



August 28, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Room 445-G
Washington, D.C. 20201

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 1651-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 and Medicaid Services' (CMS) 2018 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 4,500 patients with chronic kidney disease with the goal of avoiding, or at least delaying, the onset of end stage renal disease. As nonprofit providers, approximately 85% of our patients are covered by Medicare, including Medicare Advantage plans. Four of our five members also have experience participating in a current Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model. Together, they operate nine CEC ESCO's 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 CMS "go upstream" to address chronic kidney disease (CKD) and transplant so that fewer beneficiaries start dialysis or at least delay its start. We appreciate the opportunity to provide comments on the following provisions of the Proposed Rule and the Request for Information (RFI).

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule:

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. In the 2016 Proposed Rule, CMS reported that outlier payments were much closer to the 1% target, estimated to have been 0.9% in 2014. For the 2018 Proposed Rule, CMS reports that outlier payments fell short of the 1% target again, coming in at 0.78%, much of which CMS attributes to a shift in the use of longer acting erythropoiesis (ESA) agents away from Epoetin alfa (EPO).

Accordingly, based on its review of 2016 data, CMS proposes to increase the outlier threshold and reduce the Medicare Allowable Payment (MAP) for 2018 for adult patients. As we have advocated in each of the last several years’ comments, we urge CMS to reconsider the 1% outlier policy first implemented in the 2011 Final Rule. While an outlier adjustment is required under the statute, a 0.5% outlier threshold would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs.

Acute Kidney Injury (AKI)

Section 808(a) of the Trade Preferences Extension Act (TPEA) provided for coverage and payment for renal dialysis services by ESRD providers to individuals with Acute Kidney Injury (AKI) (Sec. 1834(r)). CMS now proposes to implement a system to measure the quality of care delivered to AKI patients. We agree that there should be a system to measure the quality of care delivered to patients with acute kidney injury. That system should not, however, be the current ESRD QIP system, nor merely some subset, for the simple reason that these are not patients with end stage renal disease and the primary goal of treatment for AKI patients is recovery of organ function.

A system for assuring and measuring the quality of care in AKI should be governed by the following key principles:

- a) Promote recovery of kidney function
- b) Promote timely discontinuation of dialysis for AKI when:
 - i) Kidney function has recovered such that it is adequate to meet patient needs;
 - ii) Patient is declared ESRD; or
 - iii) Continuation is no longer consistent with the patient’s goals
- c) Recognize the heterogeneity of patients and patient characteristics among the AKI population requiring dialysis, including the causes of AKI which span a broad range of possible causes, from acute tubular necrosis (ATN) to kidney transplant delayed function, to pregnancy, and so forth.
- d) At least initially, focus quality metrics on program-wide monitoring rather than applying them at the facility-level due to the relatively small numbers of AKI patients receiving dialysis at

dialysis facilities. Quality measures should not be applied at the facility level until the AKI population is adequately surveyed and analyzed, though a limited set of national measures could be monitored to track trends and/or emerging issues.

We recommend the following next steps:

- 1) CMS should conduct a survey to better understand the AKI population being served so that there is a better picture of patient characteristics such as age, race, the cause of AKI; place of service (to better understand what types of patients are being referred to free-standing dialysis clinics as opposed to those continuing to receive hospital-based care); duration of hospitalization; comorbid illnesses; baseline kidney function (if applicable) and so on.
- 2) Convening of a Technical Expert Panel (TEP) to assemble stakeholders in the kidney community to better define AKI (e.g., when does likelihood of recovery indicate continued treatment for AKI, and when does it indicate transition to ESRD) and collect and organize data to increase access to information and limit reporting burden.
- 3) CMS should also address operational issues, such as date of ESRD start for purposes of:
 - a) kidney transplant listing,
 - b) Medicare eligibility, and
 - c) incident patient modifier.

Specifically, if a patient with AKI does not recover kidney function, are all of these items backdated to the initiation of dialysis? For example, because AKI patients dialyze with a catheter, and might be on dialysis for several weeks, this could affect a facility's catheter rate.

There are some basic, initial, *reporting only* metrics that CMS could consider while undertaking a more thorough approach as outlined above: baseline kidney function; serum creatinine levels; fluid; frequency of treatment; and, frequency of labs.

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.

CMS rightly points to the difficult balance to be struck 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. 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. Some work has already been undertaken by CMS, notably with respect to dual-eligibles in the Medicare Advantage program, where limited, interim adjustments have been developed. We would also point to the approach suggested in the 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. We also note MedPAC's recommendation, also drawing on the 2016 ASPE report, that in accounting for social risk factors, CMS "Stratify providers into groups by proportion of risk." 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.

Performance Score Certificate

CMS proposes to shorten the Performance Score Certificate (PSC) in order to make the PSC a more effective and understandable document. We agree that the PSC can be a more useful tool for patients and families to be aware of a facility's performance. However, we question whether shortening the Certificate would make it more effective and understandable. Moreover, while Sec. 1881(h)(6)(C), which CMS cites, only refers to the total performance score in describing what is to be included in the Certificate, Section 1881(h)(6)(A) calls upon the Secretary to make information available to the public including the total score, comparisons to the national average, and performance on individual measures.

The more important question which CMS raises is what kinds of information and in what formats will better inform the decisions a patient (or others acting with or on their behalf) must make. While some patients may prefer a brief document posted at the facility like the PSC, others will prefer to look behind the posted numbers to better understand the meaning of the terms, their implications, and any limitations in interpreting their meaning. Patients, as consumers, are increasingly familiar with web-based information presented at a summary level, accompanied by multiple "pull-down" menus that enable them to delve deeper. While a printed PSC does not lend itself to pull-downs, it can include links to other ESRD resources, much as it does now, with a link to a CMS web address where they could see the PSC with more detail available behind it.

Beyond the proposed change in the PSC, but apropos of more effective and understandable information for patients, CMS could make a further improvement by integrating the QIP program and the Star Rating system. While not addressed in this proposed rule, we recommend that CMS consider, in future rulemaking, consolidating the Star Ratings with the QIP system. Under such an integrated system, Star Ratings could be a subset of the QIP metrics that the public would find useful. In sum, we agree with CMS' stated goal of moving to a more streamlined and understandable approach, and recommend that it work with stakeholders, including patients, in doing so.

QIP 2021 Vascular Access Measures

We support CMS' proposal to remove the two existing Vascular Access measures and replace them with two new measures, which have been endorsed by the National Quality Forum (NQF): Hemodialysis Vascular Access: Standardized Fistula Rate (NQF #2977) and Long-Term Catheter Rate (NQF #2978). The new fistula measure adds adjustment for factors associated with illness severity and comorbid conditions that may limit fistula success while the catheter measure excludes patients who may be more appropriately treated with a catheter; for example, dialysis with a catheter in a hospice patient will not be counted against a facility.

We appreciate the effort by CMS over the past few years, including the convening of a Technical Expert Panel, to assess best practice in Vascular Access. We note CMS acting on the TEP's recommendation to align these two measures in a manner that recognizes that while a fistula is the better option for most patients, for some patients it is not appropriate and a catheter is the better clinical choice. We hope that these measures continue to be reviewed and revisited when necessary to account for factors that may warrant further refinement.

Request for Information (RFI) on Medicare Flexibilities and Efficiencies

CMS asks for recommendations to improve patient care and reduce unnecessary burdens on clinicians, providers and patients, including, among other things, payment system redesign, streamlining of reporting and documentation, operational flexibility, and data sharing to enhance patient care. Within the existing Medicare ESRD program, there are several things CMS could undertake through rule-making or sub-regulatory guidance that would simplify the program, and reduce administrative burden without compromising patient care.

Reduce Bundle “Leakage”

When the ESRD PPS bundle was implemented in 2011, certain factors were included 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. We refer to this lost reimbursement as “leakage.”

The following recommended changes would decrease leakage and allow all providers to receive the full base rate intended for the treatment of patients on dialysis.

Suspend the Comorbidity Adjustors. Not all dialysis providers are able to capture the data necessary to document all comorbidities for patients. In the 2016 Final Rule, CMS did remove two comorbidity factors—monoclonal gammopathy and bacterial pneumonia—due in large measure to the administrative burden they posed. We believe CMS can and should go further in exercising its discretion 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.

Indeed, in the case of the remaining acute comorbidities, the same case can be made as with bacterial pneumonia. For example, “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. This only contributes to a reduction of the base rate, making it that more challenging for providers to cover the cost of care.

We are concerned that smaller and nonprofit providers are disproportionately impacted by the inclusion of comorbidity factors because they do not have the infrastructure of larger providers and therefore are less likely to capture all of the data, particularly for acute comorbidities. The net effect is that a provision that was originally put into place to protect small providers is actually penalizing them by decreasing the base rate. The Secretary has discretion under Section 1881(b) as to what may be included in the case mix adjustment. While CMS does not address this in this year's Proposed Rule, we urge that it consider this change for future rulemaking.

Suspend or Decrease to 0.5% the Outlier Payment. From the outset of the ESRD bundle, CMS projected 1% outlier amount has never been achieved. The shortfall in 2011 resulted in only about 52% of the outlier pool being used. As a result, over \$1 per treatment was effectively removed from the base rate. In one year, outlier payments represented only 0.2%, well short of the 1% target. 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. As we have in each of the last few years' comments, we urge CMS to reconsider the 1% outlier policy, first established in the 2011 final rule. As we have noted in this year's (see discussion above on the proposed 2018 rule) and prior comments, while an outlier adjustment is required under the statute, no fixed percent is needed. Thus a 0.5% outlier threshold would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs

We are concerned that smaller, independent providers are disproportionately impacted by this current provision because they do not have the infrastructure of larger providers and therefore are less likely to capture all of the required documentation. The net effect is that a provision that was originally put in place to protect small providers is actually penalizing them by decreasing the base rate. While CMS does not propose a change in the 1% threshold outlier policy in the 2018 Proposed Rule, we urge the agency, in considering comments under this RFI, to reconsider the matter in future rule-making.

Beyond ESRD—Going Upstream

As noted previously, NKCA members have been very active in the development of the CMMI CEC model and the launch of the ESRD Seamless Care Organizations (ESCOs). We appreciate CMS' continued commitment to growing and evolving the model. 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 chronic kidney disease (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 that CKD care is not just to better prepare for dialysis. Indeed, CKD patients, when managed early, 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 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 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, education, and navigation of treatment options.

We recommend that a program focused on improving care for patients with CKD start with patients with a Glomerular Filtration Rate (GFR) < 30 and an Albumin-to-creatinine ratio (ACR) of 300. 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.

We estimate that a program managing this population would have the following distribution of patients¹:

- Stage 4a (GFR 20-30): 15.0% (3,200 patients per 1 million patients)
- Stage 4b (GFR 15-20): 7.5% (1,600 patients per 1 million patients)
- Stage 5, *not* on dialysis (GFR < 15): 6.6% (1,450 patients per 1 million patients)
- Transitioning to renal replacement therapy each year: 1.7% (359 patients per 1 million patients)

The cost of care for patients with chronic kidney disease (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 stage², 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 we can delay the start of dialysis, 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 even more significant. For patients who dialyze in a clinic, their week is dominated by the necessity of a dialysis

¹ Based on NHANES data, provided in the most recent USRDS report

² Based on an analysis of 2013 Medicare 5% claims data

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 USRDS, only 7.7% of patients with stage 3 CKD even know that they have kidney 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.

Medical Management Without Dialysis

For most patients starting dialysis, they are committing to start a therapy that will require them to receive three, four-hour treatments per week. After including the time for travel to and from dialysis, and the recovery from dialysis care, many patients lose three out of seven days a week because of the obligations of dialysis care. Based on recently published literature³, we know that patients who are older than 80 with multiple comorbidities who choose medical management without dialysis have similar survival outcomes compared to those who choose dialysis. This choice must include coordination with the family of the patient and intensive management of care.

Finally, end of life care is an important part of the care continuum, particularly for our patients in order to educate them on their options and plan early based on their wishes. NKCA applauds CMS for including reporting on Advanced Care Planning in the ESCO and encourages CMS to include it in other models as well.

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 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.

Conclusion

Thank you for the opportunity to comment on the 2018 ESRD PPS Proposed Rule and the Request for Information. 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,

A handwritten signature in blue ink that reads "Martin Corry". The signature is written in a cursive style with a long, sweeping tail on the letter "y".

Martin Corry
Executive Director