N K
C A
Nonprofit Kidney Care Alliance

September 2, 2014

The Honorable Marilyn B. Tavenner
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 1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Proposed Rule; July 2, 2014

Dear Administrator Tavenner:

The Nonprofit Kidney Care Alliance (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 18,500 patients at more than 260 facilities in 30 states. As nonprofit providers, we receive approximately 85% of our payments from Medicare. Our goal is to provide the best service possible for patients on dialysis and to improve care for all patients with kidney disease, including those not on dialysis, thereby decreasing the number of patients needing dialysis and increasing the number who can benefit from transplants. We believe that, on balance, the end-stage renal disease (ESRD) prospective payment bundle has allowed us to innovate and 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, such as overuse of separately billable medications.

Comments Regarding Specific Aspects of the ESRD PPS Proposed Rule:

Revised Labor Share

In conjunction with a rebasing and revision of the ESRD market basket, the Centers for Medicare and Medicaid Services (CMS) proposes an increase in the labor-related share via a two year phase-in. CMS proposes to increase the current labor-related share of 41.737 to 46.205 in 2015, and then to 50.673 in 2016. CMS notes that implementing this 21 percent increase in the labor related share would adversely affect rural clinics and those in core based statistical areas (CBSAs) with a wage index below 1.0. We appreciate CMS's attention to the negative effect on these clinics and its proposal for a two year phase-in. However, given the few months remaining before this and other changes would be implemented, we urge CMS to utilize a three year phase-in to allow ESRD facilities time to adjust to the a new labor-related share.

Pharmaceuticals

CMS proposes to use the producer price index (PPI) for "Vitamin, Nutrient, and Hematinic Preparations" as a proxy for pharmaceutical acquisition cost on the grounds that it "includes drugs that are most similar to erythropoiesis-stimulating agents (ESAs) and other drugs used in the ESRD setting, such as iron supplements." In fact, the drugs in this index are over the counter vitamin supplements; whereas the drugs provided by dialysis facilities are prescription drugs. Indeed, the iron supplement in this category is the same supplement on which CMS commented on in the CY 2011 final rule: "Oral iron is generally available over the counter and not covered under Parts B or D. Therefore, it is not included in the payment bundle. (49042 Federal Register / Vol. 75, No. 155 / Thursday, August 12, 2010 / Rules and Regulations)"

Since ESAs account for most of the cost of pharmaceuticals included in the ESRD bundle, the more appropriate PPI category is "biological product for human use." Accordingly, we strongly urge CMS to adopt this price proxy (not Vitamin, Nutrient and Hematinic Preparations) in the final rule.

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, 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.

Low Volume Payment Adjustment

CMS advises stakeholders that, notwithstanding a recent U.S. Government Accountability Office (GAO) report, it will defer any major changes in the Low Volume Payment Adjustment until 2016 when CMS can undertake a more comprehensive assessment. We support CMS's decision to take a more holistic view, and urge the agency to consider the following issues. We urge CMS to maintain the current "grandfathering" provision, recognizing that those ESRD providers have made their decision to operate in what are often underserved areas, with the current provision in mind.

CMS does, however, outline two clarifications. CMS clarifies that Medicare Administrative Contractors (MACs) should make their determinations on a facility-by-facility basis including treatment counts, rather than aggregating them with affiliated clinics, unless they are under both the same parent organization and within 25 miles. The second clarification addresses inconsistent treatment, in which there is a change in ownership and when the new owner accepts the existing

provider number. In that situation, CMS clarifies—consistent with long-standing Medicare policy—that the provider continues to enjoy eligibility and should include data from both the pre and post periods. We appreciate CMS's clarification of both policies and ask that if providers have encountered decisions or actions inconsistent with these policies that there be an opportunity to seek corrective action.

Outlier Policy

When the ESRD bundle was established, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. However, as an unintended result of these policies providers do not receive the full base rate for each treatment. We refer to this lost reimbursement as "leakage." While Section 1881(b) calls for an outlier adjustment, the Secretary is not bound by any specific threshold for outliers and could set a lower threshold in the Final Rule. According to the 2015 ESRD Proposed Rule, CMS only used about 0.5% of the outlier pool in 2013. Similarly, the projected outlier payments in 2011 and 2012 also fell well-short of the 1% target at 0.5% and 0.2% respectively. We recommend that CMS either suspend or, if that is not feasible, lower the outlier withhold from 1.0% to 0.5%.

In a similar vein, the Secretary has discretion under Sec 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 be considered for 2016. We are concerned that smaller and nonprofit providers are disproportionately impacted by this provision 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. We urge CMS to review this matter for the 2016 rule-making.

Adult Hemodialysis Kt/V Adequacy Measure

For the 2015 quality incentive program (QIP), patients are included in QIP scoring for the Adult Hemodialysis Kt/V Adequacy measure if they had received at least two treatments at a facility within one month; a change from prior policy that focused on at least seven treatments within a month. This change has had undesirable consequences both for patients and facilities, and we ask that CMS restore the minimum of seven treatments.

Facilities treating many transient patients—notably those in vacation areas that treat many transient patients—have been unduly penalized. The goal of transient hemodialysis is to give a modicum of freedom to patients whose ability to travel is restricted due to their medical treatment. Facilities are penalized not only for treating transient hemodialysis patients, but also for providing hemodialysis back up treatments to peritoneal dialysis patients, whose situation is also not adequately addressed by the exclusion criteria.

As a practical manner, it is unlikely that a facility providing a few treatments to a transient patient will be effective in changing that patient's hemodialysis prescription. If the blood is drawn at the second treatment, there would rarely be an opportunity to make a change in prescription. If the blood is drawn at the first treatment, and the result suggests that the prescription should change, the physician

responsible for the transient patient's care may or may not be making rounds at the second treatment to discuss a change in prescription with the patient.

More importantly, and as a matter of principle, dialysis facilities treating transient patients twice should not, except in the most exceptional circumstances, be altering the hemodialysis prescription for patients whom they barely know. Any change affecting only a few treatments is unlikely to make a long term difference, and the hemodialysis prescription should be reserved to the patient and her or his physician at the patient's home facility.

Finally, there is the administrative obstacle. In the past, CMS has suggested that facilities could satisfy this requirement by submitting Kt/V values measured at another facility. However, submitting a claim requires the facility to complete "Value Code D5: Result of last Kt/V reading," and "Occurrence Code 51: Date of last Kt/V reading." If the occurrence date is not within the range of treatment dates specified on the claim, the claim is returned to the provider and not paid.

Anemia Management: Hemoglobin (Hb) > 12 g/dl

We recommend retirement of the Anemia Management: Hemoglobin (Hb) > 12 g/dl measure or alternatively shifting it to a reporting, rather than a clinical measure. High hemoglobin values are now rare, and economic factors will prevent their resurgence if the measure is retired. Indeed, our assessment of the national data is that that low hemoglobin values are becoming a problem. Moreover, the construction of the Hb > 12 measure also poses scoring anomalies for the QIP.

Updating the National Healthcare Safety Network Bloodstream Infection Measure

CMS proposes to update the bloodstream infection measure to reflect a change in the National Quality Forum (NQF) endorsed revision to adjust for facility patient volume. This revision was proposed by the Centers for Disease Control and should contribute to an improved measure. However, we continue to be concerned that this measure may have the unintended effect of imposing a penalty on clinics who exercise greater diligence in care—as well as candor in reporting. It creates an incentive to administer antibiotics, based on observed symptoms, such as fever, rather than obtaining blood cultures, since obtaining blood cultures would hurt the facility's QIP score. Moreover, to the extent that this leads to over-use of antibiotics it will contribute to antibiotic resistance. Until CMS and dialysis clinics gain more experience with this measure, it should be a reporting measure rather than count toward a clinic's score.

Revision to In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Measure

In response to concerns that it is often difficult for facilities to predict whether they will have the requisite number of patient surveys—justifying the cost—CMS proposes an "eligibility" period prior to the performance period by which facilities could better judge the likelihood of reaching the required 30 or more surveys. While we appreciate CMS's effort to address this concern, we urge CMS to consider other means of reducing facilities survey costs—notably a return to an annual rather than twice a year survey. Clearly, administering the survey twice a year is more expensive. More importantly, this survey policy creates a greater burden on the dialysis beneficiary population than

other beneficiary populations. Surveying dialysis patients is fundamentally different from surveying patients discharged from hospitals or visiting physician offices, in that the ESRD population is fairly small, and the same people will be surveyed over and over again. Unlike the hospitalized population where 1/3 of beneficiaries discharged from the hospital are surveyed, each dialysis patient receives ICH-CAHPS twice in a year. To make matters worse, this survey burden falls on a beneficiary population having a large burden of disease and lower socioeconomic status than the general Medicare population. Over time, this twice a year policy will lead to "survey fatigue" and response rates will decline yielding less usable information. It also risks decreased response rates to other surveys administered by dialysis facilities such as the required KDQOL-36 survey and other patient experience surveys that are common for many providers.

Standardized Readmission Ratio (SRR) Measure

For PY 2017, CMS proposes a new clinical measure for all-cause 30-day hospital unplanned readmissions. The proposal is based on, but different from, the 30-day readmissions measure applied to hospitals, because as CMS acknowledges the characteristics of the ESRD patient population are different. CMS also acknowledges that not only is it invoking its authority to employ a measure which has not been approved by its own consensus based contractor—NQF—but also that the technical expert panel which it convened was unable to reach a consensus. We appreciate that CMS has made adjustments in the measure to exclude certain conditions, notably cancer and mental health conditions. We also appreciate CMS's application of risk adjustment around certain comorbidities and high risk conditions. While these and other refinements to reflect the ESRD population are welcome, the underlying "all cause" scope of the measure remains a major concern. We recommend that CMS exercise its authority—the same by which it is creating the measure—to focus on those causes of readmission that ESRD facilities can actually influence, rather than the "all cause" policy it proposes. In addition, there should be a recognition that it may be 3 to 4 days post discharge before a patient is seen by the ESRD clinic. particularly if Friday is the day of discharge from hospital care.

Standardized Transfusion Ratio Measure

For PY 2018, CMS proposes to introduce a new Standardized Transfusion Ratio (STrR) Measure, under its authority under Sec.1881(h)(2)(B)(ii), while also submitting the measure to NQF for review at its next call for measures. CMS proposes a number of adjustments and exclusions to the measure, starting with a 90 day "cooling off" period during which transfusions would not count against a facility. It also proposes to risk-adjust for several patient characteristics, such as age, BMI, diabetes, and duration on ESRD. CMS also proposes that the measure focus on the incidence of transfusion, not the number of units of blood or blood products.

We support the concept of a transfusion measure. By comparing STrR across facilities, it should be possible to identify those facilities that are consistently allowing hemoglobin (Hb) values to fall, presumably by limiting ESA administration. However, it is important to recognize that transfusions occur in two situations: a) in the case of a chronically low Hb, which the facility could arguably have influenced by giving more ESA; b) in the case of an acutely low Hb, such as would occur following hemorrhage, over which the facility probably had less control. One way to distinguish these situations would be calculate a hemoglobin-adjusted STrR, factoring in either the last outpatient Hb reported on an ESRD claim before the transfusion, or the Hb three month rolling average. If the Hb was greater

than some cutoff value, the transfusion would not be included in the hemoglobin-adjusted ratio. If the Hb was below the cutoff, the transfusion would be included. For example, one could count transfusions if the chronic Hb had been below 9.5 or 10 g/dl. An alternative to assigning a weight of 1 or 0 to transfusion would be to use a continuous variable, assigning each transfusion a weight inversely proportional to the prior chronic hemoglobin concentration. If this proved too complicated, a simple approach would be to assign weights on a linear scale, where a chronic Hb of 7 or 7.5 might have a weight of 1, and a chronic Hb of 12 a weight of 0. Finally, the measure could also factor in ESA dose, which is also reported on claims.

Conclusion

Thank you for the opportunity to comment on the proposed ESRD PPS Proposed Rule. The NKCA is concerned about the various proposals listed above and believes that, if finalized as proposed , will have a significant adverse effect on the quality of care to the patients we serve. We would be glad 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