reporting, provide clear and concise instructions and definitions, and provide information accurate and sufficient for CMS to manage the End Stage Renal Disease (ESRD) Prospective

[1]KCC Membership 2020: American Renal Associates, Atlantic Dialysis Management Services, Centers for Dialysis Care, DaVita, Dialysis Clinic, Inc., Fresenius Medical Care North America, Northwest Kidney Centers, The Rogosin Institute, Satellite Healthcare, and U.S. Renal Care.

Payment System (PPS). Cost reporting structures have not changed with any significance since the launch of the ESRD PPS in 2010.

CMS and OMB propose that the effective date of the changes to the Independent Renal Dialysis Facility Cost Report would be *retroactive* and apply to reported costs beginning January 1, 2022. As a general matter, we do not believe it is appropriate for CMS and OMB to impose *ex post facto* reporting requirements on facilities. The proposed Cost Report changes would require significant changes throughout a dialysis organization and facility operations including, but not limited to electronic medical records, accounting, staff training, procurement and contracting, insurance contracts, service, and maintenance contracts, and more. To make complex changes providers and facilities generally need at least 12 months' notice of the specific changes to implement those changes throughout our financial and clinical systems.

However, having had the opportunity to review the proposed Cost Report changes contained in the current proposal, we believe that it is most essential that OMB and CMS amend the effective date of policies related to new data collection and reporting of costs associated with capital assets and pediatric patients, as discussed in greater detail in Sections (2) and (5) of this letter, respectively. We believe OMB can proceed with finalizing the Cost Report on the current timeframe, but amend the instructions related to the new reporting on capital assets and pediatric costs to make clear that such reporting will commence with costs beginning on January 1, 2023.

In this unique instance, we are supportive of the retroactive effective date of January 1, 2022, for data collection related to TDAPA, TPNIES, and the mandatory ESRD Treatment Choices Model (ETC Model) to ensure accurate reporting of current-year costs, as discussed in Sections (3) and (4) of this letter.

Going forward, we ask that OMB and CMS ensure that amendments to the Cost Report related to TDAPA, TPNIES, the ETC Model or other updates to the ESRD PPS be made in advance of such payment changes taking effect. We ask that CMS and OMB more regularly review and update the Cost Reports and related instructions, especially when there are changes to the payment system. Making small changes over time, when needed, is far superior to proposing massive overhauls of the Cost Report after long intervals.

Finally, changes in reporting for facility Cost Reports and claims increase the reporting and administrative burden on providers. These changes and increases in burden come at a time when dialysis facilities and providers are facing significant shortages in both our clinical and administrative labor forces as well as unprecedented and steep rises in the costs of labor. As such, the administrative burden of making changes to the cost reporting requirements at this time will be felt more acutely now than in times past. OMB and CMS should therefore ensure that any changes to claims and facility Cost Reports are required to deliver useful, accurate information for a specific purpose that is of sufficient value to patients, providers, and Medicare to justify the expenditure of administrative resources by providers and Medicare. While we are supportive of accurate cost reporting, we are not supportive of redundant cost reporting that unjustifiably increases burden on both clinical and administrative staff, notwithstanding the financial support personnel

and systems which are critical to the successful completion of Cost Reports. We also believe that OMB and CMS should identify a mechanism to compensate providers for the one-time costs associated with making these changes as well as the ongoing, increased administrative burden of compliance with a burdensome reporting system.

(2) KCC supports reporting on cost data related to Capital Cost Centers beginning January 1, 2023, as facilities may not be able to make complex systems changes to accurately capture data on a retroactive basis.

KCC does not object to reporting capital related and maintenance costs related to in-center, home HD, and home PD machines, and other capital related costs. We appreciate that CMS' efforts to collect cost data related to dialysis machines, including data related to owned and leased capital assets, may support future policymaking to further refine the TPNIES policy and incentivize innovation for capital assets, such as in-center dialysis machines.

While we do not object to this data collection, KCC's member companies do not necessarily currently track data related to capital assets in specific categories and sub-categories that OMB and CMS propose be reported on the Cost Report. We therefore cannot support CMS and OMB's proposal of a *retroactive* effective date that would apply these rules to all cost data going back more than six months to January 1, 2022. Given the complexities of capital asset cost allocation, the proposed changes represent a significant burden on providers. Indeed, it may not be possible for facilities to accurately calculate some, or all required costs on a retrospective basis, thus jeopardizing the integrity of the Cost Report data and placing facilities in a concerning position of being unable to comply with an *ex post facto* regulation.

Compliance with the proposed changes to the Cost Report related to capital assets will require significant changes throughout a dialysis organization and facility operations including, but not limited to electronic medical records, accounting, staff training, procurement and contracting, insurance contracts, service, and maintenance contracts, and more. Facilities require lead time to make such changes and ensure they are operating effectively throughout our systems. In general, we have asked CMS and OMB for 12-months lead-time to prepare for complex and comprehensive changes.

However, having reviewed these proposed changes, we believe facilities could comply with these changes for cost data related to capital assets effective January 1, 2023. We therefore ask OMB and CMS to modify the instructions for the new section of the Cost Report entitled "Analysis of Capital Cost Centers" to clarify that this section shall be effective and apply to cost data beginning on January 1, 2023. This will allow CMS and OMB to proceed with finalizing the revised Cost Report on the current regulatory timetable and give facilities the time they require to comply with the complex changes that relate to capital costs on a prospective rather than inappropriate, and potentially inaccurate, retrospective basis.

KCC does not object to reporting actual costs for capital expense related to the purchase or lease of dialysis machines, including reporting separately the costs for in-center HD, HHD, and PD machines beginning with cost data for January 1, 2023. However, it may be difficult or impossible for facilities to report actual costs for certain maintenance and related costs, such as insurance, taxes, and other capital

related costs. For example, current contracts for maintenance and insurance arrangements may cover service and coverage for all or a subset of machines and may not have valuations broken out by modality. Requiring separate agreements based on modality could potentially increase costs to providers with no benefit to patients or Medicare. Therefore, we recommend that OMB and CMS clarify in the instructions that facilities may continue to make good faith efforts to report proportional allocation of maintenance and related costs based on modality and other subcategories on the Cost Report.

(3) KCC supports amending the Cost Report to collect data related to TDAPA and TPNIES.

KCC supports amendment of the Cost Report and instructions to account for costs associated with the Transitional Drug Add-On Payment Adjustment (TDAPA) for drugs and biologicals and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for supplies. KCC has recommended this change on the record for several years, and we are appreciative to see this proposed change to the Cost Report.

However, the proposed Cost Report revision includes one line item for TDAPA and one line item for TPNIES. While there are currently only one drug receiving TDAPA and one supply item receiving TPNIES, it is possible that in future years there will be multiple drugs and devices receiving TDAPA and TPNIES in the same year. We believe that CMS and other policymakers will find it important and useful to be able to track costs associated with individual TDAPA and TPNIES products rather than have them reported in the aggregate. We therefore recommend that CMS add several line-items to each the TDAPA and TPNIES reporting and provide instructions that each product receiving the TDAPA or TPNIES add-on payments are to be reported separately on their distinct line-item.

In this unique instance, KCC supports the retroactive effective date of January 1, 2022, with regards to the TDAPA and TPNIES changes proposed to the Cost Report. We believe it is important that the Cost Report accurately capture costs associated with the TDAPA and TPNIES products during calendar year 2022.

However, reporting TDAPA and TPNIES will not be as straightforward a task as OMB and CMS may perceive it to be due to the nature of CMS' billing and reimbursement for these items. As you may know, when CMS pays a claim that includes a TDAPA and/or TPINIES add-on payment(s), facilities simply receive one payment for the adjusted base rate plus the TDAPA and/or TPNIES payment. The TDAPA and/or TPNIES payment is not indicated on a separate line item by CMS. While the ESRD PPS is a bundled payment system with a standardized base rate, most claims are adjusted based on a dozen patient and facility characteristics. As a result, in order to accurately report TDAPA and TPNIES payments on the Cost Report, providers will need to crosswalk each reimbursement to relevant patient claims and/or medical records in order to identify those for whom TDAPA and/or TPNIES payment was requested, then determine if and at what amount the TDAPA and/or TPNIES was paid (note that the TDAPA and TPNIES payment amount fluctuates based on CMS policy), and then report those figures on the Cost Report on a facility basis. For some providers this will be a manual, and not an automated exercise that would be applied both retroactively and prospectively for calendar year 2022. Going forward, if OMB and CMS

require separate reporting for TDAPA and TPNIES on the Cost Report, which we support, CMS should also amend billing and reimbursement procedures to flag these items separately on itemized reimbursement systems so that we can more effectively and efficiently identify and flag these items for accurate reporting into the Cost Report.

Going forward, and in the event of future changes to the TDAPA or TPNIES policies, we ask that CMS and OMB amend the Cost Report and/or instructions to make clear when and where payments received through TDAPA and TPNIES should be reported for specific products. Changes to the Cost Report and/or instructions should be made in advance to ensure providers have the proper systems in place to accurately collect and report this data onto the Cost Report.

(4) OMB and CMS should ensure that both bonuses, including the HDPA, and penalties associated with the ETC Model are recorded clearly on the Cost Report.

CMS proposes to collect revenue data related to the Home Dialysis Payment Adjuster (HDPA), which is paid to certain dialysis facilities pursuant to the mandatory ESRD Treatment Choices Model (ETC Model). KCC supports amending the Cost Report to collect cost data related to the HDPA. However, the Cost Report must also be amended to collect and identify cost reductions incurred by facilities as a result of the penalties associated with the ETC Model.

The Independent Renal Dialysis Facility Cost Report should collect data on both the bonuses and penalties associated with the ETC Model to give an accurate picture of ESRD facility reimbursement and economics. OMB and CMS should ensure that both bonuses and penalties will be reported on the Cost Report in a timely manner.

However, reporting the HDPA will not be as straightforward a task as OMB and CMS may perceive it to be due to the nature of CMS' billing and reimbursement. When CMS pays a claim that includes an HDPA bonus, facilities simply receive one payment for the adjusted base rate plus the HDPA bonus. The HDPA payment is not indicated on a separate line item by CMS. While the ESRD PPS is a bundled payment system with a standardized base rate, most claims are adjusted based on a dozen patient and facility characteristics. As a result, to accurately report the HDPA payments on the Cost Report, providers will need to crosswalk each reimbursement to relevant patient claims and/or medical records to identify those for whom the HDPA payment was requested, then determine if and at what amount the HDPA was paid, and then report those figures on the Cost Report on a facility basis. For some providers this will be a manual, and not an automated exercise that would be applied both retroactively and prospectively for calendar year 2022. Going forward, if OMB and CMS require separate reporting for the HDPA on the Cost Report, CMS should also amend billing and reimbursement procedures to flag the HDPA separately on itemized reimbursement systems so that we can more effectively and efficiently identify and flag these items for accurate reporting into the Cost Report.

(5) KCC supports updates to the Cost Report to help identify pediatric costs.

KCC supports proposed changes to the Cost Report related to pediatric patients. CMS proposes to require pediatric labor data reporting for Child Life/Other Specialists for Pediatric Patients, Registered Nurses – Pediatric, Nutritionists and Dieticians – Pediatric, and Pediatric Unit Staff. CMS also proposes to require reporting of Pediatric-specific supplies as a unique line-item.

Although we do not object to the changes regarding data collection of costs related to pediatric labor and supplies, we do not believe that facilities can accurately comply with this requirement retroactively to January 1, 2022, as proposed. We therefore ask OMB and CMS to modify the instructions for the new data collections related to pediatric labor and pediatric supplies to clarify that these sections shall be effective and apply to cost data beginning on January 1, 2023. This will allow CMS and OMB to proceed with finalizing the revised Cost Report on the current regulatory timetable and give facilities the time they require to comply with the data collection of pediatric cost data on a prospective rather than inappropriate, and potentially inaccurate, retrospective basis.

We are sympathetic to the fact that pediatric patients are few and the costs associated with their care can be greater than and more variable than the adult dialysis population. We are greatly supportive of CMS identifying these costs and ensuring that adequate costs are conveyed to providers to deliver quality pediatric dialysis care. As these costs were likely never accurately captured in the ESRD PPS and as the base rate has historically been underfunded for adults, we believe CMS and OMB should make any such changes in a manner that is *not* budget neutral and should add funds, as needed, to ensure appropriate care for children with kidney failure. However, patient-level costs are difficult to ascertain from facility Cost Reports. We offer to work with Administration and others in the kidney community to identify effective ways to identify pediatric costs to best serve this unique patient population.

(6) OMB and CMS should recognize the Network Fee required in statute on the Independent Renal Dialysis Facility Cost Report.

Congress created the ESRD Network Fee through the Social Security Act (SSA), which reads:

> The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2).[2]

[2]Social Security Act (SSA) § 1395rr(b)(7), as added by section 9335(j)(1) of OBRA '96.

The composite rate, of course, has been replaced by the ESRD PPS, but the 50 cent reduction has remained intact.

When the Congress first created the ESRD Networks in 1978, the programs were funded through the appropriations process.[3] The goal of establishing funding for the programs through a Network Fee that reduced payments to dialysis facilities was to ensure stable funding for these programs.[4] The history is silent as to whether this Network Fee should be accounted for on the ESRD cost reports.

To account for the Network Fee on the Cost Report, KCC recommends that CMS account for it as a "revenue reduction." A column entitled "ESRD Reductions (8.0)" would be added to Worksheet D after current column 7.02. Column 8.0 would be changed to 9.0. The instructions for Column D would read: "Enter the amount that results from Column 4 (Medicare treatments) X -$0.50 for the Network Fee." The instructions for Column 9 could read as: "Enter the sum of columns 7, 7.01, 7.02, and the negative amount from Column 8 into their corresponding line in column 9." The Provider Statistical and Reimbursement (PS&R) could be used as a reference to confirm the amounts included in the new Column 8.

The Network Fee is a clear cost to facilities imposed by the federal government, yet it is not acknowledged at all on the Cost Report. This causes margins to be overstated and gives policymakers an inaccurate picture of the health of the dialysis benefit in Medicare. OMB and CMS should rectify this issue as soon as possible and make needed changes for which KCC has long advocated to recognize the required Network Fee on the dialysis facility Cost Report.

Conclusion

KCC appreciates the opportunity to provide comments to proposed changes to the Independent Renal Dialysis Facility Cost Report Form. We stand ready to work with OMB and CMS on these important policy issues. Please contact me at ccepriano@kidneycarecouncil.org or (202) 744-2124 to discuss any of these issues further.

Respectfully Submitted,

Cherilyn T. Cepriano
President

[3] H.R. Rep. No. 727, "Omnibus Budget Reconciliation Act of 1986," 99th Cong., 2d Sess. 78 (1986).
[4] *Id.* (emphasis added).