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Nonprofit Kidney Care Alliance

September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1691-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Furnished to Individuals with Acute Kidney Injury, and End Stage Renal Disease Quality Incentive Program (CMS-1691-P).

Dear Administrator Verma:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations regarding the Centers for Medicare & Medicaid Services' (CMS) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System, Payment for Renal Dialysis Services to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program Proposed Rule (Proposed Rule). NKCA represents five nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve over 20,000 patients at more than 280 clinics in 30 states. Consistent with our belief that we can do more to keep patients *off dialysis*, we also serve more than 5,000 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 plans. Four of our five members are participating in the Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model. Together, they operate nine CEC ESCOs with over 4,700 patients.

Our goal in caring for dialysis patients and others with kidney disease is to provide the best care possible by improving patients' quality of life, reducing the risk of kidney failure, and increasing the number of kidney disease patients who can benefit from transplants. We believe that, on balance, the prospective payment bundle has allowed us to provide better care to our patients while achieving efficiencies in our delivery of care. It has also removed financial incentives that were not aligned with patient care. At the same time, we believe that it is critical that the Centers for Medicare & Medicaid Services (CMS) "go upstream" to address CKD in a more comprehensive manner. In doing so, more patients will benefit from transplant, fewer beneficiaries may start dialysis or at least delay its start, and those who do, will be better prepared and more aware of their options, including home dialysis. We appreciate the opportunity to provide comments on the following provisions of the Proposed Rule.

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule:

Transitional Drug Add-on Payment Adjustment (TDAPA)

To promote access to new therapies and provide dialysis providers with the ability to test new therapies during an initial uptake period, CMS proposes to expand the transitional drug add-on payment adjustment (TDAPA) to encompass all drugs (except "oral only" drugs), not just intravenous and injectable, regardless of whether a new drug falls within the current functional categories, which were established in the 2016 Final Rule. For those new drugs that fall within one of the existing functional categories, CMS proposes to pay average sales price (ASP)+0 for two years, after which they would be folded into the existing payment without any additional payment. In the case of a new drug that does not fall within the existing functional categories, a transition payment would be made for two years or longer and paid at wholesale acquisition cost (WAC) assuming ASP is not available, or manufacturers invoice price if WAC is not available. Once CMS has sufficient market data (after two years or longer) it would then determine if an additional payment to the base rate is warranted. CMS notes that this proposed policy would not only increase Medicare expenditures but also beneficiary cost sharing.

We share CMS' and others' concern that the current TDAPA policy, particularly as it is based on the existing "functional categories," may discourage development of innovative therapies as well as serve as a barrier to adoption by ESRD providers. Indeed, the current set of functional categories can be seen as a "straightjacket" on the prospect that a new drug would ever fall outside the current categories. In that sense, expanding TDAPA irrespective of the current categories can be a positive step. However, we are concerned that, as proposed, the policy would also encourage promotion of so called "me too" drugs and higher launch prices, even if moderated after two years. Developers need to have a clear roadmap and set of criteria based on whether a new drug is a significant clinical improvement—not necessarily a "breakthrough"—that warrants a higher cost to the program, and beneficiaries, as well as possible financial tradeoffs to providers. Rather than a completely open-ended policy, CMS should consider a new drug policy more in line with that which it applies in other parts of the Medicare program for new drugs and devices.

For example, under the new technology add-on payment (NTAP) policy for the hospital inpatient prospective payment system (IPPS), Congress enacted and CMS implemented regulatory criteria for a new technology to be eligible to receive an additional payment under the IPPS. Specifically, the manufacturer of a new technology (which includes "new technologies" that are drugs) must demonstrate that the technology is new, that payment for the diagnosis related group involved is inadequate for that technology, and that the technology represents a substantial clinical improvement over existing services. CMS implemented the process for manufacturers to apply for the NTAP payment, and that process includes an opportunity for stakeholders to provide input on the decision to grant or deny that application. Applicants are aware of the criteria that their products must satisfy to receive the NTAP. The law and the associated regulatory process are designed to ensure that a new technology (i.e., a drug, device, or service) will bring increased clinical value sufficient to justify the additional payment.

Under regulations, newness means the first commercial distribution of a technology such that its cost is not reflected in data used to calculate diagnosis-related group (DRG) relative weights. CMS also

examines newness in the context of whether a new product is different enough from an earlier version to justify using a newer U.S. Food & Drug Administration (FDA) clearance date as the date of first commercial availability.

With respect to the substantial clinical improvement test, current factors used to evaluate substantial clinical improvement include whether the new technology (i) offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; (ii) offers 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 improves clinical outcomes for a patient population as compared to currently available treatments. This policy is intended to spur innovation for products that do more than offer minor, if any, real clinical improvement. Such an improvement need not be "blockbuster" in nature. For example, a drug which significantly improves compliance because it is not accompanied by complications or adverse effects, such as gastrointestinal effects, that deter patient compliance might warrant higher payment.

A similar policy approach appropriate to the dialysis setting should be applied in the ESRD field which can spur investment in new innovative drugs, while not expending resources on drugs that offer only minor, if any, real clinical improvement or cause higher beneficiary costs.

Rebalancing

For payment year (PY) 2019, CMS proposes to rebase the ESRD bundled market basket, updating it to the 2016 cost structure, while retaining the existing 2012-based cost categories. CMS last rebased (and also revised) the market basket effective for PY 2015, four years ago, using data only a couple years into the implementation of the bundle.

While most of the shifts in weights are modest in their magnitude, and reflective of industry-wide developments, CMS specifically notes that two are influenced significantly by data from one large dialysis organization (LDO): pharmaceuticals and laboratories. In the case of pharmaceuticals, CMS (in Table 5) reports a 4.1 *percentage point* decrease from 2012 to 2016. In the case of the laboratory weight shift, which constitutes a smaller proportion of cost, CMS proposes to "smooth" the effect by employing a two year averaging. However, in the case of pharmaceuticals, CMS specifically notes that it is *not* proposing to take a similar approach—yet gives no rationale. This seems inconsistent on its face and we recommend that CMS consider taking a similar "smoothing" approach to pharmaceuticals. CMS routinely uses phase-ins and smoothing methods when there is a significant change, for which this certainly applies.

Comorbidity Burden Reduction

When the ESRD PPS bundle was implemented in 2011, certain comorbidity factors were included as part of the larger case-mix adjustment, to better ensure appropriate payment, particularly for sicker, higher-cost patients. However, in order to offset the cost of these factors, providers do not receive the full base rate for each treatment. While the intent behind these adjustments was admirable, the results have fallen short. Rather than compensate providers for the higher cost associated with certain patients, the documentation requirements have been too burdensome to capture, particularly for small providers, leaving them only with a lower base rate. This lost reimbursement is often referred to as "leakage."

Last year, as part of the 2018 proposed rule comment period, CMS asked stakeholders to identify policies that should be addressed to alleviate unnecessary burden. As we had in previous years, we took note of the administrative burden and payment loss in the current comorbidity policy. As we noted then, we appreciated the action CMS took in the 2016 Final Rule, when CMS removed two of the original comorbidity factors; monoclonal gammopathy and bacterial pneumonia. We believed then and still do today, that CMS can and should go further in exercising its discretion under the statute to limit further, if not withdraw completely, the comorbidities included in the current case mix adjustments. As MedPAC notes in its August 6, 2015 comment letter to CMS, the current comorbidities are "poorly identified" on claims and may cause additional, undue burden on patients who are subject to additional diagnostic procedures.

In the 2019 proposed rule, CMS acknowledges the documentation burden that the current comorbidity policy imposes. It goes further to note that these requirements exceed those which are employed for similar purposes in other parts of the Medicare program. Accordingly, CMS proposes to substitute the current documentation requirements with a new requirement to document the same set of comorbidity factors with the appropriate ICD-10 codes. We genuinely appreciate CMS listening to stakeholders concerns. As proposed, the use of ICD-10 codes to document comorbidities is an improvement over the current documentation requirements, since both pericarditis and hemolytic anemia (including sickle cell anemia) are more likely to be captured as a routine matter by ESRD providers than the current requirements. However, as we have noted before in comments to CMS, gastrointestinal tract bleeding with hemorrhage is not a diagnosis for which a dialysis clinic has ready access to the necessary documentation. As one of our members has repeatedly found, when a hospital admission is involved, gathering the required supporting documentation such as from a colonoscopy or endoscopy, can be difficult, if not impossible. Typically, the documentation only refers to "GI bleed" without reference to hemorrhage. A similar case can be made for myelodysplastic syndrome.

But *documentation* of these comorbidities misses the more important point, which we believe is whether these comorbidities are appropriate to begin with from both clinical, as well as cost vantage points. From a clinical vantage point, cardiovascular disease—which is not among the current comorbidities—is a, if not *the*, leading cause of death in the ESRD population. While not without it's own flaws, the ESRD PPS outlier policy can help address disproportionate costs that may be associated with comorbidities. The Secretary has discretion under Section 1881(b) as to what may be included in the case mix adjustment—i.e. comorbidities, per se, are not required. Therefore we urge CMS to consider suspending use of comorbidities.

Low Volume

CMS proposes four, largely technical, changes to the current low volume payment adjustment policies. Generally, these proposals contribute to a fairer set of requirements, taking into account individual low volume providers intrinsic differences. We note in particular, and support, CMS' proposal to allow Low Volume Payment Adjustment (LVPA) status when a change in provider transaction access number (PTAN) is accompanied by the acceptance of the acquired facility's provider agreement. This is consistent with CMS policy regarding change of ownership (CHOWs) in other provider contexts.

Outlier
When the bundle was established, 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. While the last two years have seen outlier payments closer to the 1% threshold, payments have yet to reach the threshold in *any* year since the implementation of the bundle. From 2011 through 2013, actual program experience fell well short of the 1% outlier target withheld (0.3% – 0.5%), resulting in an unnecessary loss to the base rate. The actual outlier expenditures have come closer to the 1% target in recent years, and most recently was at 0.8% in 2017.

Accordingly, based on its review of 2017 data, CMS proposes to reduce both the fixed dollar loss amount (FDL) and the Medicare allowable payment (MAP) for 2019 for adult patients in order to reach the 1% outlier threshold. As we have advocated in each of the last several years' comments, we urge CMS to reconsider the 1% outlier policy which was first implemented in the 2011 Final Rule. While an outlier adjustment is required under the statute, it does not specify a particular value. We believe that a 0.5% 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.

CMS also asks for comment on whether formerly composite rate drugs should be included within the outlier calculation in the future. Certainly, within the context of an expanded TDAPA policy, this will be a positive step, even if a "new drug" added to the bundle includes additional payment. If a new drug is folded into an existing functional category without additional payment it could be even more important. However, as CMS points out, the data necessary to implement such a policy is not currently collected and asks for recommendations. We believe this may have merit and encourage CMS to continue to seek stakeholder input in future rule-making in the context of whatever final policy it establishes for an expanded TDAPA in this year's 2019 final rule.

Solicitation for Information on Transplant and Modality
We wholeheartedly agree with CMS that for an individual with failing kidneys "the best treatment is receiving a kidney transplant." We further agree with CMS that transplantation "offers recipients a longer, higher quality of life without the ongoing risk of dialysis." Unfortunately, as CMS notes, the number of people on transplant waiting lists far exceeds the available organs. CMS has it within its power to address the gap between available organs and the number of people on wait lists seeking transplant. In addition, we believe more should be done to encourage and eliminate barriers to living organ donation.

Unfortunately, today there is far too little collaboration nationwide to increase access to transplantation. Dialysis clinics, nephrologists, organ procurement organizations, and transplant centers all address transplantation, but there is no cohesive approach to kidney transplantation. In addition, the CMS Conditions of Participation, written with the honorable goal of improving outcomes of transplant programs, has had the unintended consequence of limiting access to kidneys that are not optimal or higher risk.

Specifically, in the 2007 revision to the transplant center Conditions of Participation, CMS set transplant center criteria for patient and graft survival, where CMS had observed problems. Transplant centers that did not meet these criteria have been required to implement a corrective action plan.

Although the goal of the revised Conditions of Participation was to improve patient outcomes, the unintended effect was to decrease the number of kidney transplants in these programs. As a part of corrective action plans, or to avoid being cited in the first place, many transplant centers set more stringent criteria for recipients and donors. As a result, outcomes have improved, but the number of transplants decreased.

Even recent studies have investigated this issue. In a 2013 American Journal of Transplantation study, Dr. Jesse Schold looked at the change in transplantation in transplant centers considered to have low performance. He found a mean decline of 22.4 to 26.8 transplants in those centers. He also looked at the transplant outcomes for these "low performing" transplant centers. When he compared the survival rate for patients receiving a transplant from lower performing transplant centers to the survival rate for patients on dialysis and on the transplant waiting list, he found that the adjusted hazard ratio was 0.38. In effect, he found that the mortality rate for a patient receiving a transplant from "low performing" transplant centers was 1/3 of the mortality rate for a patient on dialysis and on the transplant waitlist.

We greatly appreciate that CMS has made some changes to the criteria in 2016. However, we strongly believe that much more can be done. Unfortunately, the reality is that transplant centers are not accepting kidneys with a ≥ 85 kidney donor profile index (KDPI) score because of the risk of a poor outcome relative to the Conditions of Participation. We believe that transplant center performance will change, and more people will have access to a transplant, if kidneys with a KDPI ≥ 85 are not included in the evaluation under the Conditions of Participation. Until this change is made, we do not expect to see a large change in behavior in transplant programs.

At the same time, CMS expresses concern that despite Conditions for Coverage (CfC) requirements for patient education on modalities and assessment and referral for transplant candidacy, the percentage of patients wait-listed has declined. CMS also expresses concern that too many dialysis patients are unaware of the option for home dialysis, and the opportunities for greater independence and quality of life that home dialysis can offer.

Ironically, CMS puts its finger on a problem that contributes significantly to both the low use of home dialysis and transplantation. As CMS notes, many patients experiencing kidney failure have had little or no prior nephrology care or awareness of their options. Indeed, as we and others have pointed out previously, waiting until a patient "crashes" into an emergency room with kidney failure is too late to have a meaningful discussion about modality, at least from a pre-emptive vantage point, which would offer better opportunity for improved care and quality of life.

NKCA believes the single most important change that can occur for patients with kidney disease is to alter the focus of the current reimbursement system from care for patients *on dialysis* to care for patients *with kidney disease*, at whatever stage of their renal condition. Rather than seeing the patient as someone who will inevitably need dialysis in the future, we believe it is critical to go "up-stream" to screen for, educate, and care for patients with CKD including better integration of care through primary care models such as Accountable Care Organizations (ACOs) that identify and refer appropriate patients for CKD care. It is also important to note that CKD care is not just to better prepare for dialysis. When managed early, CKD patients can have a number of options for their care including avoidance of further renal decline, medical management, and transplant. For those individuals who choose or need dialysis as a therapy, it is still necessary to begin education as early as

possible so when they do transition to dialysis, they are prepared and aware of their care options—*particularly home dialysis*—and less likely to "crash" into the emergency room.

NKCA also believes that early CKD education and intervention will decrease the likelihood that a patient who does progress to end-stage renal disease ***will not*** receive his or her first dialysis treatment in a hospital. We see this as an important improvement in care since patients avoiding a hospitalization will also be able to avoid the complications from a hospitalization. We estimate that the cost of hospitalization and follow-up care is $25,000 for a patient on dialysis. Moreover, by providing early education and counseling, patients are able to understand their treatment options, such as home dialysis, and maximize the opportunity of receiving a kidney transplant. Transplant education is an important part of CKD education and works best with early identification of CKD, patient (and family) education, and navigation of treatment options.

We recommend that a program focused on improving care for patients with CKD start with patients at Stage 4 and 5 CKD with a Glomerular Filtration Rate (GFR) < 30. While probably too complex to address now, patients with a GFR > 30 *and* an Albumin-to-creatinine ratio (ACR) of 300 should eventually be considered for inclusion in a CKD program, but more would need to be done with primary care and other physicians to check for ACR. Although optimally we would like to provide care for all patients with CKD, the number of patients with GFR > 30 is so large that it would potentially overwhelm any program, hence the ACR factor.

The cost of care for patients with CKD is significant and as the patient's kidney disease progresses, the cost of care increases—but still much less than for a patient on dialysis. The following is an estimate of cost of care by stage[1]. Note the change in cost of care for a patient with stage 5 CKD *not* on dialysis and a patient on dialysis:

- Stage 4: $33,374 per year (3.1 times the cost of care for typical patient with Medicare coverage)
- Stage 5 *not* on dialysis: $36,147 per year (3.3 times the cost of care for typical patient with Medicare coverage)
- Stage 5, on dialysis: $84,645 per year (7.8 times the cost of care for typical patient with Medicare coverage)

Put another way, for every month that start of dialysis is delayed, we can decrease the cost of care for Medicare by more than $4,000 per patient. These costs can also be compounded since many CKD patients also have diabetes and hypertension.

Moreover, as significant as the difference in cost is, the difference in quality of life is priceless. For patients who dialyze in a clinic, their week is dominated by the necessity of a dialysis session three times a week, for 4-5 hours per session, plus travel to and from the clinic.

There is a significant opportunity to improve care for patients with CKD not on dialysis since most of these patients are not receiving care related to their kidney disease. In fact, according to the U.S. Renal Data System (USRDS), only 7.7% of patients with stage 3 CKD even know that they have kidney

[1] Based on an analysis of 2013 Medicare 5% claims data

disease. For patients with stage 4 CKD, only 53% of the patients even know that they have kidney disease.

Stage 5, not on dialysis (GFR < 15)
We want to particularly note that patients can still be effectively managed at stage 5 CKD, without dialysis. These patients should be seen more often to manage their symptoms and push back the start of dialysis as far as possible, while recognizing that each patient is different and should be treated as such. Overall a GFR of 5-10 is optimal for many patients to allow for a smooth transition to dialysis.

To be able to address CKD before reaching dialysis, individuals need to be aware of their kidney disease before they reach the point of needing dialysis treatment. One place to start would be for estimated GFR (eGFR) to be reported by primary care physicians. Currently, very few physicians are billing the ICD-10 code for CKD stage 3, thus it is difficult to track and identify patients. Yet, ideally, this is when we should begin managing CKD with the patient. We recommend this be a requirement in claims data to capture eGFR for patients with diabetes and hypertension, which are typically precursors to kidney disease. This requirement could be expanded in the future to track for additional patients at risk. Physicians receiving lab reports should have a protocol for patients that begins with closer monitoring with an eGFR less than 45, and then additional testing for ACR for those with less than 30 eGFR so that patients can be informed and referred to a nephrologist to offer opportunities to manage the progression of kidney disease.

Accounting for Social Risk Factors in the ESRD QIP
The Improving Medicare Post-Acute Care Transformation Act (IMPACT) mandated a study from the Department of Health and Human Services (HHS) on social risk factors, which the HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) released in December of 2016. Along with other studies, including from the National Academies of Sciences and the National Quality Forum, the ASPE study focused attention on whether, and if so how, CMS value-based payment systems, including the ESRD QIP, should account for social risk factors. Under the IMPACT Act, ASPE is to release a second, follow-up report in the fall of 2019. We hope that it will provide options for CMS to consider the balance that CMS has rightly pointed out previously, between the risk of masking disparities in care for certain populations while also assuring that the quality of care provided by facilities is accurately and fairly assessed. In the interim, CMS may want to consider a temporary policy that draws on the experience CMS has with respect to risk adjustment payment for dual-eligibles in the Medicare Advantage program.

We appreciate CMS' commitment to working with stakeholders to develop appropriate and administratively workable options, including the commitment to notice and comment rulemaking. Many of the factors to be considered will be complex and time-consuming. We would also point to the approach suggested in the 2016 ASPE report in which public reporting metrics promote transparency to avoid the risk of masking disparities, while payment is adjusted for social risk so as not to discourage providers from serving disadvantaged populations. Additionally, MedPAC's recommendation, also drawing on the 2016 ASPE report, is that in accounting for social risk factors, CMS "stratify providers into groups by proportion of risk," --in effect what was called for in the CURE's Act in the hospital readmissions program. We believe that a framework reflecting these features can help achieve both the goal of transparency, so that disparities are not masked, and the goal

of fair and adequate payment so that providers have the resources to serve more challenging patients, such as dual eligibles.

Conclusion

Thank you for the opportunity to comment on the 2019 ESRD PPS Proposed Rule. The NKCA appreciates the opportunity to provide input to ensure the rule's impact continues to support quality of care to the patients we serve. As nonprofit providers, these changes impact us much differently than others. We would be pleased to discuss any of these 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