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Nonprofit Kidney Care Alliance

August 25, 2015

Andrew Slavitt
Acting 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: CMS 1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program Proposed Rule; July 1, 2015

Dear Administrator Slavitt:
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) 2016 End-Stage Renal Disease (ESRD) Prospective Payment System and 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. As nonprofit providers, we receive approximately 85% of our payments from Medicare. NKCA members have been very active in the development of the Center for Medicare and Medicaid Innovation's (CMMI) Comprehensive ESRD Care Initiative and look forward to the formal launch of the ESRD Seamless Care Organizations (ESCO's).

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.

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule:

Comorbidities
While CMS is required to include case mix adjustment in formulating the ESRD PPS, it has discretion as to how many and which factors to include. While case mix adjustment makes sense in principle, in practice it has been very uneven in terms of effectiveness, particularly since every adjuster comes at the expense of the base rate. This has been particularly true when it comes to adjustment for comorbidities which have proven to be very difficult to document—a concern which the NKCA, among others, have brought to CMS' attention over the past few years. Accordingly, we commend CMS for proposing to eliminate two of the current comorbidities: monoclonal gammopathy and

bacterial pneumonia. In both cases, CMS points to public comments and stakeholder meetings in which the administrative burden and difficulty in obtaining documentation from other providers has proven to be a significant barrier.

At the same time, we believe CMS can and should go further in exercising its discretion to further limit, 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.

Certainly, 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. Again, this indicates it is readily apparent that it is not working and only contributes to diminution of the base rate, making it that more challenging for providers to cover the cost of care.

Low Volume Payment Adjustment

We support CMS' proposed changes to the eligibility criteria and adjustment upward in payment for low volume facilities. The changes in eligibility respond in part to recent recommendations from the Government Accountability Office (GAO) and MedPAC that the low volume payment adjuster (LVPA) needs better targeting to assure that it is serving its intended purpose. We commend CMS for its proposed change to restrict geographic proximity from 25 miles to 5 miles, regardless of when a facility was certified. We believe this change will better target the LVPA to address access to care. We also appreciate CMS' recognition of the higher costs borne by low volume facilities as a result of their more limited patient base. CMS could improve its proposal and further increase access to care by providing that continuation of LVPA status be based on a three year rolling average, rather than the current one year eligibility period. This less volatile criteria would also reduce the incentive to hold down the number of patients served in any given year for fear of exceeding the cap.

Rural adjuster

Like the LVPA, the proposed rural adjuster can further the goal of assuring access to a patient population which needs ready access to care three times a week. Unlike its finding in the 2011 Proposed Rule, CMS' analysis now points to a modest cost difference related to rural location. Whether the proposed modest adjustment will improve access is unclear. Being in a rural wage area does not always mean that a facility faces higher costs.

Moreover, while the assumption is often made that "rural" equates with "small", this is not always the case. Since volume of treatments (i.e. number of patients) is a strong predictor of clinic financial health, there is not always a strong case for additional payment adjustment simply by virtue of being in a rural county. Sometimes the difference between being in a county within a CBSA and being in a rural county, is little more than location on one side or the other of a line on a map. While CMS rightly points out that "low volume" and "rural" are distinct variables, in reality, they do overlap in many cases and every adjustment comes at the expense of the base rate, and ultimately resources that can be

directed to patient care. Therefore, if CMS retains the new proposed rural adjustment, it should not allow a facility to benefit from both LVPA and rural status at the same time. That is, once a facility which benefits from the rural adjustment satisfies the LVPA criteria it should have to choose which to forgo.

To ensure that the rural clinic adjustor is effectively targeted to only those clinics that provide an improvement in access to care, we recommend that the rural adjustor be limited to clinics that provide less than 7,000 treatments per year. In addition, we recommend that the rural adjustor only be available for clinics in which there is not another clinic (any dialysis clinic, not just a clinic operated by the same provider) within five (5) miles of the clinic that is otherwise eligible for a rural adjustor payment.

Body Surface Area (BSA) and Body Mass Index (BMI)

Unlike certain other case mix adjusters in the ESRD PPS, body surface area (BSA) and body mass index (BMI) are readily available. CMS regression analyses point to higher cost for patients with higher BSAs as well as for those, often more frail or malnourished, with lower BMI. Unfortunately, the two factors interact in the payment formula and can offset each other. While BSA and BMI are often discussed in parallel, in fact, they were intended under the original design of the bundled ESRD PPS to address two separate and distinct issues:

- BMI of less than 18.5 kg/m is considered underweight and indicative of a patient who is undernourished or subject to a comorbidity such as wasting syndrome.
- In contrast, BSA, while a measure of weight and height, addresses *the duration and intensity* of dialysis that is required to achieve dialysis adequacy targets.

Because a lower BSA reduces payment, it can have the effect of mitigating the benefit of the low BMI adjustor. We ask CMS to address the potential interaction of these two related but separate factors. One option would be to create a "floor" below which a negative BSA adjustment would not apply to avoid interaction with the BMI adjustment. Specifically, we recommend that the BSA adjustor not be applied to a patient with a BMI of less than 18.5 kg/m.

If doing so would cause an additional offset to the base rate, we suggest the elimination of comorbidities, as we recommend above. Over the longer term, this may be addressed further if CMS develops a single regression analysis.

Age adjuster

CMS notes that in both the pre-2011 composite rate and in the ESRD PPS there is a significant relationship between age and cost, with higher cost at the lower and upper ends of the adult age distribution ("a U-shaped relationship"). Intuitively, that is understandable. What is not understandable—at least on its face—is the proposed shift in the reference age group in the 2016 Proposed Rule; nor is it apparent what the basis is for the growth within each of the age bands which were in the range of 2% to 17% and under the Proposed Rule would be 7 to 25%.

Under the Proposed Rule, the reference group would shift from 60-69 to 70-79. As a result, the payment multiplier for the younger 60-69 age group increases, while the multiplier for the 70-79 group declines, as this becomes the new reference group with a multiplier of 1.0. The Proposed Rule indicates that this is the result of the regression analysis based on 2012 and 2013 data, but offers no

further explanation. It is unclear what is producing such a seemingly anomalous result. Perhaps, as MedPAC suggests, this is the result of the two equation system, or some other factor(s) in the model. Whatever the cause, it does strongly suggest that the better course at this time is to leave the reference group unchanged pending further analysis, and we urge CMS to do so.

We also request that CMS carefully review whether an age adjustor for patients older than 80 years old is warranted. We note that recently numerous articles have indicated that medical management without dialysis provides comparable outcomes for certain patients, including patients who are older than 80 years old who have multiple comorbidities. Perhaps CMS is seeing an increase in cost of care for this population because it includes patients who are not good candidates for dialysis.

One of our members, DCI, has implemented a pilot for Chronic Kidney Disease (CKD) Care Coordination serving 3,100 patients in 26 locations. In this pilot we are seeing patients, especially those older than 80 years of age choosing medical management without dialysis if given this choice before they start dialysis. As we and other providers gain more experience educating our patients about their options, medical management without dialysis, can be a choice for a better quality of life for some patients.

Yet, an increase in payment for patients older than 80 could unintentionally provide a disincentive for providers to discuss medical management without dialysis with patients approaching the need for dialysis. This is yet another reason for CMS to withdraw the proposed increase in payment for this patient population.

Outlier

When the bundle was established, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. To account for these higher "outlier" payments, providers do not receive the full base rate for each treatment. From 2011 through 2013, actual program experience fell well short of the 1% outlier target withhold, (0.3% – 0.5%) resulting in an unnecessary loss to the base rate. In the Proposed Rule, CMS reports that outlier payments have now come much closer to the 1% target, estimated to have been 0.9% in 2014. While this is a significant improvement, and the statute calls for an outlier factor, it does *not* set a specific number. Moreover, the current outlier threshold was based on work by CMS and its contractor based largely on separately billables with data prior to changes in utilization resulting from the FDA's "black-box" warning on Erythropoiesis Stimulating Agents (ESAs). We continue to believe that the outlier factor should be set at 0.5%, rather than 1.0%, which is closer to the actual rate that has occurred since 2011 when the ESRD PPS was implemented.

Home Dialysis Training Adjustor

We urge CMS to review and update the home dialysis training adjustor annually. We appreciate that CMS updated the training payment in the 2014 Final Rule to $50.16, which represents 90 minutes of nursing time (up from 60 minutes previously). However, as we have noted previously, we believe that this payment is still well below the cost of providing this required service and contributes to the lack of access to home dialysis modalities, particularly home hemodialysis. We ask that CMS continue its review of payments for home dialysis training generally and ask that the agency establish training rates that are more closely related to the actual cost of providing the service.

Additionally, CMS should provide for an annual inflationary adjustment to the payment. A separate inflationary adjustment is necessary, as the training add-on payment is outside the bundled base rate and is not adjusted by the annual market basket update. Given that the training add-on adjustment is directly related to nursing salaries and those salaries and staffing costs go up over time, the training add-on payment should be adjusted accordingly.

Process for new functional categories placement of drugs and biologics
CMS proposes to codify a set of "functional categories," previously referred to as drug categories, that it has utilized since the 2011 final rule to determine whether or not a drug or biologic falls within the ESRD bundle. CMS proposes a process by which it would determine whether a new drug falls within one of the existing functional categories, and if so, it would be placed in that category and no additional payment would be made. If, however, a new drug or biologic does not fall into one of the functional categories, then CMS would either modify an existing category or create a new one, in which case, it proposes to pay for such drug at ASP+6 for two years to allow sufficient time to gather claims data. In effect CMS creates and "either/or" situation.

Since it is rather apparent that CMS will make every effort to place a drug within the existing, rather expansive, set of categories, it should also avail itself of a third option, when warranted. Specifically, CMS seems to overlook the possibility of a third scenario: a drug or biologic which would fall within an existing category that also represents a significant clinical improvement and might warrant a higher payment. Under this scenario there is no room under the bundle payment and the only recourse CMS offers is that there might be outlier payment—which of course ultimately comes at the expense of the bundle base rate as well and does not cover the full cost. While this scenario might not occur often, CMS should avail itself of the ability to provide for a higher payment, based on the evidence at the time, and not just assume that it can be absorbed.

Conclusion
Thank you for the opportunity to comment on the 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