

Appendix to Verbatim Public Comments Report

June 21, 2013

These comments are restricted to the Anemia of CKD: ESA management to avoid transfusion, and the Anemia of CKD: Hemoglobin less than 10 g/dL.

The proposed measure description for the 2014 transfusion QIP is “Percent of adult HD or PD patients at a facility during the year for which a patient had a low achieved hemoglobin (<10g/dL or missing), a low ESA dose (<75 units/kg/session of epoetin...and was followed in the subsequent month by a red blood cell (RBC) transfusion event.” (measure development pg 2).

The decline in Hgb to below 10g/dL is largely unpredictable, and takes weeks or months to correct. The need for transfusions is even more unpredictable, as most transfusions occur during hospitalizations for medical or surgical emergencies. As facilities cannot avoid Hgb <10g/dL, and cannot manage to avoid many transfusions, this CMS proposal effectively boxes facilities into avoiding “a low ESA dose (<75 units/Kg/session)”.

As outlined below, the CMS proposal makes unsupported assumptions about what constitutes appropriate ESA dosing when Hgb falls below 10g/dL. The proposal would require massive deviation from the FDA label, ignores the prudent comments of KDIGO and FDA that physicians and patients (not regulatory authorities) should weigh the risks and benefits of anemia management, and places a disproportionate number of obese patients and African Americans at risk from excessive ESA dosing, and is therefore discriminatory.

The CMS description in paragraph 1 effectively classifies as improper anemia management the failure to administer Epoetin of at least 75 units/Kg/session (or 225 units/Kg/week) whenever the Hgb is less than 10 g/dL. Such management exceeds any recommendation by KDIGO related to anemia management, and would force centers to violate the FDA label’s stated proper use of ESA. I have appended portions of those documents below that highlight the deviations of this CMS proposal.

Nature of the problems with the CMS proposal:

Our facility targets hemoglobin to 10-11 g/dL. Approximately 10% of patients received no ESA and maintain Hgb >11g/dL. Should any of these patients have hemoglobin fall below 10g/dL, the CMS proposal would classify as improper management failure to initiate Epoetin at less than 75 units/Kg/session. The FDA package inserts recommends a starting dose as low as 50 units/Kg/session. Given these patients clearly have recently had adequate endogenous epoetin production to avoid ESA treatment, using even a lower initial dose may be indicated (see FDA and KIDGO guidance on taking into account the patients’ characteristics when determining anemia management).

In our facility, the median dose of ESA among the remaining patients is ~7200 units/week. As our facility is mostly African American, the average weight is about 80 kg. Consequently, the median dose is approximately 30 units/Kg/session. The mean dose is approximately 38 units/Kg/session. We initiate epoetin therapy at 50 units/Kg/session because this achieves a Hgb >10g/dL in 75% of patients.

If Hgb declines to <10g/dL, the CMS proposal considers it improper anemia management if I do not immediately increase the ESA dose to at least 75 units/Kg/session. However, this would require me to

ignore the patients' sensitivity to ESA, and increase the dose by massively more than 25%. As an example, I have 120 Kg patients receiving 2200 units per week. If the Hgb fell to 9.9 g/dL, the CMS proposal would consider any epoetin dose less than 27,000 units/week to be inferior anemia management.

This CMS "forced" management dangerously deviates from the FDA label which recommends 25% dose increases every four weeks, to consider the sensitivity of the patient to epoetin, to look for other causes of anemia, and that the goal is not to necessarily maintain Hgb >10g/dL. The CMS proposal deviates from the KDIGO guidance which does not insist Hgb be maintained >10g/dL, does not recommend large changes in ESA dose, and does not classify a transfusion as a failure of proper anemia management. Instead, KDIGO recommends physicians and patients weigh the risks and benefits of more ESA versus the higher risk of transfusion. Lastly, the only outcomes trial of hemoglobin targets in hemodialysis showed patients targeted to 9-11g/dL were much less likely to die than those targeted to 13-15g/dL, despite an increased number of transfusions in the lower Hgb target group (see Coyne DW Kidney Int 2012, and the FDA label). It is presumptuous of CMS to believe they know that aggressive Epoetin dose increases when Hgb is <10g/dL is superior management than the FDA label instructions and the results of the largest anemia outcomes trial in dialysis.

In 80 Kg patients, the CMS proposal only classifies Epoetin doses >18,000 units per week as appropriate management of Hgb <10.0 g/dL. Assuming a 25% increase in ESA dose may be indicated when Hgb falls below 10 g/dL, for any 80 Kg person presently on less than 14,400 units per week of epoetin, the CMS proposal would suggest I increase the epoetin dose by more than 25%. That would mean the CMS proposal would lead me to deviate from the FDA label guidance of 25% increases in >90% of my patients, because 90% of my patients are maintained on less than 14,400 units per week of epoetin.

Note that the FDA label states some Hgb excursions should NOT necessarily lead to ESA dose increases. Therefore, there are circumstances where no change in ESA is the appropriately management when Hgb is <10 g/dL. Examples include a transient fall in Hgb follow a vascular access procedure or inadvertent blood loss during dialysis, uncontrolled hypertension, or when administering a course of IV iron to a patient deemed iron deficient (see the FDA label). These exclusions are not among the exclusionary diagnoses provided.

If an 80 Kg patient has a hemoglobin of 8g/dl and is given 75 units/Kg/session of ESA, the Hgb could rise rapidly (>1g/dl in 2 week2s). The FDA label instructs to decrease the epoetin dose. However, if the Hgb is still less than 10g/dL, CMS classifies this a inferior anemia management.

This CMS proposal places heavy patients in particular, and African Americans in general at great risk, and is therefore discriminatory. Because African Americans average higher weights that non-African Americans, and because the CMS proposal evaluates ESA dose based on units/Kg/session, this proposal exposes a disproportionate number of African Americans to higher ESA doses. All obese patients would be forced to receive higher ESA doses whenever Hgb is <10g/dL under this CMS proposal. The relationship of maintenance epoetin dose to weight is very weak. Shown below is the graph from Uehlinger DE, et al. Clin Pharmacol Ther. 1992;51:76-89 which examined the relationship of weight to

maintenance epoetin dose. They concluded their RBC kinetic results “call into question the need for weight-adjusted (Epoetin) doses.”

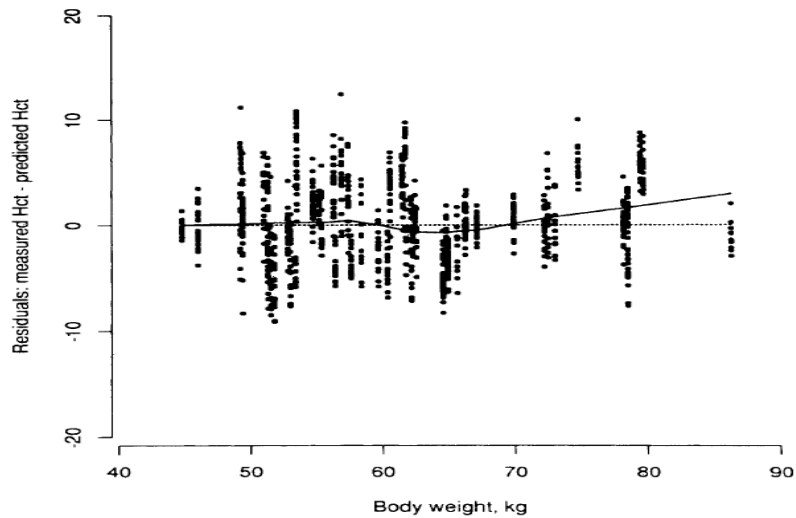
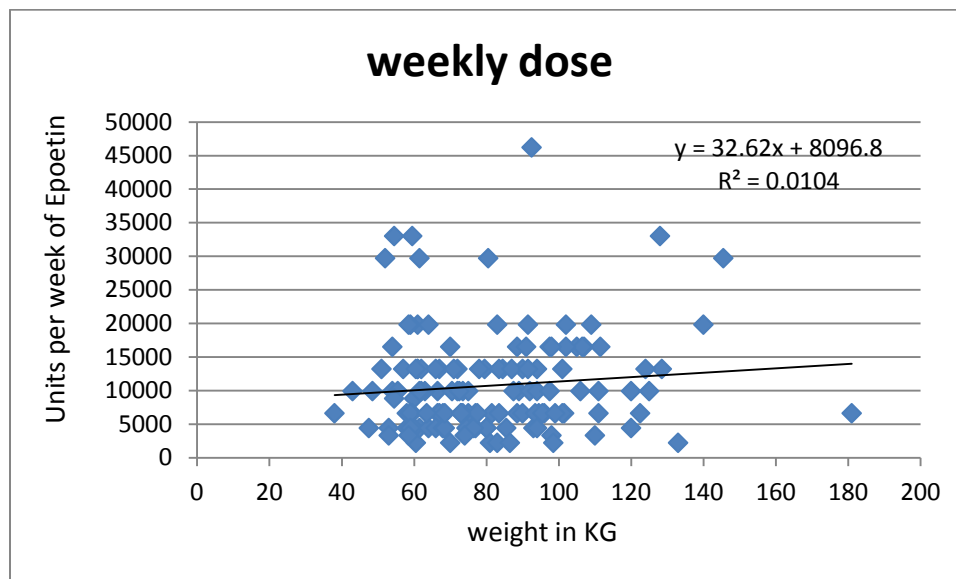


Fig. 9. Plot of the residuals (measured minus predicted Hct values) versus body weight. The curve represents a smooth (moving average) of the data.

Consistent with the results of Uehlinger, we find minimal relationship of epoetin dose to weight in our population of 136 patients receiving epoetin. See figure below. Note the R^2 value is 0.0104 for weight to weekly epoetin dose.



Lastly, the CMS could say that this regulatory measurement doesn't force anyone to exceed the FDA label. However, that is nonsense, as the purpose of the measure is to identify and label inferior facilities. As stated initially, facilities cannot avoid Hgb <10g/dL in some patients, and have extremely limited ability to predict or manage who is transfused as most transfusions are for acute problems and occur in the hospital. Consequently, facilities are forced to avoid the "inferior" label by avoiding <75units/Kg/session of ESA in any patient who develops Hgb <10g/dL.

RECOMMENDATIONS

This proposed measure should be withdrawn. Less ideally, the Hgb threshold should be lowered to 9g/dL for at least 2 consecutive months prior to the index transfusion month, and the definition of "inadequate epoetin dosing" should be changed to "failure to increase the ESA dose by 25% in the previous month and the dose is less than 5,000 units per session" and "no documented reason for the failure to increase the dose." Documented reasons for failure to increase the ESA dose should include rising hemoglobin, poor BP control, recent IV iron administration, patient preference, and recent blood loss. DOPPS data from Europe indicates only 1-5% of EU dialysis patients receive more than 18,000 units per week of epoetin, and therefore providing 15,000 units per week of epoetin in patients with Hgb <9g/dL after 2 months is reasonable, and may not warrant further dose increases despite the degree of anemia (see FDA label for comments on futility of repeated dose increases).

Below I have extracted and underlined the portions of the FDA label and the KDIGO guidelines which undermine or contradict this CMS proposal.

Select FDA Epogen Label details related to comments on this proposal:

CKD Patients: Initial dose: 50 to 100 Units/kg 3 times weekly (adults) and 50 Units/kg 3 times weekly (children on dialysis). Individualize maintenance dose. Intravenous route recommended for patients on hemodialysis (2.2).

Hypertension: Control hypertension prior to initiating and during treatment with Epogen (5.4).

Patients with CKD: Adverse reactions in ≥ 5% of Epogen-treated patients in clinical studies were hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion, and upper respiratory tract infection (6.1).

In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL. No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks. Individualize dosing and use the lowest dose of Epogen sufficient to reduce the need for RBC transfusions [see Warnings and Precautions (5.1)]. Physicians and patients should weigh the possible benefits of decreasing transfusions against the increased risks of death and other serious cardiovascular adverse events [see Boxed Warning and Clinical Studies (14)].

For **all** patients with CKD: (the **BOLDING** is in the package insert)

When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly. When adjusting therapy consider hemoglobin rate of rise, rate of decline, ESA responsiveness and hemoglobin variability. A single hemoglobin excursion may not require a dosing change.

- Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments.
- If the hemoglobin rises rapidly (e.g., more than 1 g/dL in any 2-week period), reduce the dose of Epogen by 25% or more as needed to reduce rapid responses.

- For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%.
- For patients who do not respond adequately over a 12-week escalation period, increasing the Epogen dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue Epogen if responsiveness does not improve.

For patients with CKD **on dialysis**:

- Initiate Epogen treatment when the hemoglobin level is less than 10 g/dL.
 - If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of Epogen.
 - The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously.

Select KDIGO guidelines related to comments on this proposal:

3.4.3: For adult CKD 5D patients, we suggest that ESA therapy be used to avoid having the Hb concentration fall below 9.0 g/dl (90 g/l) by starting ESA therapy when the hemoglobin is between 9.0–10.0 g/dl (90–100 g/l). (2B)

3.8.1: We recommend determining the initial ESA dose using the patient's Hb concentration, body weight, and clinical circumstances. (1D)

3.8.2: We recommend that ESA dose adjustments be made based on the patient's Hb concentration, rate of change in Hb concentration, current ESA dose and clinical circumstances. (1B)

The QIP for 2014 on hemoglobin values <10 g/dL

The Measure description is “Adult dialysis patients with hemoglobin (Hgb) values reported for at least 2 of the 3 study months who have a mean Hemoglobin <10.0 g/dL in the 3 month reporting period.”

This QIP is similarly replacing the FDA guidance and the conservative statements of KDIGO about balance risks. As outline extensively in response to the transfusion QIP, CMS has not data to support that more aggressive treatment to Hgb >10g/dL in 2 out of three or three out of three months *causes* any patient to do better. The CMS QIP ignores the FDA label which recommends slow, graded improvement in anemia via q4 weekly increases in epoetin. This QIP could force facilities to increase the ESA dose rapidly whenever the Hgb fell below 10g/dL.

Many factors may make increasing epoetin dose despite a Hgb <10 g/dL a poor medical decision. See the discussion above. Additionally, re-creation of this de facto hemoglobin floor will make ALL facilities push the mean hemoglobin bell curve toward higher hemoglobin values and that would likely be via higher epoetin doses for all patients.

A cynic might say that is exactly the point – this hemoglobin floor will force providers to target 11g/dL rather than 10 – 11g/dL, leading to greater epoetin use. In addition to increasing epoetin sales for the manufacturer, this QIP driven increase in epoetin sue will favor the two large chains over their competitors as the major providers receive major discounts on epoetin relative to small dialysis chains and facilities,. While certainly not intended, this QIP smacks of crony capitalism via regulatory authority.

There is no proven benefit of such management, and there is possible harm to patients. CMS lacks the expertise to adjudicate this clinical issue, in large part because CMS lacks adequate evidence that more aggressive targeting Hgb to >10g/dL is better for patients. CMS’s QIP also deviates from the only outcomes trial in this population, the Normal Hematocrit trial which targeted 9-11 g/dL in the lower, superior outcomes arm. (see Coyne Kidney Int 2012, and the FDA label).

I recommend this QIP be withdrawn, as its unintended effects will be a perceived necessity to more aggressively treat all patients when Hgb falls below 10g/dL.

Thank you for the opportunity to comment on these QIPs.

Sincerely,

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To Whom It May Concern:

DaVita Healthcare Partners is pleased to submit its comments on the Centers for Medicare & Medicaid Services (CMS) contracted Arbor Research/UM-KECC anemia management measures and 30-day hospital readmission measure for the ESRD population. We understand the purpose of the project is to develop quality measures that can be used to promote the delivery of high quality care to Medicare beneficiaries with ESRD.

We are asked to comment on the following measures:

- Anemia of chronic kidney disease: Patient informed consent for ESA treatment
- Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion
- Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio
- Anemia management of chronic kidney disease: Hgb > 12 g/dL
- Anemia of chronic kidney disease: Hgb < 10 g/dl
- Standardized 30-day readmission ratio for dialysis facilities

By way of general context-setting, we'd like to provide the following conceptual framework around clinical measures. At the highest level there are system level outcomes which generally reflect the health of the ESRD population as a whole and are the basis of many of the reported outcomes in the USRDS reports. Next there are facility level measures, areas where the sphere of influence and the locus of responsibility for the outcome are clearly with the facility. Lastly there are individual patient outcomes which as a result of variances in risk, benefit and other factors are only applicable to an individual patient and are highly dependent on patient needs and preferences.

We believe that this framework is important to understand with regards to the following discussion about the proposed measures. It has become clear as the science continues to evolve regarding the care of ESRD patients that achieving the best outcomes requires a complex interplay of patient, physician, dialysis facility and in the case of rehospitalizations, the hospital. When facility-level accountability metrics are developed they must take into account this reality in order to avoid any unintended consequences to patients, facilities or the overall ESRD program.

Anemia

Patient informed consent for ESA treatment

We believe that Arbor's management of the TEP failed to clarify the differences between the FDA approved REMS program involving the medication guide and the concept of informed consent. As a result, Arbor is proposing a measure that contradicts the guidance of another federal agency, namely the FDA. Based on guidance issued by the FDA as recently as June 2nd, 2011, the FDA requires the following for the administration of ESAs in a dialysis center:

" This letter is in reference to the Risk Evaluation and Mitigation Strategy (REMS) approved on February 16, 2010, under Section 505-1 of Federal Food, Drug, and Cosmetic Act (FDCA), for Epogen/Procrit (epoetin alfa). Epogen/Procrit is one of a class of drugs collectively referred to as Erythropoiesis Stimulating Agents, or "ESAs". One element of the approved REMS for the ESAs requires the distribution of a Medication Guide in accordance with the requirements of Part 208 of our regulations (21CFR Part 208).

FDA approved Medication Guides for the ESA products on November 19, 2008. On December 18, 2008, we issued a letter which outlined our intent to exercise enforcement discretion with respect to the frequency of the distribution of the Medication Guides in physicians' offices, and in certain inpatient or clinical settings, under specified conditions. When the Medication Guide was approved as part of a REMS under section 505-1 of the FDCA, we informed you of our intent to continue to exercise enforcement discretion as outlined in our letter dated March 12, 2010.

Since the issuance of the enforcement discretion letter we have changed our thinking about our intent to exercise enforcement discretion with respect to the frequency of Medication Guide distribution in certain situations and specified conditions. We now intend to exercise enforcement discretion in the following circumstances.

When ESAs are administered by a healthcare provider (e.g., in a physician's office, clinic, hospital inpatient setting, or dialysis center) to patients who do not have cancer, we intend to exercise enforcement discretion with respect to the requirements of 21 CFR 208.24(e) as long as the Medication Guide is provided to each patient or patient caregiver at the initiation of therapy and again if the Medication Guide is materially revised or updated.

When ESAs are administered by a healthcare provider (e.g., in a physician's office, clinic, hospital inpatient setting, or dialysis center) to patients with cancer, we intend to exercise enforcement discretion with respect to the requirements of 21 CFR 208.24(e) as long as the Medication Guide is provided to each patient or patient caregiver at the initiation of therapy; once a month during regular office visits — or, if regular office visits occur less frequently than once a month, at the next regularly scheduled office visit — for as long as treatment continues; and again if the Medication Guide is materially revised or updated."¹

This materially differs from the concept of informed consent, where a patient signature is required. We therefore believe that the proposed measure is not consistent with FDA

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<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM152179.pdf>

regulatory guidance and further does not address the level of detail of that guidance, specifically that regarding the frequency of distribution of the medication guide.

More importantly we believe that having such a discussion regarding individual risk and benefit, takes place between a health care provider such as a doctor or NP and the patient. This is also consistent with the FDA REMS guideline. As a result this measure is more appropriate as a physician measure rather than a facility measure.

Anemia management of chronic kidney disease: Hgb > 12 g/dL and Anemia of chronic kidney disease: Hgb < 10 g/dl

While we are supportive of the concept of appropriate anemia management that balances the risk and benefits of treatment at the systems level, we are concerned regarding how the baseline for comparative outcomes for a facility level hemoglobin < 10 g/dl metric will be set.

As a result of the regulatory changes that have taken place regarding anemia drugs over the past few years (referenced in the supporting documents) we believe that anemia management no longer is suitable for population-based metrics. That is, scientific evidence and regulatory guidance clearly shows that the care of each individual patient needs to be customized regarding the appropriate lower level of hemoglobin at which either ESAs or blood transfusions are appropriate. Attempting to have an aggregate facility-level lower hemoglobin level, therefore, is difficult, since there is no existing benchmark for which to set the target.

Recognizing this issue, we offer our physicians multiple choices in anemia management customized to the patient level. We offer three core protocols each with a different implied hemoglobin. Physicians are able to select any protocol for any individual patient, following an individualized risk benefit discussion with that patient. Further, physicians may write their own protocols or orders at the patient or unit level. Therefore, any hemoglobin distribution observed at the facility level is the result of this “wisdom of crowds “ approach, and we believe reflects the best individualized care for those patients.

In November of 2012, physicians prescribed Protocol A only 4.6% percent of the time, Protocol B only 29.6% of the time and Protocol C only 22.9% of the time. Physicians used more than one protocol more than 30.7% of the time, and none of these protocols 12.1% of the time. That translated into the percentage of patients on Protocols A, B, C and none as 7.6%, 47.3%, 37.5%, and 7.7% respectively.

Given this variation, hemoglobin outcomes at the protocol level also varied with hemoglobins <10 g/dl varying across protocols and no protocols from 19.1% to 16.4% to 16.1% to 19%.² What the documents supporting this measure show us is that there is both potential risk and benefit to treatment of anemia in ESRD with ESAs. Physicians are best able to ascertain the tradeoffs between those risks and benefits. The fact that individual risk and benefit varies, which in turn affects implied hemoglobin means and hemoglobin <10 g/dl percentages at the unit

² Evidence of Practice Variation and Individualization in Anemia Management, Van Wyck et al. Presented at NKF April 2013 meetings.

makes having a uniform facility level metric across all patients difficult. For these reason, we are uncertain how to implement a population based hemoglobin <10 g/dl metric, but do recognize that contemporary baselines in the time period of q3 to q4 of 2012 reflect some semblance of steady state after the FDA label changes and could be used.

The actual value of what that lower end number should be is less clear. One could use < 10 g/dl as previously but with the appropriate baseline as discussed above. Alternatively, as a 2 gram hemoglobin range has been used repeatedly in the past, one could use 9 g/dl as the lower limit.

From a technical aspect, we do remain concerned that the TEP proposed measures contradicts in methodology the currently used >12 metric. We are at a loss to understand why this is the case as Arbor developed the anemia measure currently in use, and supervised the TEP. That being said, we believe that the measures at the top and lower range of hemoglobin should be the same, and in that paradigm would advocate the measure currently in use today for >12 for the lower end. Specifically the current measure uses a yearly average hemoglobin with a minimum number of claims in a month. In contrast, the proposed measure for <10 and >12 as specified describes a 3 month period. It is not clear if this is a rolling three month period, the average of 4 separate time periods in a given year or some combination thereof. Without such basic clarity we ask for the CMS to provide another round of commentary with these data and assumptions better defined. Only then could we comment on validity of measure with regards to inherent hemoglobin variability. Additionally, while Arbor lists of number of co morbidities, our prior experience with the case mix adjustors and the discrepancy between what was proposed in terms of ICD9 codes and the eventual direction given by CMS leads us to request that these co morbidities are also clarified to a much greater extent.

In summary, we are conceptually agreed to the concept of lower and upper bounds but think this important measure requires more broad discussion and thought before implementation.

Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion and Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio

While we are supportive of understanding the population based impact of changes in anemia management on transfusions, we are not clear that transfusion metrics at the dialysis unit level are appropriate or feasible. We therefore recommend that CMS and the USRDS continue its population based surveillance of transfusions and hemoglobin <10 g/dl for the reasons outlined .

Based on the discussion above, and the fact that transfusion occurs proportional to that individual patients mean hemoglobin³ and that patients individual comorbidities, believe that holding a facility to a transfusion metric is difficult. Again, care is being individualized to a patient level, by an attending physician, based on decisions made by that physician and not the dialysis unit.

³ Increased Transfusion Rates Under New ESA Guidelines in Patients With ESRD at an LDO. Sibbel et al. Presented at NKF 2013 Spring Meetings.

With regards to the low dose of <75 units/kg/session of ESA's mentioned in the first measure, it should be noted that EPO has a 40 fold pharmacokinetic variance such that specifying a single value across a patient populations will not be reasonable.⁴ Additionally, we are seeing an increased number of patients whose doses are held in accordance with the ESA label guidance which makes the metric of low dose difficult to interpret.

Transfusion data is not readily available in real time to the dialysis units. The vast majority of transfusion events occur in the hospital and the decision to transfuse is that of the inpatient attending or consulting physician and not the dialysis unit. As a result dialysis units do not have a complete understanding of how many transfusions are being administered and have not ability to modify their transfusion rates at a unit level.

We have made efforts to collect transfusion data from discharge summaries and have met with limited success. Using that subset of the patients in whom we have transfusion data, we have been able to create a predictive model for transfusion events which has been presented previously. That research shows us that many, many clinical variables from the electronic medical record are needed to accurately predict transfusion events. Given that, we find it extremely difficult to believe that a claims based prediction on which the "expected" transfusion rate is to be calculated for a standardized transfusion ratio would be accurate.

For these reasons, we believe that Arbor's proposed transfusions measure is not appropriate for a dialysis unit level quality measure. We also believe that the proposed ESA management to avoid transfusions is not consistent with the known data or science of ESAs and are not supportive of its use.

30 day readmission

It is clear that readmissions to the hospital are an important source of clinical morbidity and cost for ESRD patients. There was broad agreement that the area of readmissions for ESRD patients was one of shared accountability involving the dialysis facility, the hospital, the hospitalist or other treating physician and the attending nephrologist, and separating out the relative contributions of each was extremely challenging. A recent publication from the Robert Wood Foundation has clearly shown that:

"The burden of readmissions falls unevenly on Medicare beneficiaries, and is closely linked to their place of residence and the health system providing their care," the Dartmouth researchers conclude. "Patients with similar illness have very different chances of hospital readmission depending on where they live. The variation in the quality of care between health systems is hard for patients and doctors to see, but the differences are substantial. Many patients are readmitted simply because they live in a locale where the hospital is used more frequently as a site of care for illness, leading to both higher initial admissions and higher readmissions."⁵

⁴ Eschbach et al: Correction of the anemia of end-stage renal disease with recombinant human erythropoietin. Results of a combined phase I and II clinical trial. N Engl J Med 316:73-78, 1987

⁵ The Revolving Door: A Report on U.S. Hospital Readmissions. RWJ Foundation. February 2013

However, as with many things, when one examines the details around the assumptions that Arbor is making, it is clear the proposed measure lacks validity and will penalize dialysis units unjustly.

The premise Arbor uses is the desire to harmonize with other CMS readmission measures. In our mind, this bears little merit. First, by definition, hospitals are responsible for every admission in the denominator of their metric, as they are responsible for all discharges. This is not the case for the dialysis unit, as only a subset of hospitalizations are directly modifiable by the dialysis unit. Therefore, holding the dialysis unit responsible for readmissions due to say trauma, or orthopedic readmissions makes little sense. Our own internal data suggests that 45% of readmissions are non-controllable even with the most liberal of definitions by the dialysis unit. We would instead advocate that a ESRD cause specific measure be tested and validated, limited to modifiable domains in dialysis, such as fluid overload and dialysis related infection which are more appropriate than all cause hospitalization given the sphere of influence of the facilities. In fact, the very paper cited in the measure by Chan et al. utilizes only the Fresenius dataset, which by definition is a dialysis centric, rather than system level view of all possible admissions, thus making the case for cause specific rather than all cause readmissions.

We are proponents of integrated care and believe that the dialysis unit could serve as the patient's "Medical Home" and could impact these outcomes.

With regards to validation, CMS was previously correct in stating the data needed to calculate the proposed SRR-Admissions measure has been regularly reported to Dialysis Facility Reports (DFR) since 1995 (previously known as Unit-Specific Reports) and has been used by providers/facilities and ESRD Networks for quality improvement activities.” However, the predictive equation utilized as the core part of this calculation has never been subjected to validation or peer review by any entity external to its developer. Additionally, the case mix adjustment methodology has not been evaluated or reviewed by anyone other than the measure creator. This differs markedly from the SHR measure used for hospitals by CMS where, given the importance this measure has on providers, the measure was made very transparent and published in a peer reviewed journal.⁶ We urge CMS to consider the same amount of transparency and discussion around the SRR metric for ESRD from a credibility and scientific validity standpoint before considering its use as a quality metric.

Separately we are concerned about the lack of sensitivity testing around the effect of outliers or unit size on the SRR. We note that previous similar work on SMR showed a high degree of variability associated with a single patient in the SMR method currently developed by the same group. This commentary was published in a peer reviewed journal.⁷ Again, this underscores the need for transparency and validation of this important metric of patient care.

⁶ Krumholz HM, et al. *Circ Cardiovasc Qual Outcomes*. 2011 Mar 1;4(2):243-52.

⁷ Lacson et al. *American Journal of Kidney Diseases*, Vol 37, No 2 (February), 2001: pp 267-275.

Next, even for these, the dialysis unit only has a limited time to intervene. Our internal data suggest that the percent of readmits that occur within 1-3 days is 11%, while at 3-8 days, it's 30%. Given that dialysis occurs on a three times a week cycle, these early readmissions are not amenable to dialysis unit intervention as the patient may have been seen in the unit from as little to zero times after discharge. The cited Chan paper itself excludes the first 10 days post discharge presumably for this very reason. Therefore we would advocate that even for cause specific hospitalization that the first 1-8 days be excluded from the readmission metric. Further, some patients are discharged to nursing homes and rehabilitation facilities, but continue their outpatient dialysis at their home centers. Again, responsibilities for those readmissions fall not solely with the dialysis providers.

Globally, despite our best efforts and requests, dialysis units do not have access to real time discharge data from hospitals. As with any quality improvement effort, having access to the data will be key to ensuring success. We urge CMS to make available claims data on hospitalization to the dialysis units in order to help coordinate care.

Dialysis patients are clinically and physiologically distinct from any other patient population. That there is an ESRD program within CMS, a dedicated surveillance system for ESRD patients (USRDS) and a need for a dialysis-specific readmission measure is testament to this. Given the distinct nature of these patients, and the difference between the care that they receive versus any other patient group, argues that existing CMS readmission measures are not germane to dialysis patients. Thereby, harmonization with these is a logical paradox.

Next, there is no adjustment for physician decision making in the proposed performance measure. KECC provides three rationales for its choice not to include physicians in the model. First is encouraging cooperation between dialysis facilities and physicians. However, it seems paradoxical that this could be accomplished by excluding physicians from the model, thereby ignoring any risk on their behalf. Furthermore the assumption that adjusting for physician practice removes the potential role of the dialysis facility in modifying physician practice incorrectly presumes that dialysis facilities have any leverage to exert on how physicians behave in making hospital rounds. For example, the dialysis facility has no ability to influence how often physicians see patients in the hospital, how often they chose to dialyze hospitalized patients, how aggressively dry weight is probed in the hospital. In essence, this choice has given physicians a free pass.

Arbor cites difficulties in attributing patients to a specific physician. CMS (and by extension Arbor) has full claims histories on all patients. Ergo, KECC could feasibly identify physician claims for monthly ambulatory dialysis services. Let us not conflate analytical expediency with analytical rigor.

Finally, it seems illogical to exclude diabetes and various cardiovascular conditions from the vector of covariates. It is incontrovertible that certain comorbidities (eg, coronary disease, diabetes) are associated with greater hospitalization rates overall and readmission rates by extension. By excluding these from the vector of covariates, we are creating perverse disincentives to care for such patients. If the issue is one related to causal intermediacy, these conditions could be considered as of dialysis initiation (eg, CMS form 2728, or claims history preceding first dialysis care).

In summary, the proposed performance measure for SRR as written is not appropriate for use in ESRD. CMS has at its disposal the data to address a number of these issues. Specifically, the ability to understand the types of readmissions that dialysis patients experience, the length of time post discharge when those readmissions occur in relationship to when outpatient dialysis unit care resumes, and the sites of service that patients are discharged to. We believe that a more evidence based approach would be preferable to that through which this measure was developed, namely a literature review and 2 day TEP process with expert **opinion**. We would advocate that CMS consider the points above with regards future measure development.

Regards,

A handwritten signature in black ink, appearing to read "AR Nissenson", with a stylized flourish at the end.

Allen R. Nissenson, M.D., FACP
Chief Medical Officer, DaVita Healthcare Partners Inc.

Cc: Patrick Conway



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April 26, 2013

VIA ELECTRONIC DELIVERY

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To Whom It May Concern:

Amgen appreciates the opportunity to provide comments on the draft Anemia Management Measures and the 30-Day Hospital Readmission Measure for End Stage Renal Disease (ESRD) Population. As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals for Medicare beneficiaries. For more than a quarter century, Amgen has developed, manufactured, and marketed products for treatment of patients with ESRD. ESRD patients are among the most vulnerable in the Medicare population with multiple co-morbidities requiring extensive clinical management and with high rates of hospitalization and mortality. Significant anemia – one of the most prevalent co-morbidities – is, in the absence of effective treatment, nearly universal, may be highly symptomatic and associated with decreased health related quality of life in dialysis patients.¹

Currently, the ESRD Quality Incentive Program (QIP) lacks clinical quality measures to protect patients from negative outcomes associated with hospital readmissions or anemia undertreatment. As the manufacturer of EPOGEN[®] (epoetin alfa) - a widely used anemia therapy – we appreciate the efforts to develop new measures for potential inclusion in the QIP addressing anemia management in particular. The draft anemia measures represent different approaches to anemia management, including some that we support, but also others that we feel are inappropriate.

Below we provide an overview of the core principles by which Amgen assesses whether it will support ESRD quality measures, and we prioritize the draft anemia measures that, in our view, best improve patient care as well as include technical comments for each of these measures as

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Eschbach JW, Adamson JW. Anemia of End-Stage Renal Disease (ESRD). *Kidney Intl.* 1985; 28:1-5.

appropriate. In addition, we provide comments on those draft measures that we cannot support at this time.

Amgen believes that meaningful and relevant quality measures specific to dialysis care should be clinically appropriate in that they:

- **must be evidence based** – the measure must be grounded in evidence supporting the relationship of an outcome to a process of care;
- **must have a high impact on patient care** – the measure must make a meaningful difference for patients;
- **be actionable by ESRD providers and clinicians** – the measure must demonstrate that dialysis providers and clinicians can understand the results and find them useful for decision-making; and
- **be operationally feasible** – the measure must not require an undue burden on dialysis facilities.

Specific Comments on Draft Anemia Management Measures:

1. Meaningful and relevant quality measures in anemia management are vitally important to protect patients from both the risks associated with overtreatment of anemia (*i.e.*, treatment to high hemoglobin targets), but also the risks associated with undertreatment, including the consequences associated with increased red blood cell (RBC) transfusions. Avoiding the need for transfusions is a widely recognized treatment goal and therefore an important outcome in this vulnerable population. It is well-known that the dialysis population has unique vulnerabilities to RBC transfusion; most notably, transfusions can jeopardize chances for successful renal transplantation. Specifically, transfusions can cause increased levels of harmful antibodies in the blood^{2,3,4} which can increase time spent on the transplant waiting-list, decrease or preclude transplant eligibility, and for patients who receive a transplant, shorten graft survival.^{5,6} Accordingly, the ESRD QIP is statutorily required to include measures on anemia management and such measures must reflect product labeling for anemia therapies. Below is a prioritization of those draft measures that best address the need to safeguard patients from these risks.

A. Anemia of Chronic Kidney Disease (CKD): Hemoglobin (Hb) < 10 g/dL

Amgen supports a Hb < 10 g/dL measure and recommends the unit of measurement be at the facility rather than the patient level. This measure is supported by a large body of evidence, is the most actionable by dialysis providers, and is operationally feasible because hemoglobin is; routinely measured, its elevation is the most proximate effect of erythropoiesis stimulating agent (ESA) administration, and low Hb at the facility level

² United States Renal Data System (USRDS) 2009 Annual data report: Atlas of end-stage renal disease in the United States. Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive Kidney Diseases, 2009.

³ Hardy S, Lee S-H and Terasaki PI: Sensitization 2001, in PI, CjaT (ed): Clinical Transplants 2001, UCLA, 2001.

⁴ USRDS 2004 Annual data report: Atlas of end-stage renal disease in the United States. Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive Kidney Diseases, 2004.

⁵ Lietz K, Lao M, Paczek L, et al. The impact of pretransplant erythropoietin therapy on late outcomes of renal transplantation. *Ann Transplant*. 2003;8(2):17-24.

⁶ UNOS: United Network for Organ Sharing. <http://www.unos.org/>. Accessed June 14, 2012.

predicts the risk of transfusion. Therefore, implementing this measure would produce the most meaningful difference for dialysis patients.

The labeled indication for EPOGEN[®] is for the treatment of anemia due to CKD to decrease the need for RBC transfusions.⁷ In addition, treatment of the anemia of CKD in patients on dialysis has been shown in randomized controlled trials (RCTs) to improve the patient reported outcome (PRO) of physical functioning, as well as exercise tolerance, an objective measure of physical functioning.⁸ Transfusions were frequently administered to dialysis patients with anemia prior to the availability of ESAs.⁹ They were and remain an unsatisfactory routine treatment for chronic anemia for a number of reasons that have been extensively discussed and therefore the occurrence of transfusion represents an important outcome in dialysis patient care.^{10,11} Treatment to Hb level greater than 10 g/dL – approximately the lower end of the target range studies in registrational trials- was shown to be effective in reducing the need for transfusions.¹² The full surveillance of US patients on dialysis by the United States Renal Data System (USRDS) has provided confirmatory evidence showing that the use of RBC transfusions dropped substantially as patients Hb levels were raised and maintained above 10 g/dL. Thus, a Hb of 10 g/dL is familiar to nephrologists as a level effective to reduce transfusions.

Since mid-2011, following the removal of the Hb < 10 g/dL QIP measure, the mean Hb levels among dialysis patients has declined and the transfusion rate has increased.^{13,14} While a number of events occurred during 2011 that contributed to this transfusion trend, including the implementation of the ESRD prospective payment system (PPS), the removal of the Hb < 10 g/dL measure eliminated a structural safeguard against the undertreatment of anemia and consequently, the transfusion rate increased. In fact, the Centers for Medicare and Medicaid Services (CMS) previously acknowledged that the Hb <10 g/dL measure for the QIP was important in light of concerns that had been raised that the new bundled ESRD payment system could improperly incentivize providers to undertreat patients with anemia by underutilizing ESAs.

The rationale for removal of the previous Hb < 10 g/dL measure was due to inconsistency with ESA labeling that was revised in June of 2011. The revised labeling removed the concept of a uniform target Hb applicable to all patients and recommended more individualized treatment. Amgen has acknowledged that the QIP performance

⁷ EPOGEN[®] (epoetin alfa) Prescribing Information. Amgen, Inc. Thousand Oaks, CA (v26 05/2012).

⁸ Ibid.

⁹ Churchill, D. N., D. W. Taylor, et al. (1992). "Canadian Hemodialysis Morbidity Study." *Am J Kidney Dis* 19(3): 214-234.

¹⁰ Amgen Inc. Comments on Proposed Decision Memorandum for Erythropoiesis Stimulating Agents for Treatment of Anemia in Adults with Chronic Kidney Disease Including Patients on Dialysis and Patients Not on Dialysis (CAG-00413N). 2011. Accessed at <http://www.cms.gov/medicare-coverage-database/staticpages/public-comment.aspx?commentID=22053&ReportType=nca> on April 9, 2013.

¹¹ Amgen Inc. Comments on CMS-1577-P Proposed Rule: Medicare Program: Changes to End-Stage Renal Disease Prospective Payment System for CY 2012. Accessed at <http://www.regulations.gov/#!documentDetail;D=CMS-2011-0129-0119> on April 9, 2013.

¹² EPOGEN[®] (epoetin alfa) Prescribing Information. Amgen, Inc. Thousand Oaks, CA (v26 05/2012).

¹³ Centers for Medicare and Medicaid Services (CMS). CMS Claims-based Monitoring. Accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html> on April 5, 2013.

¹⁴ USRDS ASN Presentation http://www.usrds.org/2012/pres/ASN2H/Gilbertson_USRDS_2-hour_Full.pdf

standards supporting the previous Hb < 10 g/dL measure were inconsistent with the revised labeling. However, the reason for this is not the measure itself; rather it was the achievement standard that compared current anemia management practices under a revised labeling to a baseline established by CMS prior to the labeling change in order to measure whether a facility had met the standard. At the time (CY 2011 performance) the standard would have required less than two percent of patients with an annual mean Hb < 10 g/dL, and thus almost all patients, would have to be treated to a Hb > 10 g/dL in order to meet the performance standard. Amgen agrees that this requirement would have been inconsistent with the modified labeling and therefore would not have been appropriate to implement a payment penalty based on standards no longer consistent with EPOGEN® product labeling.

While the standard became inappropriate, the measure remains valid. Several recent analyses demonstrate that such a measure is still grounded in sound epidemiologic evidence. An analysis using data on approximately 200,000 patients per year over the past decade demonstrated that after adjusting for changes in patient case-mix and anemia management, the risk of receiving a transfusion is consistently four-fold higher for patients when the Hb drops below 10 g/dL compared to Hb levels above 10 g/dL.¹⁵

A more recent investigation using the entire Medicare hemodialysis population has shown that the proportion of patients within a dialysis facility with a three-month average Hb < 10 g/dL is strongly predictive of future transfusion risk.¹⁶ This analysis shows that the proportion of patients with Hb < 10 g/dL rose modestly between 2007 and 2010 as ESA doses declined, presumably in response to the emerging safety signals identified in RCTs. During this time, transfusion rates remained relatively constant indicating that a lowering of population Hb in an effort to avoid treating to high Hb (> 12 g/dL), can occur without incurring an increase in transfusion rates. However, following the 2011 policy changes, a further decline in facility Hb and increase in facility Hb < 10 g/dL occurred and transfusion rates abruptly increased. This suggests a threshold level of facility Hb < 10 g/dL beyond which transfusions will begin to rise as well as verifies that a performance standard for such a measure can be determined objectively. This work was recently presented at the 2013 National Kidney Foundation (NKF) annual meeting and is currently under review for publication.¹⁷

In addition and unlike previous work showing the strong relationship between Hb < 10 g/dL and transfusion risk that has been based on patient-level analyses and thus potentially subject to unmeasured confounding, comparisons across dialysis facilities (*i.e.*, facility-based analyses) may be subject to less bias because patient case-mix is fairly balanced across facilities.^{18,19,20,21} As a result, facility-level effects may better

¹⁵ Gilbertson, D. T., K. L. Monda, et al. (Under Review). "Red blood cell transfusions among hemodialysis patients (1999-2010): Influence of hemoglobin concentrations below 10 g/dL." *Am J Kidney Dis*.

¹⁶ Molony, J. T., S. Li, et al. (2013). Association Between Facility Hemoglobin (Hb) Concentration and Patient Risk of RBC Transfusions. *National Kidney Foundation*. Orlando, FL.

¹⁷ Collins, A. J., K. L. Monda, et al. (2013). "Effect of facility-level hemoglobin on dialysis patient risk of transfusion." (Under review).

¹⁸ Johnston, S. C. (2000). "Combining ecological and individual variables to reduce confounding by indication: case study--subarachnoid hemorrhage treatment." *J Clin Epidemiol* 53(12): 1236-1241

¹⁹ Johnston, S. C., T. Henneman, et al. (2002). "Modeling treatment effects on binary outcomes with grouped-treatment variables and individual covariates." *Am J Epidemiol* 156(8): 753-760.

represent the relationship between facility treatment decisions (e.g., treating patients to lower Hb levels) and facility results. Support for this view can be found in the recent analyses by Molony et al., wherein adjustment for case-mix differences had little to no effect on facility-level risk of transfusion.²²

Therefore, Amgen supports the measure, but recommends the unit of measurement for this measure be at the facility rather than the patient level. A facility-based anemia metric has the advantage of placing adequate anemia treatment to reduce or avoid RBC transfusions directly under the control of the dialysis facility.

B. Dialysis Facility ESA Management to Avoid Transfusion

In the absence of the Hb < 10 g/dL measure, Amgen appreciates the intent of this measure, as it appropriately recognizes the widely accepted hemoglobin threshold for transfusion risk and intends to be actionable, which is an important objective. However, the measure as written is not fully supported by the evidence and not operationally feasible because of the highly confounded relationship between ESA dose and response, as well as the circumstances leading to a transfusion. Therefore, we cannot support its use in its current form.

Importantly, there is no evidence to support the precise dose or dosing strategy that is specified in the measure description. The EPOGEN[®] USPI recommends a range for the starting dose and continued dosing based on individual patient response and need.²³ Additionally, there are no RCTs that have identified a specific dose that is appropriate for all patients in order to reduce or avoid the risk of transfusion. EPOGEN[®] is a titrated biologic that has to be individualized to specific patient response; there is no basis in physiology, RCTs or labeling to select a specific dose as indicative of inadequate treatment. Additionally, a low EPOGEN[®] dose is often prescribed to patients who are highly responsive to therapy; conversely, high doses are prescribed to patients with poor response to EPOGEN[®] therapy and most likely to have low Hb levels below 10 g/dL. Therefore, we do not believe that a quality measure should include a specified dose that may not be appropriate for all patients and is subject to such confounding.

Additionally, the clinical situation in which a patient has a Hb < 10 g/dL, is simultaneously receiving low ESA dose, and subsequently receives a transfusion may arise for one or more reasons; most commonly occurring during or immediately following a month where the patient was hospitalized. ESA dosing information is only captured during outpatient dialysis sessions; patients admitted to the hospital have lower total exposure to ESAs^{24,25} and this can vary substantially based on length of time spent in the hospital. The literature has shown that recent hospitalization is a strong predictor of transfusion

²⁰ Wolfe, R. A., T. E. Hulbert-Shearon, et al. (2005). "Improvements in dialysis patient mortality are associated with improvements in urea reduction ratio and hematocrit, 1999 to 2002." *Am J Kidney Dis* 45(1): 127-135.

²¹ Brookhart, M. A., S. Schneeweiss, et al. (2010). "Comparative mortality risk of anemia management practices in incident hemodialysis patients." *JAMA* 303(9): 857-864.

²² Molony, J. T., S. Li, et al. (2013). Association Between Facility Hemoglobin (Hb) Concentration and Patient Risk of RBC Transfusions. *National Kidney Foundation*. Orlando, FL.

²³ EPOGEN[®] (epoetin alfa) Prescribing Information. Amgen, Inc. Thousand Oaks, CA (v26 05/2012).

²⁴ Solid, C. A., R. N. Foley, et al. (2007). "Perihospitalization hemoglobin-epoetin associations in U.S. hemodialysis patients, 1998 to 2003." *Hemodial Int* 11(4): 442-447.

²⁵ Bradbury, B. D., O. Wang, et al. (2008). "Exploring relative mortality and epoetin alfa dose among hemodialysis patients." *Am J Kidney Dis* 51(1): 62-70.

risk. Thus, the clinical situation leading to a low Hb and low ESA dose is potentially more reflective of poor prognosis and less an indicator of inadequate anemia management. The measure as described only excludes months with six or fewer dialyses and therefore cannot identify the clinical scenario of hospitalization unless the patients miss more than half of the scheduled outpatient dialysis sessions. Thus, this measure cannot discriminate undertreatment from events associated with hospitalization.

C. **Dialysis Facility Standardized Transfusion Ratio (STrR)**

Transfusion avoidance is the indication for ESA therapy and therefore a standardized transfusion ratio measure may be a reasonable construct for consideration as a metric to detect the result of under-treatment. This measure appropriately recognizes that transfusion avoidance is an important clinical outcome for patients. However, as written, several factors will make this measure infeasible to implement as a protection against under-treatment of anemia. Most notably, the majority of transfusions are administered outside of the dialysis facility, and therefore dialysis facilities may not always be aware when patients receive the transfusions until the end of the reporting period, likely up to a year later. Thus, there would be little opportunity for such a metric to enable effective intervention, and therefore it would not result in timely and meaningful improvements to dialysis patient care.

A number of recent investigations have shown that the development of a transfusion metric is feasible using Medicare data on patients on hemodialysis.^{26,27} There are, however, important issues regarding the feasibility and practicality of using such a metric for evaluating undertreatment of anemia. These considerations include:

- Dialysis unit anemia management practices and the fraction of patients with low Hb at a given unit clearly do affect the resultant transfusion rate. However, since more than 80 percent of transfusions occur in hospitals and there is substantial regional variation in transfusion rate, it is unclear at this time how to attribute performance against a fixed transfusion rate metric to dialysis facility practices versus regional practices. While there is a clear relationship at the facility level between increased facility Hb < 10 g/dL and increased transfusion, the absolute transfusion rate experienced by patients cared for at any specific facility may be influenced by region, making application of a uniform rate to all dialysis units as described in this measure problematic at this time.²⁸
- The transfusion rate in dialysis patients displays strong seasonality.²⁹ As has been shown recently,³⁰ in order for a transfusion metric to have desirable statistical properties (validity and precision), a long time interval over which transfusion rates would be assessed (e.g., one year) is necessary. As such, there would be a substantial delay between the period of assessment and when facilities would be

²⁶ Li, S., J. Liu, et al. (2012). Regional Variation in RBC Transfusions in Hemodialysis Patients. American Society for Nephrology. San Diego, CA.

²⁷ Liu, J., S. Li, et al. (2012). Development of a Facility-Level Transfusion Quality of Care Metric. American Society of Nephrology. San Diego, CA.

²⁸ Li, S., J. Liu, et al. (2012). Regional Variation in RBC Transfusions in Hemodialysis Patients. American Society for Nephrology. San Diego, CA.

²⁹ USRDS ASN Presentation http://www.usrds.org/2012/pres/ASN2H/Gilbertson_USRDS_2-hour_Full.pdf

³⁰ Ibid

notified of their value. Thus, there would be little opportunity for such a metric to enable effective intervention.

- While calculation of a standardized transfusion ratio metric is feasible, it is not simple and recent work has shown that complex methodology may be required to reduce the likelihood that small facilities will be unfairly penalized.³¹ This complex methodology can be difficult to understand, and a measure based on complex statistical modeling may appear opaque and not find wide acceptance, regardless of validity.

Amgen maintains that the proposed facility Hb < 10 g/dL metric is the preferable metric to protect against under-treatment of anemia in that it is directly under the control of dialysis units, is actionable, and on a national level closely correlates with the rate of transfusion. While a useful reporting measure, STTrR would not be directly and meaningfully actionable to assure immediate benefit to patients. Therefore, Amgen recommends that further work is needed, and that STTrR is more suitable as a reporting measure on Dialysis Facility Compare at this time.

D. D-Anemia of CKD: Hb >12 g/dL

Amgen recognizes this as an important patient safety measure that is similar to a measure that has been incorporated into the QIP since the program was implemented (Payment Year (PY) 2012). While the measure is supported by the evidence and is operationally feasible, the impact on patient care may be marginalized as improvements on measurement scores may be unattainable for many facilities. Over time the fraction of patients with Hb > 12 g/dL has fallen substantially-as of early 2012, USRDS reports that this is generally under 10 percent and continues to fall.³² In addition, the implementation of the PPS removed the perceived incentives for overutilization of medical therapies, so concerns about anemia overtreatment have diminished. Thus, the Hb > 12 g/dL measure has been effective, but the need for it may have decreased. Therefore, as the Agency determines when to retire or remove measures from the QIP, consideration should be given to retiring this measure.

2. Amgen does NOT support the following two measures, "Patient Informed Consent for ESA Treatment" and "Standardized 30-day Readmission Ratio for Dialysis Facilities."

A. Patient Informed Consent for ESA Treatment

It is highly questionable whether a metric of informed consent is actually a measure of healthcare quality or safety. No major quality organization, including the National Quality Forum (NQF) or the National Committee on Quality Assurance (NCQA), endorses informed consent as a quality indicator. Specifically, there are no NQF-endorsed quality measures or NCQA Healthcare Effectiveness Data and Information Set (HEDIS) measures regarding informed consent. Therefore, including a quality measure on informed consent for a specific medication would be unprecedented.

³¹ Liu, J., S. Li, et al. (2012). Development of a Facility-Level Transfusion Quality of Care Metric. American Society of Nephrology. San Diego, CA.

³² USRDS ASN Presentation http://www.usrds.org/2012/pres/ASN2H/Gilbertson_USRDS_2-hour_Full.pdf

Amgen supports informed discussions on the risks and benefits of therapies between patients and their physicians and recognizes that dialysis providers often document that these discussions have occurred. Amgen notes that health care providers (HCPs) are already required to distribute the ESA medication guide, a Food and Drug Administration (FDA)-approved document summarizing the risks of therapy, to patients when they are initiated on ESA therapy and when the medication guide is substantively changed. However, with respect to obtaining signed consent, patient informed consent is subject to state laws and in some cases is required by FDA when implemented as a component of Risk Evaluation and Mitigation Strategy (REMS) programs. In creating the ESA REMS, FDA required a signed patient attestation (comparable to an informed consent) for the initiation of ESA therapy only in the context of oncology patients; FDA excluded nephrology and other indications.

Therefore Amgen does not believe that a signed patient informed consent is appropriate or needed as a quality measure and should be left to regulatory bodies such as the FDA.

B. Standardized 30-day Readmission Ratio for Dialysis Facilities

Amgen supports the direction of this measure because hospitalization rates are an important indicator of patient morbidity and quality of life. Avoiding hospitalizations, particularly readmissions, is an important treatment goal for all patients, including dialysis patients who have a high rate of hospitalization. On average, dialysis patients are admitted to the hospital twice a year and spend an average of 11.8 days in the hospital per year.³³ Additionally, hospitalizations account for approximately 38 percent of total Medicare expenditures for ESRD patients³⁴ with a significant percentage (30%) of ESRD patients being discharged from the hospital having an unplanned readmission within 30 days.

The roles of both hospitals and dialysis providers in managing dialysis patients to reduce re-hospitalization is likely complex and has not been well-defined; we are therefore concerned that hospitals appear to have no culpability in this measure when readmissions may occur due to care received in the initial hospitalization and at no fault of the dialysis facility. As readmission is a focus of other CMS initiatives directed towards hospitals, Amgen does not feel that this measure should be implemented at this time.

We believe this is a fruitful area for further study and development, particularly where specific dialysis provider practices can be directly related to readmission (e.g., fluid management). In a general sense, a readmission measure is likely more appropriate for an ESRD seamless care organization (ESCO) or accountable care organization (ACO); environments where multiple aspects of patients' medical care can be addressed by the responsible provider.

³³ United States Renal Data System. USRDS 2011 Annual Data Report: Atlas of End-Stage Renal Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2011. pp 208.

³⁴ United States Renal Data System. USRDS 2011 Annual Data Report: Atlas of End-Stage Renal Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2011. pp 284.

Conclusion:

Amgen is committed to principles and tools aimed at improving the quality of healthcare, particularly in the ESRD population. We acknowledge the importance of ESRD quality measures and support their use when appropriate. Meaningful and relevant measures should be grounded in the evidence, be actionable by the appropriate providers, operationally feasible, and represent a true impact to patient care.

Amgen appreciates the opportunity to provide these comments and looks forward to working with you to ensure Medicare beneficiaries have appropriate access to new and important therapies. Please contact me by phone at (202) 585-9659 or by email at jspangle@amgen.com if you have any questions regarding our comments. Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Spangler', with a long horizontal flourish extending to the right.

Jason Spangler, MD, MPH
Executive Director
U.S. Health Policy and Reimbursement

cc: Patrick Conway, M.D., Director and Chief Medical Officer, Center for Clinical Standards and Quality, CMS
Wesley Perich, M.D., Deputy Director, Center for Clinical Standards and Quality, CMS
Shari Ling, M.D., Deputy Chief Medical Officer, Center for Clinical Standards and Quality, CMS
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Service to those affected by chronic kidney disease

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April 30th, 2013

Patrick Conway, M.D.
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Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

Reference: Medicare Program; End-Stage Renal Disease Quality Incentive Program

I am writing as the Founder and President of the Renal Support Network (RSN). We would like to thank you for the opportunity to comment on the two new proposed measures for the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP).

Hemoglobin (Hb) <10 g/dL

The Centers for Medicare & Medicaid Services (CMS) has proposed to reinstate Hb < 10 g/dL as a QIP measure. RSN supports this revision as a positive development that will improve the quality of care for people on dialysis.

As patients, we understand the very real and extremely negative impact lower Hb levels can have on our quality of life and ability to function. Hb levels < 10 g/dL are also associated with an increase in red blood cell transfusions, which, in turn, can result in an increase in panel reactive antibodies (PRAs) that limit or eliminate a patient's ability to receive a kidney transplant.

Current trends in the management of anemia in patients on dialysis are being affected by a variety of factors, including guidance from the Food and Drug Administration (FDA) on the use of erythropoietin stimulating agents (ESAs), QIP metrics, and financial pressures from the bundle. Removing the Hb < 10 g/dL metric from the QIP quickly led to a decrease in Hb and an increase in transfusions. While some decrease in Hb might have been warranted, it seems that we have gone too far. The FDA guidance to maintain Hb levels "to avoid

An illness is too demanding when you don't have hope!

Renal Support Network

transfusion” is often not being followed, and the continuing trend of progressively lower Hb levels is placing many patients on the brink of needing a transfusion.

The only way to ensure that Hb levels do not drop too low is to have a QIP measure that provides a financial disincentive for facilities that maintain too many patients at levels that increase their risk for transfusions. Therefore, RSN supports reinstating a QIP measure to discourage Hb < 10 g/dL.

Hb > 12g/dL

We acknowledge the potential safety concerns involved in raising Hb > 12 g/dL. We also realize that the FDA has rejected as inconclusive study data assessing the effect of levels >12 g/dL on quality of life, either because the data were not reported directly by patients or because the instrument used to collect these data was not validated. We believe that Hb levels have already decreased significantly and that physicians are no longer trying to attain levels > 12 g/dL. As a result, we believe that the metric should become a process measure rather than a performance measure. The percentage of the 2% withhold that has been diverted to incentivizing physicians not to maintain Hb > 12 g/dL could be used to incentivize other areas of care.

Informed Consent for ESA Treatment

Educating patients on the risks and benefits of treatment is essential to providing them with a choice. RSN supports education on all prescribed therapies and believes that a discussion of the risks and benefits of therapies should be a required part of the interaction between patients and physicians. A QIP measure centered on only one aspect of patient education is too narrowly focused and puts too much weight on a particular aspect of therapy while ignoring all of the other aspects that require holistic education. As a result, RSN does not support the proposed ESA informed consent QIP provision and urges CMS to develop a carefully thought out measure that encompasses a much broader range of patient education needs.

Standardized Transfusion Ratio

Lower Hb levels are associated with an increase in red blood cell transfusions. Data have shown that transfusions result in an increase in PRAs, which limit or eliminate a patient’s ability to receive a kidney transplant. RSN supports the CMS proposal on the timely monitoring and reporting of the transfusions ratio as a first step toward tracking the use of transfusions in patients on dialysis. We also suggest that CMS collect data and provide timely public reporting on the percentage of patients with Hb levels < 10, < 9, < 8, < 7, and < 6 g/dL. These data can be merged with individual patient transfusion data to determine the Hb level or levels that are typically associated with a transfusion. These data could be used to develop future best practice guidelines on the use of transfusions in people on dialysis.

ESA Management by Dialysis Facilities to Avoid Transfusions

The Epogen label directs prescribers to “Use the lowest Epogen dose sufficient to reduce the need for red blood cell (RBC) transfusions.” In my experience, dialysis facilities are typically not the ones that prescribe or administer transfusions and often do not know when patients receive them in other settings such as hospitals. As stated previously, having CMS collect data and provide timely public reporting on the percentage of patients with Hb levels < 10, < 9, < 8, < 7, and < 6 g/dL would result in the best data for developing future clinical guidelines.

Renal Support Network

30-Day Hospital Readmissions

RSN agrees that increased attention needs to be paid to the challenge of minimizing readmission within 30 days of discharge, but do not believe this is the best approach. However, we encourage CMS to carefully consider a metric that focuses on this challenge and on the potential contribution of not only the dialysis facility, but also the patient, the physician and the hospital.

We thank you again for the opportunity to add the patient's voice to your consideration of quality measures and would welcome the opportunity to have an active seat at the table when future measures are being deliberated.

Sincerely,

Lori Hartwell

A handwritten signature in black ink that reads "Lori Hartwell". The signature is written in a cursive, flowing style.

Founder and President



The End Stage Renal Disease Network Of Texas, Inc.

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Medical Review Board Comments Proposed ESRD Measures April 2013

1. Anemia of chronic kidney disease, Hemoglobin <10 g/dL and ESA management to avoid transfusion:

The MRB supports re-establishment of a “floor” for hemoglobin; however, there are concerns that monitoring of the hemoglobin floor in conjunction with transfusion rate could result in facilities being penalized for transfusions that would not have been authorized by the facility, such as hospitalist practices related to transfusion. The MRB is also concerned with the lack of randomized controlled trials demonstrating when transfusions are beneficial and therefore the lack of evidence of an acceptable transfusion rate, or any evidenced based Practice Guideline. There is also concern of the measure’s potential inability to capture those facilities that are following protocol or demonstrating improvement. In summary, the MRB supports the concept of monitoring low hemoglobin rates but concludes that there needs to be CMS guidelines on appropriate transfusions before the measure is ready to be implemented.

2. Anemia of chronic kidney disease, Dialysis facility standardized transfusion ratio (STrR):

Discussion for this measure centered on concerns over STrR data which would be outdated and irrelevant for measuring current performance as well as the lack of data from randomized controlled trials. In summary, it was the consensus of the MRB that there is insufficient data and a lack of CMS guidelines to allow direction for facilities related to this measure.

3. Anemia of chronic kidney disease, Hemoglobin >12 g/dL:

MRB determined since this measure is currently in use and supported by the QIP, there is no comment necessary.

4. Standardized readmission ratio (SRR) for dialysis facilities:

Discussion for this measure focused on concern related to the potential unintended consequences for patient care due to the development of access to care issues. The measure would provide a disincentive for facilities to accept the sickest patients as there is already a disincentive for hospitals to readmit a patient within 30 days. An additional concern that was discussed is the lack of previous testing of the algorithm used to risk-adjust the SRR. In summary, the MRB determined that there is a lack of sufficient data and a high risk of unintended consequences that prevents the MRB from being able to support the measure.

General Comment: Though the intention is good the MRB has concerns regarding unintended consequences especially for those where there are currently no CMS endorsed guidelines or a strong evidence-basis. In particular for the readmission measure, the MRB believes that reducing avoidable readmissions by keeping patients healthy after a hospital discharge is a very important goal, but that the MRB is particularly concerned about the unintended consequences of this measure; a measure that might encourage some facilities to find ways to deny access to care for the more difficult patients with multiple comorbidities, those new to dialysis with catheters, or those with a prior history suggesting a high likelihood of noncompliance.



April 30, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

The Renal Physicians Association (RPA) appreciates the opportunity to submit comments on the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population. RPA is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease.

RPA's comments on the individual measures are included below.

- **Anemia of chronic kidney disease: Patient informed consent for ESA treatment**
While patient informed consent for ESA treatment is an important necessity, RPA does not believe that it is a quality measure; rather, it indicates compliance with a regulatory requirement. Further, there is no evidence that it improves patient centered outcomes.
- **Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion**
RPA finds this measure to be too imprecisely worded and is not sufficiently validated to assure that the factors being measured are fully appropriate. The threshold doses for EPO and Aranesp appear to be arbitrary rather than evidence-based.
- **Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio**
RPA supports the concept behind this measure but believes it requires much more rigorous validation before it can be used as a quality measure, as there are no clear guidelines or basis of evidence to support when patients should be transfused in this population. RPA is concerned about facilities being held responsible for transfusions provided by practitioners outside of the facility. RPA believes the process under the physician's control to avoid transfusion is maintenance of Hgb > 10 g/dL.
- **Anemia of chronic kidney disease: Hgb > 12 g/dL**
RPA supports this measure as it is aligned with an existing AMA PCPI measure that is NQF endorsed (NQF #1666).

- **Anemia of chronic kidney disease: Hgb < 10 g/dL**

RPA believes this is an important reporting measure for transfusion avoidance and improved quality of life. A series of studies have demonstrated that treatment of anemia with erythropoietic stimulating agents to Hgb > 10 g/dL in patients with CKD reduces symptoms and in many studies led to demonstrable improvement in quality of life. A similar physician-level Hgb < 10 g/dL measure for the pediatric patient population has been endorsed by NQF (NQF #1667); the matching adult patient population physician-level measure developed by AMA PCPI and RPA was not endorsed by NQF. However, RPA understands that the hemoglobin less than 10 g/dL measures may not be an appropriate payment measure at the current time, due to the evolving understanding of the risks associated with ESA use which have culminated in label change for incorporating a Black Box Warning that make it difficult to rely upon historic data to evaluate the quality performance of dialysis facilities and providers. At the same time, as soon as an appropriate, clinically relevant hemoglobin measure is available, RPA would support inclusion of such a measure for payment.

- **Standardized 30-day readmission ratio for dialysis facilities**

The RPA does not believe that this measure has been sufficiently validated and tested. Further, we believe the following questions related to the measure remain unanswered: 1) To what extent is variation in re-hospitalization rate attributable to other quality metrics in the dialysis facility? 2) Are the proposed case-mix adjustments reliable? 3) What are the risks of unanticipated consequences - will such a measure result in failure to re-hospitalize patients where it is appropriate? RPA is aware that during the discussions of the TEP meeting there was a strong argument that the responsibility for re-hospitalization was a shared responsibility among the discharging hospital, the dialysis facility and the nephrologist/nephrology group - however adjustment for this last portion was removed from the measure. Further, the concept of shared accountability between hospitals and dialysis facilities has not been formally established and there is no definitive nor mandatory financial linkage at the present time between or among these providers. Moreover, the quality of care rendered by the hospital prior to discharge is out of the control of the dialysis unit. This measure appears to be heavily, and somewhat unpredictably, influenced by the quality of the care rendered during the patient's hospitalization and by the quality of the hospital's discharge planning processes and procedures.

RPA believes that this measure requires robust validation and testing to assure that it is appropriately designed, that the complex model for calculation is appropriate and that the values for the 30-day readmission ratio pass basic validation as reflecting dialysis facility quality.

As always, the RPA appreciates the scope of CMS' efforts in the area of quality improvement, and we look forward to future collaboration with the Agency whenever possible. Questions regarding this communication should be directed to RPA's Project Manager, Amy Beckrich at 301-468-3515, or by email at abeckrich@renalmd.org.

Sincerely,



Robert Kossmann, M.D.

President

FORUM OF END STAGE RENAL DISEASE NETWORKS

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Andrew Howard, MD, FACP
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May 1, 2013

Jennifer Stone, Project Assistant
Arbor Research Collaborative for Health
340 E. Huron, Suite 300
Ann Arbor, MI 48104

Dear Ms. Stone,

The Forum of ESRD appreciates the opportunity to submit comments on the proposed measures for Anemia and Re-hospitalization from the work of the Technical Expert Panels convened by CMS and Arbor in 2012; measures that will be considered for future inclusion in subsequent rule making for the Quality Incentive Program. These comments are representative of the patient voice and perspective and were generated by members of the Beneficiary Advisory Council (BAC) of the Forum. The BAC was created in 2012 to bring the patient into the boardroom and consists of a patient representative from each of the eighteen Networks with an elected chair and vice-chair who serve on the Forum's Board of Directors. The Medical Advisory Council which is the corresponding physician council of the Forum comprised of the chairs of each Network's Medical Review Board, provided guidance and input to the BAC in the preparation of these comments but importantly, the Forum wishes to emphasize that these comments are entirely representative of the views of the patient representatives in their own words. The BAC members have provided summary comments for each of the 6 measures below with supporting comments from specific BAC members.

Sincerely,

Maggie Carey

Maggie Carey
Chair, Forum Beneficiary Advisory Council

Derek Forfang

Derek Forfang
Vice-Chair, Forum Beneficiary Advisory Council

Donald Molony

Donald Molony, MD
Chair, Forum Medical Advisory Council

Andrew Howard

Andrew Howard, MD, FACP
President, Forum of ESRD Networks

- 1) Patient Informed Consent for EPO use
 - a) The BAC feels strongly that Patient Informed Consent should be obtained and abided by. We feel, however, that biases **MUST** be checked at the door and all pros and cons to EPO need to be presented. Quality of Life **MUST** be included in this discussion. We understand that there is a risk factor to future heart health with EPO but many, many patients are unable to sustain an acceptable Quality of Life without it. Consent needs to recognize that EPO can provide them with the energy needed to go back to work, develop careers and take on family responsibilities. A lot of ESRD patients are focused on the moment because the future is so nebulous.
 - b) Patients Comments
 - i) "Quality of Life and Risk Benefit are a tradeoff. Let me choose. It's my life."
 - ii) "The patients' perspective needs to be heard on the importance of anemia management as it relates to their quality of life and the risk-benefit tradeoff. Different patients strike that balance at different places."
- 2) Dialysis facility EPO management to avoid transfusion and Dialysis facility to standardized transfusion rate
 - a) The BAC feels that the TEP handled the gradations of inappropriateness for transfusions very well and had a recognition and understanding of offsite transfusions. We would also like to emphasize that the use of use of transfusions for anemia management in dialysis patients seriously compromises their transplant options.
- 3) Hemoglobin > 12
 - a) On the issue of Hemoglobin > 12, the BAC chooses to present patient quotes to express its views.
 - i) "I am educated and informed. Let me determine how best to live my life. I know what I need to reach my life goals."
 - ii) "I am pleased to see the TEP statement that addresses individualization and quality of life allows for deviation of ESA therapy. One size does NOT fit all"
- 4) Hemoglobin <10
 - a) "All kidney patients deal with chronic fatigue on a daily basis. It is a major side effect of kidney disease. We have to choose to push past the low energy everyday to go on. It is unconscionable to not have a bottom level to keep the hemoglobin in check because of the grave impact it has on a patient's energy level and quality of life."
- 5) Dialysis facility standardized 30 day readmission rate
 - a) The BAC applauds the TEPs handling of this topic with one exception. On Page 6, it is stated that "hospitalizations exclude died in hospital." We don't agree with the logic. If a patient dies during a readmission after just one week, the stay is not counted. We would argue that this visit is the most important to track and should not be excluded.

May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

"I just got off the phone with my transplant hospital and it seems that from my two blood transfusions a couple of years ago, my antibodies have jumped from 10% post rejection to 98% now. What the Frig???? I won't lie...I used the F word. I am in shock. I have been added to the "highly sensitized list" for those of us over 95%. I am numb and went from being cautiously optimistic to devastated in a matter of minutes."

Facebook - Dialysis Discussion Uncensored group quote – May 1, 2013

Dear Dr. Conway,

As the Executive Director of the non-profit Medical Education Institute, Inc. (MEI), an advocacy group on behalf of kidney patients, I am writing to express MEI's profound gratitude and support for all five of the proposed anemia management quality measures for ESRD care.

Managing anemia in a way that minimizes patients' need for blood transfusions is vital. The patient quote above eloquently captures the profound negative impact that even just one or two blood transfusions can have on a dialysis patient's **hope** for a kidney transplant.

Hope is rarely assessed in ESRD. The one study that did so (Billington E. et al, 2008 *Br J Health Psychol* 13:683-699) found that dialysis patients who were more hopeful felt:

- Less depressed - important because depression predicts a loss of ability to follow the care plan, and a dramatically increased risk of stopping dialysis
- Less anxious
- Less burdened by kidney disease
- Higher mental functioning – important because this aspect of health-related quality of life predicts lower hospitalization and less risk of death

You may not receive many other comments that focus on hope—but at the MEI we consider maintaining hope to be literally a matter of life and death for patients with ESRD.

To address the specific draft measures one at a time:

- 1). **Informed consent for anemia treatment.** Informed consent for *all* medical procedures is the law in every state in the nation. It is unfortunate indeed that this needs to be a measure, but the MEI fully supports informed consent for anemia treatment—as well as informed consent for ESRD modality

choice, which might also be contemplated as a future measure of quality (as it is required in the Conditions for Coverage but is not happening.)

- 2). **Dialysis facility ESA administration to avoid transfusion.** This looks to be an eminently sensible approach to following patients' progress and treatment. MEI supports it.
- 3). **Dialysis facility standardized transfusion ratio.** An excellent idea.
- 4). **Recordings of hemoglobins greater than 12 g/dL.** This is necessitated by the FDA Black Box warning. MEI supports it.
- 5). **Recordings of hemoglobins less than 10 g/dL.** This is *absolutely essential* to ensure that patients don't continue to plummet to hemoglobins of 9, 8, 7 or even lower, particularly as paying less for now-bundled ESAs creates a perverse incentive for clinics to withhold the costly drug. Feeling like a fish out of water, aware of each breath, is not a way to remain hopeful. Below are a few quotes (also from Facebook) from patients who are suffering from undertreated anemia:

"What a awful week. Labs are in the toilet. Hemoglobin is 8.0. I can hardly walk. Pity please."

"How do y'all do it? My HGB dropped to 10.5 and all I want to do is sleep. I tire so easily. Gave a crochet class yesterday and it wore me out. I slept 12 hours last night."

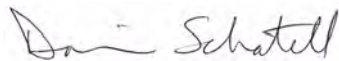
"Mine got to 5.3 (admitted to hospital as had to get emergency transfusions - 4 units and 2 of iron and my HG only rose to 10). Felt like every time I moved I could barely breathe and got dizzy just taking a shower."

"My hemo has dropped to 9.4 and I feel it! They had stopped my iron...gonna start it again on Friday plus they now have doubled my epo...hope that helps, I am so draggy."

"I feel great when I'm closer to 12. I know the risks but I would rather feel good and have energy and be able to participate in life than feel like this."

Thank you for the opportunity to comment, and for the hard work CMS has put into developing these draft measures.

Sincerely,

A handwritten signature in black ink that reads 'Dori Schatell'.

Dori Schatell, MS
Executive Director
Medical Education Institute, Inc.

May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Conway:

Dialysis Patient Citizens (DPC) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the proposed quality measures for Medicare End Stage Renal Disease (ESRD) Program beneficiaries. As America's largest patient-led organization representing dialysis patients, DPC's membership consists of more than 24,000 dialysis and pre-dialysis patients and their families. We seek to ensure the patient point of view is heard and considered by policy makers on a wide range of issues so forward progress continues in the quality of care and life for all dialysis patients.

DPC's mission is to improve the quality of life of dialysis patients by engaging policy makers, providers and the public. Through patient education, empowerment and advocacy, we work to increase awareness about kidney disease and promote favorable public policy. However, improving quality of life for patients can only go so far without improving the quality of care patients receive. DPC knows that a diagnosis of ESRD does not mean the end of life. Dialysis patients can lead long and productive lives, in many ways because Congress and CMS are committed to ensuring patients have access to quality kidney care. It is for these reasons that we respectfully submit comments on the proposed quality measures surrounding anemia management and hospital readmissions.

I. Hospital Readmissions

a. Standardized Readmission Ratio (SRR)

We are encouraged that CMS is looking at reducing the 30-day hospital readmission rate for the dialysis population. Unplanned readmissions play a key role in patient quality of life and are an important indicator of morbidity. The US Renal Data System (USRDS) finds that rates of hospital readmissions for ESRD patients are twice as high as those in the general Medicare population. This means that 36 percent of hemodialysis patients have an unplanned readmission within 30 days of a hospital stay and, for those

patients between 20-44 years of age, that number is as high as 43 percent.¹ Because hospitalization accounts for approximately 38 percent of total Medicare expenditures for dialysis patients, this is an area that could see vast improvement in both patient outcomes and in working to reduce the cost of the Medicare ESRD program.

Therefore, we believe it is critical for CMS to focus on examining and reducing the rate of hospital readmissions for dialysis patients. However, we do not believe that the proposed measure – Standardized Readmission Ratio (SRR) for dialysis facilities – is ready to be included in the Medicare ESRD Quality Incentive Program (QIP) as detailed in the measure development draft documents. We share the concerns of much of the kidney community, namely that more information is needed before the measure should be included for payment in the QIP.

We request additional information on how this measure would work for home dialysis patients. Since these individuals are not in a facility as frequently as in-center patients, there is less of an opportunity for the dialysis provider to create meaningful interventions to reduce the chance of a readmission.

Additionally, we seek clarification on how CMS would ensure that facilities don't turn away patients they feel are at a greater risk for complications. We are concerned that this type of a measure would incentivize "cherry picking" by facilities and therefore we would like additional information and assurances from CMS that this would not be permissible.

We also think further attention should be paid to the list of exclusions for this measure. To make this measure as meaningful as possible, we would want to ensure that only those readmissions that are truly "unplanned" and those that dialysis providers can make a concerted effort to reduce are counted in this measure. We would appreciate additional information regarding these questions and support other concerns raised by the wider kidney community.

We encourage CMS to continue to seek stakeholder input so an appropriate and meaningful hospital readmissions measure can be developed and introduced to the QIP. This is an area that needs serious attention and we support CMS' renewed interest in reducing these unwanted and preventable hospital stays. With the kidney community, we stand ready to assist CMS in further development of this important measure.

II. Anemia Management

a. Patient Informed Consent for ESA Treatment

As a patient advocacy organization, we appreciate the intentions behind the Patient Informed Consent for ESA Treatment proposal. We agree that ESA treatment should only be initiated after the patient is properly informed of the risks of ESA usage and has determined an appropriate course of treatment with his/her care team. However, quantifying the achievement of truly informed consent is extremely difficult. Before this proposal becomes policy, CMS will need to provide clarification on how providers would achieve truly informed patient consent for ESA treatment. As currently outlined, we believe this could be a "check the box" measure that is easily achievable for facilities but is ineffective in achieving its aim of truly educating patients on the benefits and risks of ESA treatment.

¹ "United States Renal Data System 2012 Annual Report," United States Renal Data System, page 238.

We are also concerned that this measure could create confusion and worry for dialysis patients. This new ESA treatment informed consent procedure is inconsistent with the current process laid out by the Food and Drug Administration (FDA), which could cause confusion for patients. Additionally, by creating a separate informed consent measure strictly for ESA treatment, patients may be scared-off from an appropriate treatment plan due to potentially unnecessary worry over the risks of these drugs.

We would be happy to work with the measure developers to determine what information patients would truly benefit from knowing about ESA treatment and the most effective means of communicating that material. We believe this measure has the potential to provide patients with valuable information about their care and are interested in working with stakeholders to make it more meaningful.

b. Hemoglobin <10 g/dL

As we have stated in previous comments to CMS, we strongly support the Hemoglobin <10 g/dL measurement and believe it should be reinstated in the QIP for payment. According to the clinical recommendation statement, there is general consensus that keeping patient hemoglobin levels between 10 g/dL and 12 g/dL yields optimal patient health outcomes. Since the initiation of the bundled payment rate and the subsequent change in the FDA's label for ESA treatment guidelines, there has been an observed decline in hemoglobin levels in the dialysis population. We believe this needs to be monitored and we believe dialysis facilities should be held responsible through the QIP for ensuring that patients maintain a blood hemoglobin level that produces optimal health outcomes and improved patient quality of life.

However, we share concerns raised by the rest of the kidney community that this measure needs further clarification. For instance, we encourage CMS to consult clinical stakeholders to ensure the list of measurement exclusions is expansive enough. There are dialysis patients who, due to complications from other conditions, are not able to maintain a hemoglobin level above 10 g/dL and patients for who that level might not be appropriate. Therefore, we urge CMS to work with the kidney health community to ensure the exclusions list is comprehensive.

c. Hemoglobin >12 g/dL

We support the inclusion of the Hemoglobin >12 g/dL measurement in the QIP for payment, as is current practice today. With the ESA label change in the summer of 2011 and the introduction of the bundle and QIP, there has been an observed decline in ESA utilization and blood hemoglobin levels in dialysis patients. While we appreciate that this measurement may contribute to the recent trends toward reduced rates of ESA-related cardiovascular incidents, we know this trend is relatively new and still needs additional study. Therefore, we encourage CMS to continue to monitor Hemoglobin >12g/dL in dialysis patients for payment in the QIP under the previously approved measure structure.

We appreciate CMS' commitment to ensuring patients aren't adversely impacted by over utilization of ESAs, but we think fewer QIP measures may be more effective in accurately and efficiently monitoring the quality of care delivered by dialysis facilities. Therefore, we believe CMS should focus more on the Hemoglobin <10g/dL measure as a means to monitor anemia management and we would consider prioritizing other measures over the Hemoglobin >12 g/dL. Additionally, in the future, if it becomes apparent that other factors are driving lower ESA dosing patterns and that the Hemoglobin >12 g/dL measurement is no longer a meaningful metric of patient care, then CMS should consider removing this measure from the QIP.

On the subject of the upper and lower hemoglobin limits, we suggest that these two payment measures be more congruent. We ask CMS to work with clinical stakeholders to determine the most appropriate and effective monitoring time frame and procedure that is general enough to allow for normal fluctuation of hemoglobin but narrow enough to capture improper anemia management.

d. Transfusion Measures

We are concerned about the trends toward increased reliance on blood transfusions to treat anemia in dialysis patients and have raised these issues with CMS and the Food and Drug Administration (FDA) on several occasions. According to the United States Renal Data System (USRDS), between September 2010 and September 2011, the percentage of patients who received at least one red blood cell transfusion increased from 2.4 to 3.0, a relative increase of 24 percent.² For various reasons, including an already limited blood supply, risk of infections and the potential to interfere with kidney transplantation, anemia management treatments that rely on transfusions are far from ideal for most dialysis patients.

Therefore, we would be open to a measure to discourage reliance on transfusions, such as the proposed Standardized Transfusion Ratio measure or the ESA Management to Avoid Transfusion measure. However, we do not feel that either of these measures is currently appropriate to include in the QIP for payment, as we are currently lacking critical information about how both measures would work in a clinical setting. We are worried that both measures have the potential to discourage transfusions in cases where a red blood cell transfusion would produce the best health outcomes for a patient. For instance, if the Hemoglobin <10g/dL measure were to be included in the QIP and patient's hemoglobin level falls below that threshold to the point where a transfusion is needed, we would not want the facility to hold off on providing that critical treatment in order to avoid an additional penalty under one of these transfusion measures.

Additionally, we seek clarification on the list of exclusions tied to this measure. We want to ensure that the list is comprehensive enough so as not to penalize facilities for providing transfusions to patients who have comorbidities that dictate this kind of treatment to manage anemia. We encourage CMS to take a closer look at both sets of exclusions to make sure they are appropriate and inclusive to ensure the measures are as meaningful as possible. As a member of Kidney Care Partners, we also call CMS' attention to the specific concerns raised by Kidney Care Partners in their letter to CMS.

At this time, we do not believe either transfusion measure is ready for inclusion in the QIP, but we encourage CMS to use the QIP reporting process to track any changes in the rate of red blood transfusions in dialysis patients. If transfusion rates continue to climb after reintroducing a bottom floor hemoglobin payment measure, then it will be necessary to introduce a transfusion rate payment measure. If the bottom floor hemoglobin payment measure alone sufficiently discourages reliance on transfusions, then the transfusion payment measure may not be necessary.

III. Conclusion

² "United States Renal Data System 2012 Annual Report," United States Renal Data System, page 320.

As a patient education and advocacy group, DPC is proud to share CMS's commitment to providing high quality care for all dialysis patients. We thank you for the opportunity to share our feedback and welcome the chance to work with you on this important issue in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "Hrant Jamgochian". The signature is fluid and cursive, with a long horizontal stroke at the end.

Hrant Jamgochian, J.D., LL.M.
Executive Director

May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

With more than 14,000 physicians, scientists, and other health professionals dedicated to leading the fight against kidney disease, the American Society of Nephrology (ASN) appreciates your leadership and commitment to ensuring high-quality dialysis care within the Medicare End-Stage Renal Disease (ESRD) program.

ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's goals is the preservation of equitable patient access to optimal quality kidney care and related services regardless of socioeconomic status, geographic location, or demographic characteristics—as well as the preservation of reasonably individualized patient care. The society perceives the ESRD Quality Incentive Program (QIP) as an integral component to achieving these goals, and appreciates the Center for Medicare and Medicaid Services' (CMS) ongoing efforts to improve and expand the QIP's scope and effectiveness through new measure development.

The society is grateful for the opportunity to provide comment on the new draft 30-day hospital readmission and anemia management measures for the ESRD population and appreciates CMS' extension of the deadline for public comment. This letter summarizes ASN's recommendations regarding these draft measures. Representatives of the society stand ready to meet in-person about these suggestions if requested by the Agency.

Anemia of Chronic Kidney Disease: Hemoglobin < 10 g/dL

ASN concurs with CMS regarding the vital importance of anemia management for patients with ESRD. Unfortunately, the conflicting data and ongoing debate concerning the target hemoglobin and relative risks of higher doses of erythropoiesis stimulating agents (ESAs) do not support mandating a standard hemoglobin target for all patients on dialysis. Recognizing these limitations, and the data available, ASN does generally support having a minimum hemoglobin target as a monitoring measure for the majority of patients on dialysis, but recommends the following to allow for individualized patient prescriptions with the following considerations:

- Hemoglobin concentrations should be assessed as a rolling 3-month average rather than a single monthly value. Past studies showed that hemoglobin concentration in individuals with chronic kidney disease commonly fluctuate within short periods of time such that even though the calculated time-averaged hemoglobin remained within the target range of 11 to 12 g/d, there were fluctuations above and below this range. (JASN March 2009 vol. 20 no. 3 479-487.) It is unclear as written in the Measurement Information Form whether CMS is proposing a 2- or 3-month average; ASN encourages adoption of a 3-month rolling average.
- A sizeable fraction of patients with ESRD may not be able to achieve and maintain a hemoglobin concentration of greater than 10g/dL despite receiving high ESA doses. ASN agrees with the proposed list of co-morbidities that would exclude patients with malignancies and co-morbidities specific to red blood cell production or hemolysis from being included in the metric. However, there are many other patients with complex chronic or subacute diseases that lead to ongoing blood loss, unexpected blood loss, persistent anemia or resistance to ESAs that are not included on the list. In addition, in some patients, a hemoglobin concentration somewhat lower than 10 g/dl may be clinically acceptable or may be the result of a patient and physician decision to avoid ESA use altogether. Therefore, in an effort to address these concerns without creating an excess reporting burden, ASN recommends that CMS revise this metric to specify that the 3-month rolling average hemoglobin concentration be ≥ 10 g/dL in ≥ 85 -90% of patients. This would account for patients with significant co-morbidities leading to ESA resistance, acute intercurrent events exacerbating anemia, and thus avoid incenting dialysis providers to prescribe high doses of ESA or transfusions just to attempt to achieve the measure specification and not account for individual patient choice and individualized therapy.

In sum, ASN supports draft measure Anemia of Chronic Kidney Disease: Hemoglobin < 10 g/dL and but strongly encourages CMS to make the changes described above. Especially with these modifications, the society suggests that this measure may be superior to the other draft measures that attempt to assess anemia management practices at the lower end of the spectrum.

Anemia of Chronic Kidney Disease: Hemoglobin > 12 g/dL

Current data suggest that anemia corrected to > 13g/dL is not associated with improved survival and in some settings has been associated with stroke, vascular access thrombosis and other thromboembolic disease. ASN supports the development of a unit-level quality measure that discourages inappropriately aggressive treatment with ESAs, thereby potentially avoiding some adverse events. ASN also agrees with the approach of including only those patients treated with ESAs, and receiving maintenance dialysis for at least 90 days at the start of the claim period, in the measure denominator.

For the reasons articulated above, the Society recommends the use of 3-month rolling average hemoglobin as it better reflects anemia care than a single measure. Studies show that hemoglobin concentrations in patients with chronic kidney disease commonly fluctuate over short periods of time with levels above and below a time-averaged concentration that is within the desired range (JASN March 2009 vol. 20 no. 3 479-487.) A 3-month rolling assessment of hemoglobin among patients who are receiving any ESA therapy would provide a more complete picture of patients' overall anemia management. ASN would also like to point out that there is precedent at CMS for using this methodology, as it was used in the past as part of the CMS EPO Monitoring Policy (EPM).

ESA Management to Avoid Transfusion

ASN concurs with CMS that avoiding underutilization of ESAs and overreliance on transfusions for anemia management are important goals for patients in the Medicare ESRD program. However, ASN has concerns about several aspects of the draft measure “Anemia of chronic kidney disease - ESA management to avoid transfusion.” From a technical standpoint, the epoetin : darbepoetin ratio of 375:1 used for this measure is not consistent with the package insert which reports conversion ratios of approximately 200:1-900:1 and is not evidence-based as being equivalent dosing and is not consistent with the package insert that reports conversion ratios of approximately 200:1 – 900:1. Moreover, there is also no distinction between subcutaneous and intravenous ESA use despite evidence to suggest that hemoglobin concentrations may vary substantially based on the route of administration at a given ESA dose. The society also notes that the 75 units/kg/session is not based on any data as to what an appropriate dose is for a patient, and suggests that this proposal is far too prescriptive based on the lack of supporting evidence. Beyond these technical concerns, ASN observes that there is no need for both this measure and the floor hemoglobin measure described above.

Should CMS determine to move forward with this measure, ASN requests clarification regarding the details of the patient-month calculation. For instance, are facilities expected to report this and if so, will they know how to calculate this precisely; if a patient is hospitalized, does the entire month count as a “patient month”? The administrative burden associated with this calculation is likely to be substantial; ASN would appreciate clarification whether this aspect of the measure has been tested in routine practice. Additionally, the Society requests clarification regarding how the ESA doses “per session” would apply to patients treated with peritoneal dialysis, who are also included in the measure.

ASN also requests clarification regarding the term “reporting month” and how this figures into the numerator; “the most recent value taken prior to the reporting month” vs. “at least one red blood cell transfusion event in the subsequent month”. For instance, does this mean that if October is the reporting month, the last hemoglobin from September is used for the numerator and transfusions administered in November are then counted? This would seem to exclude transfusions which occurred in October. Is there meant to be a single reporting month per year for all facilities across the country or is every month a “reporting month”? As with other measures, we are concerned about the ability of reporting agencies and dialysis facilities to obtain accurate and timely transfusion data from various health care facilities and need more detailed information about how this information will be obtained, reviewed for accuracy, and incorporated into calculations for measure reporting.

Finally, cancers with little likely impact on hemoglobin concentration and transfusion requirements are included in the exclusion list while known bleeding disorders (colon polyps, peptic ulcer disease, heavy menses, etc.) are not, and ASN recommends that CMS add these important disorders to the exclusion list. The society also suggests that the Agency specify whether the listed exclusions require the cancer to be current/active and undergoing treatment or just present without treatment or a “history of”. ASN strongly believes that the measure should exclude new acute events that require transfusion (i.e., surgery, gastrointestinal bleed, etc.) that may lead to transfusion need but could not be anticipated. ASN is also concerned that physician and facilities who are actively managing anemia in patients with low hemoglobin levels with appropriate increases in iron and ESA doses which do not prevent transfusion (though may reduce the units of blood needed) could be potentially penalized by public reporting of this measure.

In sum, while ASN feels strongly that proper management of ESA therapy is essential to maintain patient quality of life and avoid transfusions, the society suggests that this measure requires considerable clarification before it can be considered for inclusion in the QIP or any other aspect of the ESRD program. The desired goal of this measure may also be achieved with the hemoglobin < 10 g/dL measure discussed above.

Standardized transfusion ratio

ASN agrees in principle that a standardized transfusion ratio is a potentially valuable measure as a means of assessing and publically reporting outcomes of dialysis facility transfusion practices, recognizing that one of the main goals of anemia management with ESAs and iron in dialysis patients is to minimize transfusions. While the draft measure document states that the analysis will be “based on a risk adjustment model for the overall national transfusion rates”—ASN feels strongly that a dialysis patient-specific risk adjustment method that takes into account important relevant time-adjusted co-morbidities and clinical variables as possible in a manner be developed.

Furthermore, it is vitally important that a standardized transfusion ratio use regularly updated clinical information rather than relying on information obtained from the 2728 form, which is often completed months if not years prior to a transfusion event. ASN also notes that the measure does not specify whether the population to which this measure applies in in-center hemodialysis patients only or also includes home hemodialysis, non-traditional hemodialysis and peritoneal dialysis patients. The society believes that the methodology for risk adjustment and determination of the standardized transfusion ratio is likely to be very different for each of these different populations and warrants individual attention.

Similar to previous measures, ASN observes that cancers with little likely impact on hemoglobin level or likelihood of need a transfusion are in the diagnosis exclusion list while known bleeding disorders (colon polyps, peptic ulcer disease, heavy menses, etc.) are not. Again, the society requests that the agency state clearly whether the listed exclusions require the cancer to be current/active and undergoing treatment or just present without treatment or a “history of”. Finally, ASN is concerned about the ability of reporting agencies and dialysis facilities to obtain accurate and timely transfusion data from various health care facilities and requests more detailed information about how this information will be obtained, reviewed for accuracy, and incorporated into calculations for measure reporting.

Anemia of chronic kidney disease: Patient informed consent for ESA treatment

Preservation of the patient-physician relationship is of utmost importance to ASN and the Society strongly believes that patients should be engaged in decisions regarding their healthcare, particularly regarding therapies with known, definable risks. As such, ASN concurs that patients should be engaged with their physicians in a careful evaluation of the risks and potential benefits of ESA treatment prior to initiation of ESAs or if dose escalation is contemplated. However, the society has several concerns related to the draft measure “Anemia of chronic kidney disease: Patient informed consent for ESA treatment.”

First, the measure appears duplicative of the pre-existing Risk Evaluation and Management Strategy (REMS) the FDA has established for ESAs. Second, many crucial details that could potentially make this measure meaningful are not specified. For instance, it remains unclear by what standard physicians or dialysis facilities would determine a patient to be “informed” of the

potential risks and benefits. That said, it may well not be possible to establish a uniform definition of what constitutes patient “informed” status, as this would vary based on patient experience with dialysis and ESAs, knowledge base, whether or not patients have full mental capacity, and a multitude of other variables. ASN concurs that patients should be informed partners in their care decisions, but, given these and other often intangible but important aspects of communication, respectfully submits that this is one aspect of care that may not be meaningfully improved through a quality measure.

Standardized Readmission Ratio for Dialysis Facilities

ASN supports the concept of a Standardized Readmission Ratio (SRR) and recommends that such a metric should be implemented within the QIP in the next several years. However, given the complexity of the draft metric, the society maintains multiple concerns that it hopes can be clarified or addressed prior to finalization and implementation. ASN appreciates that CMS has sought the comments of stakeholders on this important measure and offers these suggestions and questions to facilitate the creation of a robust and clinically valuable rehospitalization metric.

The society’s overarching concern with this measure is that it could potentially promote ‘cherry-picking’ (i.e. avoidance of what might be perceived to be higher risk patients or selective acceptance of lower risk patients to dialysis facilities) and dismissal of patients with a high likelihood or history of hospital readmission. While the Society hopes that ‘cherry-picking’ is not something that will occur, ASN recognizes that there is substantial risk of preferential patient selection and requests assurance that CMS will actively monitor data to identify and prevent this occurrence.

ASN also observes that the rehospitalization metric for hospitals is limited to pneumonia, congestive heart failure, and myocardial infarction, with patients on dialysis only pointedly included in the congestive heart failure metric. In contrast, the draft SRR measure for dialysis facilities is intended to cover every diagnosis. Reducing ESRD patient hospital readmissions will require a partnership between dialysis facilities and hospitals. ASN suggests that CMS consider whether this draft measure might be most successful if the agency also instituted a corresponding quality measure for hospitals that includes ALL ESRD readmissions, thereby incentivizing both hospitals and dialysis facilities to collaborate to improve transitions of care for these patients.

On page 6 of the measure justification, CMS states that ‘*Justifications for applying a hospital readmission measure to dialysis facilities rest on the fact that the likelihood of readmission is influenced by process of care at the dialysis facility.*’ This statement implies that the dialysis facility has the opportunity to prevent readmission. ASN suggests that if a patient is readmitted within the first 48-72 hours—a time frame during which the patient may not yet have presented for their next dialysis procedure to their dialysis facility—it is unlikely that the dialysis facility has had the opportunity to implement care processes that can influence the likelihood of readmission for that specific patient. Accordingly, ASN recommends that readmissions occurring within a narrow time window following discharge should be excluded from the numerator. Alternatively, rather than a time-limit, CMS could use one or more post-discharge outpatient dialysis treatments (as reported on a claim form) as the initiation of the period for which dialysis facilities will have had the opportunity to intervene to reduce rehospitalization risk.

That said, it may be considerably more challenging to operationalize this measure for home dialysis patients. A home program may not even be informed of a hospital discharge and, therefore unable to intervene - say over a 48-hour weekend - and to hold the home program

accountable when it may not know about the discharge is challenging. ASN does not have a ready solution to this situation, but encourages CMS to consider the nuances of how a rehospitalization metric may impact home dialysis programs and would welcome the opportunity to collaborate with the agency to address these and other nuances in a rehospitalization metric.

ASN also believes that it is important to exclude planned admissions/readmissions from this measure, and is concerned that the draft algorithms for designating planned admissions/readmissions are not geared to the dialysis community. It is critical that planned vascular access procedures, such as fistula creation (e.g., a transposed basilic vein AVF creation can sometimes result in a brief admission) be captured as planned in this algorithm, particularly given the use of code 237 as unplanned (complication of device, implant or graft). Given that the target for this metric is dialysis facilities, particular care needs to be taken to ensure that planned vascular access creation is captured as planned. It is also important that this measure capture planned PD catheter placement, especially as PD catheter placement is substantially more likely to be a planned procedure compared to vascular access procedures.

As noted above with respect to the standardized transfusion ratio, ASN is concerned about relying on BMI data from the 2728, especially when these data may be used to inform a readmission occurring years later. Given limited accuracy of patients' BMI on the 2728 as well as issues with validity regarding temporally distant events from dialysis initiation, ASN suggests that baseline BMI not be maintained within this model.

Some patients with ESRD who undergo kidney transplant may have delayed graft function and require dialysis for an uncertain period following transplantation. ASN suggests that, given the removal of kidney transplant status as a modifier (which ASN concurs is appropriate), admissions during the first 120 days following kidney transplantation for individuals who remain on dialysis despite kidney transplantation be excluded from the numerator and the denominator.

Given the high rates of other organ failure in individuals with kidney failure, including liver failure, heart failure and bone marrow processes, ASN also requests that all transplants, not just kidney transplant, be specifically excluded as planned procedures, and that hospitalization in a finite period following transplant (e.g., 120 days) be excluded from the numerator and denominator as these are likely consistent with the surgery and immunosuppression and beyond the control of the dialysis facilities. Many other organ transplants in patients treated with dialysis sometimes incorporate kidney transplant (i.e., heart-kidney or liver-kidney).

In addition to these concerns, ASN also requests that CMS:

- Please clarify that a readmission cannot be in the numerator if it is not in the denominator; the society is curious as to how transitions across calendar years will be handled.
- Please specify whether the double random effects model remains robust in settings where there is a single dialysis facility and a single hospital which receives all of the admissions from that facility. This issue will be more common in rural areas.
- Please address the testing results described on page 11 of the measure justification, which contain some fairly extreme values. Are these small facilities with high confidence intervals that explain their marked outlier status? Are single patients driving the very high SRRs for these facilities? Given the extensive modeling that is incorporated into

the calculation of the SRR, it may be helpful to explore these outlying facilities in greater detail to assure that there are not correctable biases that have been introduced. To the best of ASN's knowledge, these analyses were not reviewed with the Technical Expert Panel convened to work on the proposed metric.

ASN acknowledges that PPS-Exempt Cancer Hospitals are excluded by law from the hospital readmission metric on which hospitals are evaluated. However, the society is uncertain as to the justification for the exclusion of discharges from these 11 hospitals from the ESRD PPS when other discharges of patients with cancer may or may not be excluded – a judgment that will be made based on the reason for admission (as it is for all other hospital discharges). ASN feels that this may unfairly favor dialysis facilities, which admit to these hospitals (especially as there are many other institutions that provide similar cancer care across the country). The Society does not feel that discharges from these facilities by necessity are excluded from the denominator based on law as the hospitals themselves are not subject to the ESRD PPS. ASN also notes that measures specific to these hospitals are currently being planned.

On behalf of ASN, thank you for your consideration of these comments regarding the draft measures. The Society's members are dedicated to providing the highest quality care for patients treated with dialysis and believe that robust quality measures play an important role in ensuring its delivery. Developing meaningful, evidence-based measures is challenging and the Society hopes that the recommendations it offers in this letter are helpful as CMS progresses toward its goals. ASN stands ready to discuss these comments, and welcomes the opportunity to continue to collaborate with CMS to develop additional quality measures in future years.

Again, thank you for your time and consideration of these comments. To further discuss ASN's comments, please contact Rachel Shaffer, ASN Manager of Policy and Government Affairs, at rshaffer@asn-online.org or (202) 640-4659.

Sincerely,

A handwritten signature in black ink that reads "Bruce A. Molitoris". The script is cursive and fluid.

Bruce A. Molitoris, MD, FASN
President



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May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the development of new measures designed to improve quality of care for individuals with chronic kidney disease on dialysis. We also thank the agency for providing additional time to submit comments as it allowed us to receive input from across the organization's membership. NKF is America's largest and oldest health organization dedicated to the awareness, prevention and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF is the founding sponsor of the Kidney Disease Improving Global Outcomes (KDIGO) initiative and has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD) and related complications since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI).

Quality measures should be meaningful, actionable and patient centric. This is particularly important for the Medicare End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) because 2 percent of payments are based on performance of quality measures so those measures need to truly reflect the quality of care patients receive. NKF believes finalization of quality measures should only be made if the measures are meaningful, actionable and patient centric. From the measures proposed, NKF believes the hemoglobin <10g/dl and the standardized readmissions ratio measure have the best potential to meet these criteria. However, both of these measures require modification before they can be used in ESRD quality programs. Below are NKF's specific comments on each of the proposed measures.

Anemia of chronic kidney disease: Patient informed consent for ESA treatment

NKF strongly believes patients should understand the risk and benefits of all medications. This important conversation should occur between the patient and the prescribing physician or advanced practitioner. This principle is central to the FDA Risk Evaluation and Mitigation Strategy (REMS) for Erythropoiesis-Stimulating Agents (ESAs). Unfortunately, this measure as developed does not meaningfully assess the patient's level of understanding of the risks and benefits of ESA treatment. In addition, we believe singling out one medication for informed consent may unduly alarm patients and cause them to refuse the medication without fully understanding the risks and benefits involved. Patients who refuse ESAs are at risk for transfusions, the subsequent consequences, and other complications. This measure was not suggested by the Technical Expert Panel (TEP) and will not improve patient outcomes. Therefore, NKF recommends that it not be considered for use in the QIP or any other ESRD quality program.

Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio (STrR)

FDA dosing recommendations for Erythropoiesis-Stimulating Agents (May 31, 2012) read: "Physicians and their patients with chronic kidney disease should weigh the possible benefits of using ESAs to decrease the need for red blood cell transfusions against the increased risks for serious adverse cardiovascular events."

There are additional reasons why transfusion avoidance for kidney patients should be a prime public policy focus. Red blood cell transfusions carry many risks that are specific to kidney patients, in addition to the general risks of transfusion errors, lung injuries, and the well-known danger of exposure to blood borne pathogens. In the presence of severe chronic anemia, transfusions may lead to congestive heart failure, particularly in the elderly. Iron overload can develop with the administration of frequent red blood cell transfusions over a prolonged period of time. Red blood cell transfusions also can induce antibodies that may interfere with kidney transplantation; and, for this reason, transfusions should be avoided, when possible, in patients awaiting a kidney transplant.

A transfusion avoidance measure may protect patients from unnecessary transfusions, but should not be the only measure used to assess appropriate anemia management. In addition, tracking blood transfusion data that are critical to understanding patient safety issues will be difficult for facilities/providers since most blood transfusions are not provided in the dialysis setting. NKF believes this is an important measure, but questions how it will be applied practically.

Anemia of chronic kidney disease: ESA management to avoid transfusion

NKF is troubled by the development of this measure as it unlikely to result in improved quality of care, does not allow for individualized dosing, or prevent under-treatment of anemia. The FDA dosing recommendations for Erythropoiesis-Stimulating Agents (May 31, 2012) calls for maintenance dosing to be individualized for each patient. A patient-centered approach should allow for physicians and advanced practitioners to tailor treatments in order to reach a mutually agreed upon goal with the patient. By including a dosing threshold for ESAs, the measure prescribes a minimum dose of ESAs

that may not be appropriate for the individual patient and also completely ignores other factors in anemia management, including the use of intravenous (IV) iron. Use of this measure in the QIP or any other quality program would not be an indicator of quality of care. In addition, we note that this measure was not suggested by the Technical Expert Panel (TEP) and strongly encourage CMS not to move forward with development of this measure.

Anemia Management of Chronic Kidney Disease: Hemoglobin >12 g/dL

Recent evidence has shown that using ESAs to treat anemia in kidney patients by targeting hemoglobin levels above 13g/dl is associated with increased death, stroke, and other cardiovascular events. The KDIGO guidelines recommend an upper range target of 11.5 g/dl. The quality measure to minimize patients with hemoglobin >12g/dl supports the evidence and allows for the natural fluctuation seen in patient's hemoglobin levels.

Anemia of chronic kidney disease: Hemoglobin < 10 g/dL

This floor hemoglobin measure is important to protect patients from unnecessary blood transfusions and to insure against loss in quality of life that results when patients experience symptoms of anemia that interfere with everyday living. This is in line with the current KDIGO anemia guideline which recommends that treatment for anemia begin when hemoglobin is between 9.0 - 10.0 g/dL. A floor hemoglobin value of <10g/dL helps to ensure patients do not suffer from the known symptoms of anemia, such as severe fatigue, which interferes with their ability to participate in activities of daily living. In addition, the latest DOPPS Practice Monitor findings suggest the need for a low hemoglobin measure. Its report on emerging trends (January 14, 2013) noted that, from August 2010 to August 2012, among patients treated with an ESA, the percentage with hemoglobin <10 g/dL increased from 9% to 19%. To support appropriate treatment of anemia for all patients, it is also important that the <10g/dL measure apply to all patients not just those being treated with an ESA. CMS data released on April 9, 2012 shows the percentage of patients treated with an ESA dropped 8% from December 2010 to December 2012. Finally, as noted above, a low hemoglobin measure provides a better proxy for a transfusion-avoidance measure as the risk of transfusions is high in those hemodialysis patients whose Hb falls below 9 g/dl (KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease).

Given that the Medicare ESRD Prospective Payment System bundles IV (and oral equivalent) medications into dialysis reimbursement and that patients' hemoglobin levels have declined significantly with the recent decline in ESA use, NKF supports including a <10g/dL measure in the QIP as a strategy to protect patient care and quality of life. However, we believe the measure should specify that performance will be assessed based on a three month rolling average.

Standardized Readmission Ratio (SRR) for dialysis facilities

Given the high number of hospitalizations and 30 day readmissions for dialysis patients, we believe a measure tailored for the dialysis population might help improve patient outcomes. However, we have the following questions and concerns about this measure and its potential use.

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The differentiation between planned and unplanned admission could be subject to arbitrary interpretation. We would like to see a list of readmissions that are considered planned or unplanned. For example, a patient may require multiple vascular access interventions in order to salvage the access, but if these interventions are considered unplanned there could be a disincentive to continue with the interventions necessary to save the access. This could cause an unnecessary vascular access replacement for the patient and potentially endanger patients by increasing catheter use if the access fails and an interim access is needed.

How this measure will be used is also important. If this measure is included in the QIP then it should focus only on admissions that are actionable for dialysis facilities, making stratification by primary diagnosis for readmission important. Examples include readmissions for congestive heart failure, fluid overload, hyperkalemia, and vascular access infection. Conversely, readmission because of hospital-acquired infection is probably not actionable for dialysis providers. Readmissions that occur within three days of discharge should also be excluded since in many cases the patient has not had any encounter with their dialysis facility. Addressing all-cause readmissions requires collaboration with other health care providers but dialysis facilities do not control discharge planning at hospitals, coordination with nursing homes, coordination with other health care providers, and with families. The primary care physician, the discharging physician, and the patients themselves are key actors in the coordination. It is important for nephrologists and dialysis facilities to play a role in this coordination, but taking on a leading role in this coordination may require additional resources that not all facilities may have.

NKF believes that improved care coordination between dialysis facilities and other health care providers is needed. However other system changes need to be encouraged before dialysis facilities can manage the holistic care of a patient. While an all-cause readmission measure may be appropriate to test in the Comprehensive ESRD Care (CEC) initiative because the ESRD Seamless Care Organization (ESCO) will receive incentives to address total patient care and partner with other health care providers, we believe that in its current form it is not appropriate for the QIP.

We thank CMS for the opportunity to comment on the proposed measures and their potential use in ESRD quality programs. We look forward to continuing dialogue with the agency on improving patient outcomes and quality of care.

Sincerely,

Joseph Vassalotti

Joseph A. Vassalotti
Chief Medical Officer



May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
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Department of Health and Human Services
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Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

Kidney Care Partners (KCP) appreciates the opportunity to comment on the proposed hospital readmission and anemia management measures for the End-Stage Renal Disease (ESRD) population and the Agency's extension of the comment deadline. As you know, KCP is an alliance of members of the kidney care community that includes patient advocates, physicians, nurses, dialysis facilities, providers, and manufacturers. KCP is prepared to continue working with CMS to develop measures that will be used to assess and improve the quality of care for Americans with ESRD.

I. CMS should provide additional clarity and make specific modifications to the hospital readmission and anemia management measures before finalizing them

We have reviewed the draft measures that were developed by Arbor Research/UM-KECC and its technical expert panels (TEPs). Our comments and recommendations focus on the clinical and technical aspects of each measure; they do not address how such measures should be integrated in the Medicare End Stage Renal Disease (ESRD) Program. Specifically, these comments and recommendations should not be viewed as endorsing any of these measures for use in the ESRD Quality Incentive Program (QIP). Our goal is to provide CMS with information to improve these measures. Once a measure has been appropriately developed and specified, a separate review should take place to determine its appropriate use in terms of surveillance, public reporting, or quality payment.

Additionally, it is critically important that to the extent CMS modifies these measures to address the specific concerns below, it must also provide transparency as to the development and adoption of the benchmarks used to evaluate performance with these measures. The benchmarks need to be established using the most current data available. Relying on older data would not present an accurate or clinically appropriate view of a facility, and reliance on these data by patients would make it extremely difficult, if not inappropriate, for people living with kidney failure who receive life-sustaining dialysis treatments to utilize these measures when making decisions.

A. Standardized Unplanned 30-Day Readmission Ratio for Dialysis Facilities (SRR)

KCP has several significant concerns and questions about the specifications as currently drafted. Given our concerns, as well as those expressed by members of the TEP during the discussion of this measure, we strongly recommend a more evidence-based approach to the refinement of this measure. As currently defined, it is not appropriate for use.

First, the SRR as specified is inconsistent with the *Dialysis Facility Risk-Adjusted Standardized Mortality Ratio* measure and the *Standardized Hospitalization Ratio for Admissions* measure. These measures include only patients who have had ESRD for 90 days or more. The proposed SRR measure does not appear to be harmonized with these measures in this respect. CMS should clarify why this difference is present and provide the data analysis on the implications of this difference.

Second, KCP notes that the specifications submitted to the National Quality Forum's (NQF) Measure Applications Partnership (MAP) had an exclusion for "index hospitalizations that occur after a patient's 6th readmission in the calendar year," which has now been revised to those that "occur after a patients 12th readmission in the calendar year." We believe the developer should be transparent about this change. In particular, KCP is concerned about the impact of this change on low volume facilities, and believe it imperative for the measure developer to report on the underlying distribution that led to this change in order to understand its implications as compared to the MAP version.

Third, we note that the *Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio* excludes patients who have incomplete claims history from the past year, but the proposed dialysis facility SRR does not. The measure developer should provide the data on readmission rates for patients who have a full year of claims versus those who do not, as well as data on the impact of such an exclusion on the sample size and performance gap. Such data and analyses are necessary in order to understand why the current measure is not and/or should not be harmonized with the hospital measure.

Fourth, we recommend the risk model also include sickle cell trait, not just sickle cell anemia, as well as angiodysplasia, myelodysplasia, diverticular bleeding, and asthma, as well as adjust for nursing home status. Additionally, we note that "poisoning by nonmedical substances," is included, but request clarification if this encompasses ongoing/chronic alcohol or drug abuse and not just acute events.

Fifth, KCP believes the model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns—in particular because the decision to admit/readmit is a physician decision. Geographic variability in this regard is well documented in other areas, and there is no reason to believe the situation is different for ESRD patients. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for.

Sixth, KCP continues to strongly recommend that the measure be limited to those readmissions that are related to or actionable to ESRD rather than the all-cause specifications promulgated in the current draft. Data from one KCP member reveal that approximately 45 percent of readmissions are not related or actionable; moreover, only a subset of the 55 percent attributable ESRD admissions are same cause-specific readmissions.

Seventh, KCP recommends that patients who are readmitted in the first 1-3 days after discharge be excluded from the measure. Data from two KCP members find that among patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 11-17 percent of patients were readmitted during this period, often even before the first outpatient dialysis encounter. Specifically, for one KCP member, 17 percent of patients are readmitted within 3 days post discharge, among whom only 35 percent of patients had been seen by the dialysis unit prior to the readmission. In other words, by an approximately 2:1 margin, rehospitalized dialysis patients had not been seen by the dialysis facility before readmission. Penalizing facilities for such situations is patently unreasonable. Further in this regard, during the first 8 days after discharge, up to 40 percent of patients were readmitted—again the dialysis center has had a limited number of encounters to intervene/affect quality of care.¹ Lastly, not all discharges are to home and a significant number of patients are readmitted before they receive care from a dialysis facility. The measure should account for this.

Eighth, the developer should provide data to demonstrate there is no bias of the SRR between rural and urban facilities; this is not simply adjusted for by the hospital as a random effect variable. KCP notes that the distance of a patient's home relative to the outpatient facility and to the hospital likely influences their choices for care, and it likely further influences their utilization of care, particularly if there are symptoms that occur on non-dialysis days. The co-pay for transportation also may influence health utilization behavior. It is important for the measure developer to evaluate the impact of these factors on readmission rates for patients with ESRD and report in the Measure Justification Form why such factors should or should not be incorporated. We posit that billing data may shed light on how to evaluate these factors, yet they were not even considered.

Overall, we are concerned with the approach and assumptions for the predictive model that posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data.

In sum, CMS has at its disposal the data to address a number of these issues—specifically the ability to understand the types of readmissions that dialysis patients experience, the length of time post-discharge when readmissions occur in relationship to when outpatient dialysis unit care resumes, the sites of service that patients are discharged to, and claims data related to physician admission/readmission for purposes of adjusting the model for this factor. We recognize it is difficult work, but it is not impossible given the data available to CMS. We strongly recommend a more evidence-based approach to this measure.

¹ See Kevin E. Chan, J. Michael Lazarus, et. al, "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge," 76 *Kidney Internat'l.* 331-43 (2009).

B. Patient Informed Consent for ESA Treatment

As a threshold matter, it is impossible to assess this measure without specific details. The Measure Information Form reports the numerator and denominator details are to be determined. In addition, informed consent is a very specific term-of-art and the risk-benefit discussion should occur between the physician and the patient. The Food and Drug Administration already has in place a REMS that requires the physician and patient to discuss the use of ESAs. An informed consent process would not be consistent with the current process and could lead to significant confusion among patients. This measure is not appropriate as a facility-level measure. Finally, it is KCP's understanding that this measure was not discussed or proposed at the in-person TEP meeting. We object that this measure has even been advanced for comment if such is the case.

C. Standardized Transfusion Ratio (STrR)

KCP has several significant concerns and questions about the specifications as currently drafted. First, the documentation makes reference to a comorbidity index, but it is not entirely clear about the details. Is the developer referring to the Charlson Comorbidity Index?

As with the SRR, the STrR does not adjust for hospital- or physician-related factors. The literature notes that both hospital and physician factors impact transfusion rates in other areas; there is no reason to think transfusions related to ESRD patients are any different. The developer should review CMS's data and document why the risk model should not account for these variables—i.e., the burden is on the developer to conduct the analyses and show that accounting for hospital-level and physician-level factors is not important in this area. Such details are particularly important because facilities do not have access to transfusion data; the Measure Justification and Measure Information Forms must therefore provide transparency.

Also, and as with the SRR, we are concerned with the approach and assumptions for the predictive model that posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. The documentation fails to demonstrate it accurately predicts and identifies those who have had transfusions. Additional analytic rigor must be brought to bear for this measure.

D. ESA Management to Avoid Transfusion

KCP has several significant concerns and questions about the specifications as currently drafted. First, the specifications submitted to the NQF's MAP excluded patients receiving dialysis <90 days, but the proposed measure does not. The developer should be transparent about this change and provide data related to incorporating the exclusion vs. not incorporating it so that the implications of the shift can be assessed. Similarly, the same should be done for the exclusion of patients who received more than one type of ESA or dialysis during both the reporting month and the subsequent month, which was in the MAP version of the measure but not the proposed draft specifications.

Second, the evidence basis for defining a "low dose" as <75 units/kg per session of Epoetin alfa or <25 mcg/kg per session of Darbepoetin alfa is unsupported. KCP is not aware of any trials

supporting a specific dose threshold for everyone and so believes the measure lacks an evidence base for the specifications.

Finally, it is KCP's understanding that this measure also was not discussed or proposed at the in-person TEP meeting. As with the informed consent measure, we object that this measure has even been advanced for comment if such is the case.

E. Hemoglobin >12g/dL

KCP has significant concerns and questions about the specifications as currently drafted. First, this measure differs from the measure in current use by changing the reporting period from 12 to 3 months and the required valid claims from 4 months to 1 month. It also requires at least 2 months with a valid, non-missing Hgb. In doing so, KCP notes that greater clarity with respect to the verbiage "3-month reporting period" must be provided.

Our understanding is that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an average value for the full performance year. The developer should clarify whether each 3-month data point counts individually as "Successful"/"Not Successful," if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is in fact a 3-month rolling average.

Second, the developers cite the 2010 paper by Hirth *et al.* as evidence that greater variation exists in facility anemia management as compared to physicians. KCP believes the developer should demonstrate and report results that demonstrate that the new measure will have a meaningful impact as compared to results using the existing specifications. Merely reporting results using the new specifications and positing that they will, hypothetically, result in improved management is insufficient to justify the burden of re-tooling current systems.

F. Hemoglobin <10 g/dL

KCP has significant concerns and questions about the specifications as currently drafted. This measure, like the Hgb >12 g/dL measure, refers to a 3-month reporting period. Our understanding is that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an average value for the full performance year? The developer should clarify whether each 3-month data point counts individually as "Successful"/"Not Successful," if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is in fact a 3-month rolling average.

II. CMS should address community concerns about the process used to develop ESRD measures

In addition, we remain concerned about the process used to develop these measures both as participants and observers of the TEP process. First, concerns remains as to the constitution of the individual TEPs. Many members of KCP continue to express concerns that the day-to-day

operations of dialysis facilities are not being discussed or considered in a meaningful manner during these discussions. Second, the process seemed pre-determined to endorse proposed measures, as opposed to an open process for responding to comments and recommendations of TEP members. Third, the process results did not always correspond with the discussions many of the TEP members understood to have occurred, leading to measures that were inconsistent with the direction the TEP suggested. For example, members on the readmissions TEP did not view the discussion as final, but rather very preliminary. Despite the need for additional discussions and refinement of the measure, the TEP was never reconvened. The process was rushed and did not allow for adequate evaluation, questioning, and refinement of the proposal. It was a suboptimal process that led to a suboptimal result.

KCP maintains its recommendation that CMS revise its TEP process to be more transparent and open to the entire kidney care community. Specifically, we request that CMS:

- Share the agenda and other materials to interested stakeholders broadly through the CMS website prior to the TEP meeting;
- Provide for a more open process by allowing non-TEP members to listen in on the TEP work group calls and provide comments at the end of these calls and in writing via email to the CMS staff member coordinating the particular group that are also shared with TEP members;
- Provide TEP members all measure comments received through this process for discussion on work group calls and permit non-TEP members to participate in such calls;
- Create a transparent framework for how population measures should be created and ensure that participants consider measures at the population level;
- Require TEPs to review data from the dialysis unit level in addition to data from large randomized controlled trials/national aggregated data so that measures that are to be used at the facility level will be developed with such data;
- Instruct TEP members to evaluate measures not solely on their clinical significance, but also on the ability to implement them in the dialysis setting, their impact on morbidity and mortality (including improved quality of life for patients), and their appropriateness for being reported and and/or incorporated into the ESRD Quality Incentive Program (QIP);
- Include patients and their advocates in the process, as well as non-physicians, to ensure that any measures developed represent consensus from the entire community;
- Reinstitute the Data TEP into each TEP process, which will allow for a second level of review and consideration of all relevant aspects of the data requirements for a particular measure; and
- Publicly post all comments it receives along with the response to each in a fashion similar to that deployed by CMS during rulemaking and NQF during its review of measures.

Given the overarching concerns that the community has expressed with regard to the TEP process for the past several years, we also encourage CMS to open the bidding process for selecting the contractor that oversees it going forward.

III. Conclusion

We appreciate the opportunity to comment and strongly believe that a more effective and efficient approach to measure development requires a change in the TEP process that would result in greater transparency and increased flexibility. We also believe a more robust measure development process would have resulted in proposed measures that would not have had the series of unresolved issues or problems identified during our review. Thus, as a first step, we encourage CMS and the measure developer to collaborate with KCP and leverage its experience as a measure developer through the Kidney Care Quality Alliance and engage the community in a more meaningful process for measure development.

In terms of the specific measures, we welcome the opportunity to discuss our concerns and assist in refining these proposed measures. Before they are finalized, we once again urge CMS to solicit stakeholder comments given the magnitude of the issues that need to be resolved.

Thank you for your consideration of our comments and recommendations. Please do not hesitate to contact Kathy Lester at (202) 457-6562 or klester@pattonboggs if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald Kuerbitz", written in a cursive style.

Ronald Kuerbitz

Chairman

Kidney Care Partners

cc: Jean Moody-Williams

Kate Goodrich

Appendix: KCP Members

AbbVie
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Ventures Management, LLC
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care



THE KIDNEY CARE COUNCIL

May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

The Kidney Care Council (KCC) appreciates the opportunity to provide comments on the hospital readmissions and anemia management measures developed through the Centers for Medicare and Medicaid Services (CMS) Clinical Technical Expert Panel (TEP) process for the End Stage Renal Disease (ESRD) program. In addition to offering comments about each specific measure, we also raise the overarching issue as to how CMS plans to implement these or revised versions of these measures in the Medicare program. Finally, we strongly urge you to re-evaluate the current TEP process, which we believe is seriously flawed.

As you know, the KCC is comprised of twelve of the leading dialysis provider companies in the United States. Collectively, the KCC members provide ESRD services to nearly 80 percent of the dialysis patients in the United States. The membership includes large, small, nonprofit and for-profit entities. We strive to advocate a legal, regulatory and economic framework that supports and advances the highest standards in dialysis care delivery. Our member companies work to optimize the lives of beneficiaries through demonstrable improvements in clinical outcomes and patient safety.

I. While addressing relevant domains, the TEP measures are not specified appropriately and require significant modifications before they can be finalized.

We thank CMS for providing additional time to review the TEP readmissions and anemia management measures. We seek to provide very specific comments about each measure that are grounded in the clinical expertise of our chief medical officers and the operational expertise of those managing dialysis facilities on a day-to-day basis. Although it is our practice, as you know, to provide specific recommendations to make the revision process smoother, the lack of clarity in the document open for comment has made that impossible in some instances. Thus, we would welcome the opportunity to talk with the measure development team, including the contractor, to clarify any of the comments provided here or to help identify specific changes that would address our concerns.

A. Standardized Unplanned 30-Day Readmission Ratio for Dialysis Facilities (SRR)

The KCC members have been working to reduce hospital readmissions - that are within the control of dialysis facilities - for several years. We believe that the implementation of the new prospective payment system (PPS) provided more flexibility to providers that have led to reduced readmissions, but we agree that more can and should be done. Thus, while we agree conceptually that a metric in this domain could be helpful, the one developed by the TEP is not that measure for the reasons listed below.

- The SSR, as specified, should include only patients who have had ESRD for 90 days or more in order to make it consistent with the Dialysis Facility Risk-Adjusted Standardized Mortality Ratio and the Standardized Hospitalization Ratio for Admissions measures. There is no rationale provided for the difference.
- The SSR, as specified, differs from the measure that was submitted to the National Quality Forum's (NQF) Measure Application Partnership (MAP). Specifically, when submitted to the MAP it included an exclusion for "index hospitalizations that occur after a patient's 6th readmission in the calendar year." The measure provided for comment has changed this to index hospitalizations that "occur after a patient's 12th readmission in the calendar year." Again, no rationale is provided for this change, which could dramatically affect the performance of low volume facilities. We request that CMS provide the underlying data that led to this change in order to understand its implications.
- The SSR is not limited to those readmissions that are related to ESRD or actionable by a dialysis facility, which is inappropriate. Data from one of our members, which was also shared with Kidney Care Partners, reveal that approximately 45 percent of readmissions are not related to ESRD or actionable by the dialysis facility; moreover, only a subset of the 55 percent attributable ESRD admissions are the same cause-specific readmissions. Attaining benchmarks or improving care cannot be achieved if the measure is not actionable at the facility level.
- The SSR does not exclude patients who have incomplete claims history from the past year, making it inconsistent with the Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio. Again, no rationale is provided to explain the difference. CMS should provide the data on readmission rates for patients who have a full year of claims as compared with those who do not, as well as data on the impact of such an exclusion on the sample size and performance gap.
- The SSR ignores some significant conditions in its risk model, including sickle cell trait, not just sickle cell anemia, as well as angiodysplasia, myelodysplasia, diverticular bleeding, and asthma, as well as adjustment for nursing home and ability to ambulate status, both markers of frailty. We urge these to be added. In terms of the conditions included, "poisoning by nonmedical substances" should

be clarified to explain whether it includes ongoing/chronic alcohol or drug abuse and not just acute events.

- The SSR does not adequately account for hospital-specific patterns and does not adjust at all for physician-level admitting patterns—in particular because the decision to admit/readmit is a physician decision. The latter is critically important to understanding readmissions because the decision to admit/readmit is a physician decision, as the Agency emphasizes once again in the most recent proposed rule for the hospital inpatient prospective payment system. Geographic variability, which is well documented, is another factor that should be taken into account. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for.¹
- The SSR does not account for the fact that patients may be readmitted to a hospital even before they return to or receive care from a dialysis facility. Not all discharges are to the home and a significant number of patients are readmitted before they receive care from a dialysis facility. Data from one of our members shows that among patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 17 percent of patients were readmitted within 3 days post discharge, among whom but only 35 percent of patients had been seen by the dialysis unit prior to readmission. It is not appropriate to penalize a facility when it has not even had the opportunity to engage with the patient after the initial hospitalization. Furthermore, up to 40 percent of readmissions in the first 30 days occurred during the first 8 days after discharge, with the dialysis facility having a limited number of encounters to intervene/affect quality of care. There is no question that dialysis facilities do not have the opportunity to intervene to prevent readmissions during the first 1-3 days after discharge, because it is unlikely that a patient will visit a dialysis facility during that timeframe. During a patient's first visit after a hospitalization, the facility will take blood samples to assess the patient. The facility cannot adjust care in response to these results until the patient's second or third visit.² For these reasons, we recommend that the measure should exclude patients who are readmitted before they have had 3 outpatient dialysis treatments in the facility after discharge.
- The SSR does not account for potential differences between urban and rural facilities. This concern cannot be adjusted for by the hospital as a random effect variable. Distance to a dialysis facility, copayments for transportation, and other factors that distinguish urban and rural settings play a role in the choice of care a patient and his/her physician may make. The Measure Justification Form should

¹ See Robert Wood Johnson Foundation, *The Revolving Door: A Report on U.S. Hospital Readmissions* (Feb. 2013).

² See Kevin E. Chan, J. Michael Lazarus, et. al, "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge," 76 *Kidney Internat'l.* 331-43 (2009).

describe these factors and explain why they should or should not be incorporated. It appears that they were not considered.

- The SSR appears to be based upon an approach and set of assumptions that posits to reveal an actual versus predicted rate. The problem is that the measure is based upon claims data, which can only predict the outcome. It is not based upon actual outcomes, which would be the preferred approach.

In sum, CMS has the data necessary to address these issues, including the ability to understand the types of readmissions that dialysis patients experience, the length of time post-discharge when readmissions occur in relationship to when outpatient dialysis unit care resumes, the sites of service that patients are discharged to, and claims data related to physician admission/readmission for purposes of adjusting the model for this factor. We strongly recommend a more evidence-based approach to this measure.

B. Patient Informed Consent for ESA Treatment

The Patient Informed Consent for ESA Treatment raises three specific concerns. First, it is inconsistent with the Food and Drug Administration (FDA) REMS requirements for ESAs. Second, the measure has not been completely specified and does not appear to be ready for comment – the Measure Information Form reports the numerator and denominator details are to be determined. We also understand that this measure was not discussed or proposed at the in-person TEP meeting. The latter two concerns are clear, but we provide additional reasoning why an informed consent standard is inconsistent with current FDA requirements.

The FDA requires the manufacturer to comply with the REMS process for its ESA products. Under this process a physician, not the dialysis facility, must discuss with his/her patients the risks and benefits of using an ESA, as outlined in the FDA-approved documents produced by the manufacturer. While this conversation may take place in a facility, it must be between the patient and his/her physician. The conversation must occur every time a patient starts an ESA, his/her condition changes, or new REMS is issued. This process differs significantly from the informed consent process. Thus, if a measure related to patient understanding and agreement to use an ESA is appropriate, it should be consistent with the REMS and not introduce an additional informed consent process, which would add an unnecessary level of confusion. In addition, because the REMS focuses on the physician-patient relationship, any measure in this area should be a physician level measure, not a facility level one because it is not actionable by the facility.

C. Standardized Transfusion Ratio (STrR)

As an overarching matter, we are deeply concerned that this measure assumes that dialysis facilities are able to predict and control transfusions, which is simply not the case. Because dialysis facilities cannot predict transfusions, and do not administer transfusions except in a very small number of situations, they cannot control a physician's decision to prescribe a blood transfusion for his/her patient.

The KCC acknowledges, as the Agency's own claims-based data monitoring project shows, that there was a small increase in the number of transfusions after the FDA changed the label for ESA. However, it is equally important to note that the same data shows that the number of transfusions has decreased and leveled off.³ It is important to note that when CMS identified this small increase in transfusions it recognized that dialysis facilities did not have this information since almost all transfusions were taking place outside the dialysis facility. In light of this, CMS contacted the dialysis companies' chief medical officers and described the data the Agency had to ensure that the information was then available. This sequence of events demonstrates that transfusion rates, while appropriate for CMS to monitor as a surveillance metric, is not appropriate as an individual facility-level measure.

Facilities simply do not have the data necessary to predict transfusions. For example, one common predictor of the need for transfusions is acute or chronic GI bleeding. In the dialysis facility, our chief medical officers tell us that it is almost impossible for the dialysis facility to document GI bleeding. This is something that is done by a physician, often in the emergency room or hospital setting. The information about this diagnosis is therefore contained in patient's hospital records, but facilities do not have access to these records because hospitals are not required to share them. Another complicating factor is that the FDA labels for ESA products no longer identify an appropriate lower hemoglobin level, leaving it instead to the discretion of the physician and his/her patient. It is then within the physician's control, after a conversation with his/her patient, to order a blood transfusion based upon the patient's hemoglobin level and presenting symptoms. Facilities do not typically administer blood transfusions; they are provided in other settings.

In addition to the fact that this measure is not actionable from the perspective of a dialysis facility, KCC shares the concerns of the broader kidney care community about the TEP measure as specified.

- The measure does not describe with sufficient specificity what comorbidity index it references; thus, it is not possible to assess the measure fully.
- The measure does not adjust for hospital- or physician-related factors. As described above, as well as in clinical literature, hospitals and physicians play a central role in the decision to order a blood transfusion. There is no rationale as to why these variables are not accounted for in the measure.

In sum, this measure has not been appropriately considered or justified and, even if it had been, serious questions remain as to whether it is appropriate to apply a transfusion measure to facilities instead of to the actual providers who prescribe or administer blood transfusions.

³ We understand that this data will be made available shortly from the Agency, but has been shared by CMS with the kidney care community in a meeting in March 2013.

D. ESA Management to Avoid Transfusion

The KCC has serious clinical concerns about this measure, which is not evidence-based. While we appreciate the eagerness to include a safety measure of this nature, it is not based upon published data as described by our chief medical officers. There is no evidence basis to support defining a “low dose” for Epoetin alfa as <75 units/kg per session or <25 mcg/kg per session for Darbepoetin alfa. We are not aware of any clinical trials supporting these dose thresholds. Measures should be data driven and this one simply is not. In addition, it does not account for the variation that exists among physicians as to when and how to titrate ESAs in these patients. In fact, if this measure were finalized, our clinical experts do not believe it would have any impact on practice patterns among physicians because of a lack of an evidence base and, as a result, would not lead to a reduction in transfusions.

We are also troubled that this measure’s specifications differ from those submitted to the NQF’s MAP, which excluded patients receiving dialysis <90 days; the TEP measure does not include this distinction. Again, the measure developer should provide a clear rationale for this change and the data supporting it. The specification should also clarify and provide supporting data as to the exclusion of patients who received more than one type of ESA or dialysis during both the reporting month and the subsequent month, which was in the MAP version of the measure but not the TEP specifications.

Finally, we understand that this measure also was not discussed or proposed at the in-person TEP meeting. As with the informed consent measure, we object that this measure has even been advanced for comment if such is the case.

E. Hemoglobin >12g/dL

The KCC supports the current hemoglobin >12 g/dL metric. It is not clear and the measure developer offered no explanation as to why the current metric is not sufficient to monitor patients’ upper hemoglobin levels. While there is a citation to a 2010 paper by Hirth *et al.* as evidence that greater variation exists in facility anemia management as compared to physicians, this citation does not demonstrate that the new measure will have a meaningful impact as compared to the current metric. Merely reporting results using the new specifications and positing that they will, hypothetically, result in improved management which is insufficient to justify the burden of re-tooling current systems. Moreover, it is not clear to what extent the study evaluated the contribution of specific individual physicians and physician groups that practice in the same facility. The facility implements physician orders and respects treatment options in the physicians’ practice of medicine.⁴

In addition to this practical concern, the specification lacks clarity. First, it is not clear what is meant by the “3-month reporting period” and a definition should be provided. Second, we understand that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an

⁴ See generally, Social Security Act § 1801.

average value for the full performance year. The developer should clarify whether each 3-month data point counts individually as “Successful”/“Not Successful,” if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is, in fact, a 3-month rolling average. In summary, the measure as proposed would create a considerable increase in complexity (and attendant costs) with little discernable added value.

F. Hemoglobin <10 g/dL

The KCC supports monitoring patients’ lower hemoglobin levels (which can be done as often as monthly from claims data); yet, we remain opposed to selecting a specific lower hemoglobin level as a metric in light of the FDA’s current labels for ESA (and the statutory requirement that QIP measures with regard to anemia must be consistent with the FDA label) and the lack of new clinical data that would support such a change. While the measure developers cite clinical performance standards, the justification fails to note that these standards taken together present a range rather than a single value. Thus, we see no clinical evidence that would support a change in the existing position that the appropriate lower level for a patient’s hemoglobin should be determined on an individual basis by the patient and his/her physician, as stated in the FDA label.

We also note that the emphasis of the Agency has been rightly placed on the upper level of patients’ hemoglobin. This focus is consistent with the FDA’s actions under the REMS and black box warnings. As a result, physicians seek to manage upper hemoglobin levels to 11 g/dL. If the lower level were set by CMS at 10 g/dL, it would create a very tight window of only 1 g/dL in which the entire ESRD population would need to be managed. It is possible to achieve that 1 g/dL goal for only about 40 percent of the population at a given time because of the inherent variability in managing patients on an ESA.⁵ By creating a floor, CMS would be setting an impossible task and creating inappropriate clinical expectations for patients that could put them at greater risk. In fact, by setting such a lower hemoglobin limit, physicians would have to respond by moving the population hemoglobin curve to the right (higher hemoglobins), likely increasing the number of patients with hemoglobin above the limit FDA states is safe.

Thus, instead of this measure, we urge CMS to report the lower hemoglobin levels of patients, which dialysis facilities already provide on each monthly claim. This approach would be in concert with the current FDA language and would allow for appropriate monitoring. If FDA were to modify its current approach as to the lower hemoglobin level, then a more specific metric may be appropriate.

Again, we appreciate that other organizations within the kidney care community, including some patient advocacy groups, have called for a lower hemoglobin level metric in the ESRD QIP program. We agree that monitoring hemoglobin levels is important, but it

⁵ Eduardo Lacson, Jr., Norma Ofsthun, & J. Michael Lazarus, “Effect of Variability in Anemia Management on Hemoglobin Outcomes in ESRD,” 41 *Am. J. of Kidney Disease* 111-24 (2003); see also David T. Gilbertson, Yi Peng, et. al., “Hemoglobin Level Variability: Anemia Management among Variability Groups,” 30 *Am. J. Nephrology* 491-98 (2009); Steven Fishbane & Jeffrey S. Berns, “Hemoglobin Cycling in Hemodialysis Patients Treated with Recombinant Human Erythropoietin,” 68 *Kidney Internat’l* 1337-43 (2005).

simply does not make sense to penalize a provider when the clinical evidence has led the FDA to a different conclusion. We share the goal of ensuring that patients' anemia is appropriately managed. Public reporting of lower hemoglobin levels in ranges (such as 9-10, 8-9, etc.) would provide timely information about how anemia is being managed in the ESRD population without putting CMS in the position of making a clinical decision that is inconsistent with the FDA's evaluation and decision. While payment may drive behavior in some instances, policies that undertake this approach should be based upon clinical consensus, which in turn should be based on best current available evidence.

If CMS were to consider a lower hemoglobin measure, or to report a range of lower hemoglobin measures, it would be necessary to establish clear performance benchmarks that are based upon the most current data available that reflect practice patterns under the current FDA labels.

Finally, we also share the broader community's concerns about the specifications of this metric, which focus on the definition of the 3-month reporting period. As with the hemoglobin > 12 g/dL measure, our understanding is that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an average value for the full performance year. The developer should clarify whether each 3-month data point counts individually as "Successful"/"Not Successful," if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is in fact a 3-month rolling average.

II. Because the TEP measures have not been adequately specified or supported, CMS should clearly indicate that it does not plan to use them in the ESRD Quality Incentive Program (QIP).

While we understand that the TEP process technically does not focus on how the measures developed will be implemented by CMS, it would be naïve to assume that CMS is not considering adopting a readmission or additional anemia management measure for the ESRD QIP given the current regulatory environment. As noted, some of the TEP measures in these domains fall short of being specified in a manner that permits full comment, while others are problematic because they do not account for the clinical and operational aspects of current dialysis care. Thus, the KCC strongly urges CMS not to adopt any of these measures for the QIP during the upcoming rulemaking cycle.

Our intent is not to say that no measures should be added to the QIP in the future; however, these TEP measures are simply not ready to be considered for the reasons noted in Section I of this letter. As we have discussed, the KCC is working with other members of the kidney care community through Kidney Care Partners to develop a quality blueprint that takes into account not only the National Quality Strategy as outlined by the Agency, but also the needs of beneficiaries, providers, nephrologists, nurses, and others in the community. The blueprint will outline a strategic approach to measure development, including identifying high priority domains for which measures should be developed. It will also distinguish between those measures that are appropriate for monitoring and those that are appropriate to link to payment. The group met in March and has made solid progress. We plan to share

this report with you as soon as it is ready with the sincere hope that CMS will work with the community to support a process that will be transparent, inclusive, and meaningful for measure development on a going forward basis.

As providers, we take quality very seriously. Before the QIP, our members had instituted their own real-time quality programs that allowed those caring for patients, as well as the patients themselves, to see how the facilities were performing on a core set of metrics. Our members also participated in the public reporting of the ESRD Clinical Measures Project (CPM) before any other Medicare provider was required to report measures publicly. Because of this experience, we understand how important it is to make sure that measures are meaningful, transparent, and clearly specified. If they are not, and the measures open for comment are not, they cannot be used by physicians, dialysis facilities or patients to empower them to make decisions about their care. Thus, we urge CMS not to push measures through a flawed process, which will undermine the credibility of the effort and, more importantly, not achieve better patient outcomes.

III. The problems identified with the readmissions and anemia management TEP measures highlight a systemic problem with the TEP process that the KCC urges CMS to address immediately.

The concerns and questions raised in Section I highlight an ongoing concern that KCC and the chief medical officers of our member companies have spoken with you about previously. We believe that the TEP process used to develop the measures open for comment is seriously flawed and must be revised. This sentiment is shared by those observing the TEP process, as well as by those participating in it.

The TEP members with whom we have spoken expressed frustration and disappointment in the development process and the final document that is open for comment. We share these concerns. First, we have been told that TEP members are instructed not to consider the operational issues or whether or not measures are appropriate for data collection, monitoring, or payment as they are evaluating proposed measures. These are critically important issues that go to the heart of measure development. If TEP members are instructed not to consider how measures could ultimately be used, the measures developed may not be appropriate for use in the Medicare program. Such considerations should not be left entirely to an external contractor group.

Second, many TEP members have suggested that the process seemed pre-determined and that comments and recommendations of TEP members are often ignored in the final product. If so, this is unacceptable. The anemia management measures open for comments seem to support this if our understanding that at least two of the measures were not discussed in the in-person TEP sessions is correct.

Third, we have also been told that the final measures described as being recommended by the TEP did not always correspond with the discussions many of the TEP members understood to have occurred, leading to measures that were inconsistent with the direction the TEP suggested. For example, members on the readmissions TEP did not view the discussion as final, but rather very preliminary. Despite the need for additional discussions and refinement of the measure, the TEP was never reconvened. The process

was rushed and did not allow for adequate evaluation, questioning, and refinement of the proposal. It was a suboptimal process that led to a suboptimal result.

Fourth, we are deeply concerned that none of the measures presented appear to be finalized. As noted above, one lacks a numerator and denominator. Others are not harmonized with related measures and no explanation for the distinction is shared. Still other measures are not supported by data. The document appears more as a working draft than a set of final recommendations.

The KCC strongly supports a consensus-based process that relies upon clinical and operational experts, as well as the expertise of patient advocates, physicians, and other health care professionals. As noted above, we recommend that CMS work with the broader kidney care community to identify the priority domains for which measures should be developed. If CMS plans to continue relying upon the TEP process, we recommend restructuring it to make it more transparent and responsive to the community and the experts upon which it relies.

Specifically, we request that CMS:

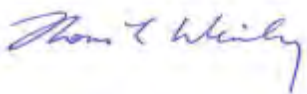
- Open the bidding process for selecting the contractor that oversees measure development for the ESRD program.
- Provide an in-person and remote way for the interested stakeholders to observe and participate in the TEP process (the in-person meetings and any follow-up phone calls) and post the agenda and other materials to interested stakeholders broadly through the CMS website prior to the TEP meeting. For example, while we understood that the TEPs held in April were eventually open to the public via a phone line, we were initially told there would not be a way for the public to observe except in person. We saw no notice of the phone-in option that we understand was ultimately made available. Notice of such options should be broadly disseminated.
- Allow for the submission of and require the measure developer to consider and respond to public comments throughout the TEP process. This would include sharing in a timely manner all comments received with TEP members for discussion. CMS should also post all comments it receives, along with the response to each, in a fashion similar to that deployed by CMS during rulemaking and NQF during its review of measures.
- Create a transparent framework for evaluating measures. Among other things, this would include:
 - How population measures should be created and ensure that participants consider measures at the population level;
 - The quality and level of data used to support each measure (requiring review data from the dialysis unit level in addition to data from large randomized controlled trials/national aggregated data so that measures that are to be used at the facility level will be developed with such data); and

- Evaluate measures using clinical and practical/operational standards (*i.e.*, do dialysis facilities have access to the data required to report or act upon the measures), their impact on morbidity and mortality (including improved quality of life for patients), and their appropriateness for being reported and/or incorporated into the ESRD QIP.
- Include patients and their advocates in the process, as well as non-physicians, to ensure that any measures developed represent consensus from the entire community; and
- Reinstitute the Data TEP into each TEP process, which will allow for a second level of review and consideration of all relevant aspects of the data requirements for a particular measure.

Both the Agency and the KCC share a strong interest in making sure that appropriate quality measures are developed. The process as currently structured will not achieve this goal. We would welcome an open dialogue with you to assist with implementing the recommendations described in this letter.

IV. Conclusion

We appreciate your review of our concerns and look forward to working with you and your team to address these issues. Please do not hesitate to contact Kathy Lester, at 202-457-6562 or klester@pattonboggs.com if you have further questions or would like to discuss our concerns in more detail.

A handwritten signature in blue ink, reading "Thomas L. Weinberg".

Thomas L. Weinberg

Chairman

Kidney Care Council

Proposed ESRD Quality Metrics: 30 Day Hospital Readmission and Anemia Management Measures for the ESRD Population 2013

Commentary: Northeast Kidney Foundation
501 New Karner Road, Albany NY 12205
northeastkidney@gmail.com 518-458-9697
Carol LaFleur, Executive Director

The Northeast Kidney Foundation is a voluntary health organization dedicated to preventing kidney disease and enhancing the lives of all of those affected. Established in 1974, the Foundation provides services to patients, family members, the general public and clinical and academic professionals throughout the Northeast. The mission of Northeast Kidney is to improve the quality of life of those affected by kidney disease and related conditions through early identification, intervention, prevention and support services, to promote organ donation, and to empower those we serve to be an effective voice for better healthcare at the local, state and federal levels.

In our role as advocates for the patients and families we serve, and on behalf of the many renal dialysis professionals we work with, we appreciate the opportunity to provide commentary to the Arbor Research Collaborative for Health, as the contract entity for CMS, on proposed quality metrics as they relate to promoting the delivery of high quality dialysis care, and hopefully in turn, improved outcomes for Medicare beneficiaries on treatment, for better life and longevity.

In observing the process of introducing payment metrics in the hopes of driving quality improvement in the ESRD program in recent years, a few things have become clear. First, mindful of the Triple Aim as initially introduced to CMS by Dr. Don Berwick, and learning lessons from the DOPPS data of other countries, better health for individuals and populations can in fact be arrived at with cost effective care. Secondly, thoughtful and careful implementation of those metrics is critical so as not to overcorrect a problem or create unintended consequences. Thirdly, there will be, in practice, changes to accommodate the new reality of care with quality measures impacting payment that can never have been foreseen by those developing the metrics. And finally, the overarching issue is – how many and which metrics genuinely best drive good quality care? Because a payment withhold for those providers that fall short can be rendered ineffective if there are either too many metrics or poorly chosen ones where there is no real performance gap, that achieving them dilutes the impact of any critical to good patient care and health.

Case in point is the anemia management issue. Since 2007, with the FDA black box warning, patient hemoglobins have been held hostage by a skittish renal community who have seen the medication developed to improve this condition first fall under strict risk management guidance and then move from a lucrative profit center to a cost center in dialysis care. So – having very little to do with what is good for patients – changes in practice have been driven, sadly, by the bottom line in the provider industry. That is not ever the intention of a prospective payment system with metrics designed for quality improvement.

Anemia management of chronic kidney disease: Hgb >12

Examining the proposed anemia management measures, beginning with the hemoglobin metrics as they reflect appropriate and high quality care. With the institution of bundled payments, reimbursement became the regulator for higher hemoglobins; DOPPS has shown that by December of 2012, the percentage of patients nationally with hemoglobins > 12g/dL had decreased to 14.4 % from a high of 31.9%. So it would seem that while tracking patient hemoglobins exceeding 12g/dL for those receiving ESAs, payment is working effectively to minimize those exposed to the risks concomitant with higher hemoglobins. It becomes redundant as a quality improvement metric.

Anemia management of chronic kidney disease: Hgb <10

However, there currently is no lower hemoglobin limit at all, and this seems to be a significant omission in terms of patient safety. While we acknowledge there is risk for those with too high a hemoglobin driven by ESA administration, there is also risk at too low a level. Furthermore, there has been countless testimony from real patients that the lower end of hemoglobin is where they have significant symptoms of anemia, and live a much lower quality of life and health, with tremendous fatigue, shortness of breath and inability to partake of meaningful activity. Anecdotal evidence shows that the farther below 10g/dL a patient sinks, the more the symptoms worsen, and that patients are sensitive to relative drops in their hemoglobin levels. So the less a patient is able to maintain a consistent hemoglobin level, the worse a patient feels, experiencing a roller coaster of highs and lows as ESAs are stopped and started again in response. This is not good quality care for patients. And with the discontinuation of a lower limit, this has been borne out in the data as more patients are existing at lower Hgb levels than previously. After bundling, by December of 2012, the percentage of patients with Hgb <10 g/dL had increased to approximately 16-17%. Similarly, those patients with Hgb<9g/dL had increased to 4.9%. Payment too has been an effective regulator here, but not in the best interest of patients. Please consider what this has meant to the lives of countless patients who are less able to have any quality of health, and who are at ongoing risk for the aggravation of cardiac problems that can result from too low a hemoglobin.

Anemia management of chronic kidney disease: Dialysis facility ESA management to avoid transfusion

Anemia management of chronic kidney disease: Dialysis facility standardized transfusion ratio

Two transfusion measures were also proposed, largely developed in response to the FDA directive that dosing of ESAs was meant to “avoid transfusions.” Given the data that shows with the decreasing use of ESAs in response to bundled care cost constraints and regulation directives, transfusions have in fact increased by more than 20% in dialysis patients, policing this relationship is undeniably important. Transfusions cause significant harm to patients who are evaluated and waiting for a transplant with the resultant sensitization and increase in reactive antibodies, diminishing their potential donor pool to almost nothing. The problem is that, as mentioned before, too many anemia measures dilutes the effectiveness of the withhold as a tool to drive better care. The truth is that with the presence of a lower safety hemoglobin limit, hemoglobins would theoretically have to be more consistently maintained in a higher, healthier, more reasonable range, which would prevent the levels drifting downward into much lower levels and therefore the necessity of “rescue” transfusions in all except emergency cases. The data collection however showing which facilities are using transfusions as a standard fall back for anemia management should certainly be tracked and reported.

Anemia management of chronic kidney disease: Patient informed consent for ESA treatment

While certainly a patient undergoing ESA therapy should be provided information regarding risks, potential benefits and alternative treatment options in order to obtain truly informed consent, the case could be argued that this is also true for all the treatments being received by those on dialysis. Further, it is specified in the conditions of coverage that this be the case. The support for the metric is the fact that many patients routinely are not given full information prior to their making a decision about ESAs, or for that matter, any other treatment in dialysis care. But while we support full patient education for informed decision making and consent, we would not make this exclusive to the treatment of anemia, but would perhaps consider a metric that looks more globally at a metric for informed consent.

Recommendation: Endorse Anemia management of chronic kidney disease: Hgb <10

Standardized 30 day readmission ratio for dialysis facilities

We support the metric to measure readmissions because it most definitely would help to foster cost effective health care, as well as invest care teams in coordinating care from the acute to chronic settings. Further, and most importantly, monitoring and preventing the causes of readmissions allows patients to enjoy a higher quality of health and life more consistently.

Recommendation: Endorse Standardized 30 day readmission ratio for dialysis facilities

Overall, the metrics are most valuable that sustain a patient's level of health more consistently; preventing detrimental changes to their health status and affording them a greater quality of life. And that is good medicine and good health care and the very point of any efforts to measure quality and drive ongoing improvement. We work every day directly with patients and their families, and hear the things that make living their lives significantly better, and those that are harmful, or to no benefit. We sincerely hope those proposed measures move forward that have the most potential to genuinely improve patients' health and allow them to live full lives.

Again, we appreciate the opportunity to offer these comments and we would be happy to provide further information or answer any questions.

I am commenting on behalf of Berkshire Medical Center Renal Dialysis Unit and South Berkshire County Dialysis Center, as well as Southwestern Vermont Medical Center Renal Services. I have some comments on each measure which we all feel are worth noting:

1. Anemia of chronic kidney disease: Patient informed consent for ESA treatment. We feel the FDA warnings on this are quite clear, and if units are giving out or offering patients Medication Guides each time ESA is administered and documenting that this was done in the patient's clinical chart (whether the patient accepts the Medication Guide or declines it) this should be sufficient, rather than obtaining true informed consent. Informed consent requires a Provider (Physician usually) sitting down with the patient to review risks and benefits, and this is neither practical nor necessary to do every time a patient receives an ESA dose. Since this is a Medication and not a procedure, we don't feel written and signed informed consent is necessary as long as the patient has been provided the information in the form of the Medication Guide and the patients are aware that they can ask questions or voice any concerns about Medication to Providers when available or to the RNs.

2. Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion. Many units do not give transfusions (it's against their policy) and have no way of tracking transfusions. Many of the patients who require transfusions will end up in the Hospital Based Units who do give transfusions. Therefore, the rates of transfusions may be higher in these units, and it would not be fair to penalize them. Also, some units (especially smaller units) may have a greater percentage of ESA resistant, transfusion dependent patients, and according to FDA warnings, they should not be given higher and higher doses of ESAs to avoid transfusions as this could lead to higher rates of Strokes or Cardiovascular Events. Therefore, we do not believe it is in the best interest of the patients for CMS to be incentivizing giving higher doses of ESAs to avoid transfusions in these patients.

3. Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio- Again, some units do not give transfusions as per their policies (and with this QIP measure in place, likely more units will opt not to give transfusions to patients which is not good for patient care). These units will have an unfairly lower transfusion rate than the Hospital Based Units who are forced to give transfusions to patients who need them since the satellite units may not. The Hospital Units should not be penalized for this, or the patients will end up having to go to hospitals to get transfusions which will increase the cost of care from Medicare, and is not the best care for the patients. Also, some units who do not transfuse patients, may not have access to transfusion data on their patients from the hospitals, so this may not

be possible to track and get accurate data on.

4. We agree with the Hemoglobin >12 and <10 measures

5. Standardized 30-day readmission ratio for dialysis facilities-

this measure is already in place for hospitals, and often when a patient is readmitted soon after discharge it may reflect that the patient was discharged by hospital prematurely in effort to reduce the hospitals length of stay. When this occurs, the dialysis unit has no control over the premature discharge and should not be penalized. If this measure is implemented, it should be normalized for the patient's length of stay based on the DRG and if patient was discharged earlier than the average LOS and then readmitted, the dialysis unit should not be held accountable. Furthermore, the Hospitals are already getting penalized for readmissions rates.

6. We also feel very strongly that some units may be over utilizing IV iron to avoid ESA use and save cost. It isn't uncommon for units to let their patient's ferritin levels run very high since one very short term study demonstrated this was safe and effective, but the long term detrimental effects to patients are unknown, and likely very real. We have seen patients with porphoreia from too much iron, liver disease from hemachromatosis, evidence of iron overload on bone marrow biopsies. We feel strongly that there should be a measure of average ferritin levels in units, or % of ferritin levels >800, which should be very low according to KDOQI and other expert panels.

Please let me know if any questions.

David E. Henner, DO
Division Chief of Nephrology
Medical Director of Dialysis Units:
Berkshire Medical Center
South Berkshire County Dialysis Center
Southwestern Vermont Medical Center
Office Phone: (413) 447-2764

April 17, 2013

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Re: Call for Public Comment
Draft Anemia and Readmission Measures for ESRD Facilities

To Whom It May Concern:

Sanford Health, a large health system located in South Dakota, North Dakota, Minnesota, Iowa, and Nebraska, with multiple end-stage renal disease (ESRD) facilities, appreciates the opportunity to comment on the draft quality measures for anemia management and readmissions. During our review of the proposed measures, we noted several areas of concern as outlined below.

1. Anemia Management

In general, Sanford supports the anemia measures as we understand the need to monitor appropriate use of ESA treatments and transfusions. However, as with any quality metric, adding additional requirements restricts the ability of physicians to practice according to changing industry guidance. The process to update and modify CMS measures includes an inherent lag time that does not allow physicians to implement the most current guidelines in a timely manner. Given this reservation, we are specifically providing comments on the proposed upper and lower limits for hemoglobin provided in the draft measures.

Upper Limit: Sanford supports an upper limit of 12 g/dL. Although an upper limit of 12 g/dL is more restrictive, we believe this limit is realistic and is in the best interests of the patient. Levels higher than 12 g/dL, as noted in the draft measures, increase the risk of clotting in dialysis patients.

Lower Limit: We support the lower limit of 9 g/dL. The lower limit of 9 g/dL is commonly used in our ESRD facilities and represents the most clinically appropriate care. In addition, this is the lower limit utilized in clinical practice guidelines such as KDIGO and KDOQI. We support the proposed three month average in the calculation of the measure. Using an average allows the ESRD to correct outlier levels without being penalized. Finally, we support the exclusions for hemoglobinopathy, myelodysplasia, myeloma, active malignancy, sickle cell, and patients over age 70.

2. Standardized 30-Day Readmission Ratio

Sanford does not support the standardized 30-day readmission ratio as outlined in the draft measure. While ESRD facilities work closely with patients, significant collaboration within the hospital setting is in its infancy. CMS announced the Comprehensive ESRD Care Initiative in February 2013. This initiative is intended to encourage ESRD facilities to improve partnerships with other settings of care and re-define processes to manage care for dialysis patients more effectively. Because of the coordination gaps between care settings, we do not support an all-cause readmission ratio at this time. An all-cause readmission ratio would be more appropriate after programs such as the Comprehensive ESRD Care

Initiative are implemented and ESRD facilities are able to explore and implement processes to coordinate care.

We object to the inclusion of all-cause, unplanned readmissions as the readmission, or the original admission, may not be related to dialysis services and may not be controllable by the ESRD facility. For example, an ESRD patient who is admitted to the hospital with a hip fracture and is subsequently readmitted due to an infection acquired at the hospital. In this situation, ESRD staff may provide dialysis services in the hospital setting and after discharge, but would not be able to control or prevent the readmission. We believe there are several diagnosis that should be excluded from a readmission measure for ESRD facilities. These may include, but are not limited to, cancer patients, accidents and trauma, orthopedic procedures, and substance abuse.

At this time, we would support a readmission measure which includes admissions and readmissions specifically related to ESRD services. This may include admissions related to chronic heart failure, access site infections, potassium levels, hypertension, calcium levels, etc. We feel strongly that the underlying cause or diagnosis should determine whether a readmission is attributable to an ESRD facility.

Even with a narrower definition of the readmission ratio, we would encourage CMS to reconsider the maximum treatments that can be provided to a patient each month. Currently, CMS will only reimburse an ESRD facility for 13 treatments/month with specific medical justification. On several occasions, we have performed extra treatments (beyond 13) and provided medical justification that is not satisfactory to the fiscal intermediary, thus payment was denied. A patient who is at risk for volume overload and hyperkalemia due to medical reasons may require more treatments than is currently allowable in order to appropriately manage the patient's care. Limiting the number of treatment may inhibit the ESRD facility's ability to provide quality care and prevent unnecessary admissions.

We look forward to CMS's responses to the issues noted above.

Sincerely,



Maria Regnier, RN, MSN, CNN
Dialysis Director
Sanford Health

Representing Sanford Dialysis Centers/Medical Directors:
USD Medical Center Hemodialysis –Dr C Lankhorst
USD Medical Center Peritoneal & Acute Dialysis-Dr Brandys
Chamberlain Dialysis –Dr Rupp
Madison Dialysis- Dr Lankhorst
Wagner Dialysis –Dr Rupp
Hospers Dialysis –Dr Brandys
Canby Dialysis –Dr Qamar
Worthington Dialysis-Dr Qamar
Detroit Lakes Dialysis and Home Program-Dr. Chemiti
Bemidji Dialysis and Home Program-Dr. Louvar
Red Lake Dialysis-Dr. Louvar
Thief River Dialysis-Dr. Levitski
Fargo Dialysis and Home Program-Dr. Levitski/Dr. Mahale

Morris Dialysis-Dr. Phadke
Jamestown Dialysis- Dr. Mahale
Bismarck Dialysis- Dr. Lebeau
Fort Yates Dialysis- Dr. Lebeau



DIALYSIS CLINIC, INC.

A Non-Profit Corporation

H. Keith Johnson, M.D., Chairman of the Board
Douglas S. Johnson, M.D., Vice Chairman of the Board
Ed Attrill, President
William E. Wood, Secretary and Treasurer

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May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

Thank you for the opportunity for Dialysis Clinic, Inc. (DCI) to comment on the proposed hospital readmission and anemia management measures for the End-Stage Renal Disease (ESRD) population. We appreciate the extension of the comment deadline. DCI is a nonprofit dialysis provider treating approximately 14,000 patients in the 215 dialysis facilities that it owns and operates in 27 states.

Hemoglobin (Hb) <10 g/dL

Hemoglobin (Hb) less than 10 g/dl is an appropriate clinical measure for low Hb and, of the several anemia floor measures proposed, is the most suitable in its current form for clinical application. We believe that the Hb < 10 g/dl measure is essential to optimizing the quality of life of dialysis patients.

The goal of the QIP is to improve care under the bundle. We are concerned that without the lower limit Hb measure, the bundle will have resulted in reduced quality of life for dialysis patients. Our data show that, among DCI patients, mortality and hospitalization increase as Hb drops below 10 g/dl [Servilla KS, et al, Am J Kidney Dis 2009 ; 54:498-510]. Other analyses support our findings. Lacson et al evaluated clinical data from a large dialysis provider, including laboratory records from October 1 to December 31, 2003, for 78,420 patients who survived until January 1, 2004 and reported that "[h]emoglobin < 11 (22% of patients) added 20 to 50% to the risk of death and 18% to 38% to the hospitalization risk." [Lacson E et al, Am J Kidney Dis 2009; 53: 79-90].

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We understand that analyses of observational, non-randomized data sets may be confounded and that statistical correction does not guarantee that the effects of such confounding have been eliminated. However, in this context, it is our opinion that conclusions based on DCI observational data are as strong as conclusions based on achieved hemoglobin values in the Normal Hematocrit (NHCT), CHOIR and TREAT Studies that resulted in the elimination of a hemoglobin floor metric. Analyses of achieved (rather than targeted) results of randomized trials do not have the strength of conclusions from the randomized comparison. Thus, in our opinion, the only conclusion that can be drawn with respect to hemoglobin in NHCT, CHOIR and TREAT that is stronger than the conclusions from the observational DCI data is that *targeting* hemoglobin of 13 g/dl or greater in these populations with substantial comorbidity is associated with worse outcomes than targeting a lower value. Inferences based on randomized trial achieved hemoglobin values are no stronger than inferences based on observational cohort data. Thus, the observation that, in TREAT, *targeted* hemoglobin values between 12 and 13 g/dl were associated with increased stroke should not carry greater weight than observational DCI data, which show that *achieved* hemoglobin values between 12 and 13 g/dl are associated with better survival than are lower achieved hemoglobin values. The fact that several randomized trials show danger at higher hemoglobin values does not mean that any higher hemoglobin is more dangerous than any lower hemoglobin.

We do not make the recommendation to restore the Hb < 10 g/dl measure lightly; in fact our financial penalty will probably increase if the Hb < 10 measure is reinstated because of the difficulty of maintaining patients in such a narrow range of 10 to 12. However, we are willing to accept this financial penalty because we see it as an investment in the quality of life of DCI patients specifically and of all dialysis patients in general. As you know, there is a strong financial incentive to decrease the use of EPO because it is the most expensive medication provided under the bundle. In our opinion, it is essential to have a financial penalty for low Hb to help offset the financial incentive to decrease EPO use.

The proposed measures regarding dialysis facility ESA management to avoid transfusion and dialysis facility standardized transfusion ratio will be superfluous if the if Hb < 10 g/dl is adopted.

Standardized Unplanned 30-Day Readmission Ratio for Dialysis Facilities (SRR)

We share the goal of optimizing the use of inpatient care in ESRD: hospitalizing appropriately, but not too frequently, discharging hospitalized patients only when they are stable, and coordinating inpatient and outpatient care to avert avoidable readmissions. Dialysis patients who have been discharged from hospital are readmitted from a variety of settings: some are sent from the dialysis facility to the hospital emergency department or admitting office. Others are sent to the hospital from rehabilitation facilities and nursing homes. Those who have been discharged home may present to the emergency department on their own initiative, or on referral from a physician office or from a physician covering at night or on the weekend. We are not aware that patterns of dialysis patient readmission have been described in adequate detail to define the relative importance of these sources of readmission. Dialysis facility staff, through their treatment of the patient and their interaction with the nephrologist, can presumably most

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directly influence the probability of readmission directly from the dialysis facility; it is more difficult for a dialysis facility to influence a readmission according to other processes.

We note that it is possible for a patient to be readmitted to the hospital before the patient receives his or her first treatment in the dialysis clinic after discharge from the hospital. Since it would be very difficult for a dialysis provider to impact these readmissions, it is our recommendation that dialysis providers not be penalized for these readmissions.

We have commented on previous occasions that facilities with a small number of reportable cases should not be included in the QIP; we are concerned that the threshold selected by CMS is too low to mitigate statistical variance. We are concerned that many facilities are too small to absorb the risk of the rare individual with many readmissions. Counting a single patient up to 12 times in the denominator gives an individual patient too much weight. We therefore recommend that a provider only be penalized for up to six readmissions per year per patient.

We think there should be more specifics on how patients post-transplant who remain on dialysis due to delayed kidney transplant function are attributed to a dialysis facility's re-admission rate. In order to avoid disincentives for transplant, we suggest creating a window post-transplant during which readmissions are not counted against the facility. We point out that readmissions in this setting are often prompted by urinary tract infections, pneumonia, viral infection, other complications of immunosuppression, and by the sequellae of surgical complications. In our opinion, these admissions are primarily due to the recent transplant for these patients and not the current dialysis treatment for these patients.

Finally, to avoid other unintended consequences when evaluating dialysis facilities, admissions to PPS-Exempt Cancer Hospitals should not be exempted from the dialysis facility metric unless the exclusion is related to the specific admission cause and can be applied to any hospital admission. If this is not addressed, it could lead to more referrals to an exempt cancer hospital rather than to a not exempt hospital for non-excluded admission types (as, under the current proposal, not all admissions in a cancer patient are for reasons that would be excluded from this metric).

Thank you for your consideration of our comments and recommendations. Feel free to contact Doug Johnson at doug.johnson@dcinc.org or 615-342-0435 if you have any questions about this letter.

Sincerely,

A handwritten signature in black ink, appearing to be 'DJ', written over a horizontal line.

Doug Johnson, MD
Vice Chairman



National Renal Administrators Association

April 29, 2013

Marilyn Tavenner
Acting Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: End-Stage Renal Disease (ESRD) Quality Measure Development and Maintenance Clinical Technical Expert Panel Draft Summary Report on the Development of a 30-Day Hospital Readmission Measure and Anemia Management Measures

Dear Ms. Tavenner:

The National Renal Administrators Association (NRAA) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) comments on the Technical Expert Panel (TEP) Draft Summary Report on the development of a 30-day hospital readmission measure and anemia management measures for the ESRD population.

NRAA is a voluntary organization representing independent, regional and community based dialysis providers throughout the United States. Our membership is primarily small and medium sized dialysis organizations, both for-profit and non-profit providers serving patients in urban, rural and suburban areas in both free-standing and hospital-based facilities.

NRAA fully supports CMS efforts to develop measures to help ensure quality patient care and outcomes. We also appreciate having the opportunity to offer our perspectives on these measures before they are proposed in the rulemaking process. However, NRAA does have some concerns with some of the issues raised by the TEP as outlined below.

30-Day Hospital Readmission Measure

NRAA has expressed concerns about proposed hospital readmission measures in previous comment letters because there are many factors outside of a dialysis facility's control that can lead to hospitalizations. Moreover, there are many instances when our patients are admitted to the hospital and dialysis facilities are not aware of the hospitalization until after the fact. However, we understand a paradigm shift to shared accountability is upon us. NRAA urges the agency to take into account some of the limitations dialysis clinics, particularly small dialysis organizations (SDOs) and medium dialysis organizations (MDOs), have in terms of accessing all of the patient data that is being contemplated for this measure. One issue that is particularly challenging for SDOs and MDOs is the variability of the acceptance of medical justification for additional treatments, which can be very helpful in helping to prevent hospital readmissions.

There are challenges with the coordination of care in terms of ensuring good communications between physicians and between the hospital and dialysis facility. Dialysis facilities need to receive discharge summaries from the hospital for each of their patients to inform them of discharge diagnosis and required follow up care as well as for medication reconciliation. Availability and interoperability of electronic medical record systems remain a challenge for many dialysis organizations. We encourage CMS to support the necessity for hospitals, physicians and outpatient dialysis clinics to share information in an electronic format to improve care coordination efforts for our patients.

Data Sources

As we mentioned, dialysis clinics have limited ability to capture all of the comorbidities listed in Table 1 of the TEP summary report. NRAA will urge its members to do a better job of completing the CMS Medical Evidence Form (Form 2728) to capture as much patient data as possible, as well as to include all applicable comorbid conditions on Medicare claims. However, there are many of these conditions that will not be made known to the dialysis clinics. The agency should use both hospital data and dialysis facility data in developing and implementing this measure.

Denominator Specifications

NRAA appreciates the decision to exclude discharges against medical advice (AMA). However, we recognize the large number of AMA patients and agree that further study is warranted including a regional analysis.

NRAA also supports excluding pediatric patients. Pediatric patients have unique challenges that necessitate more frequent hospitalizations than the adult population. We also support the other exclusions identified by the TEP.

NRAA supports limiting the number of readmissions one patient can contribute in a year. In addition to outliers, there are many patients that are frequently admitted for reasons that are unrelated to the care provided to the patient in the dialysis facility such as drug seeking behavior related to addiction or brittle diabetics who have difficulty regulating blood sugar levels.

Numerator Specifications

NRAA would prefer the use of a cause-specific (specifically conditions within the influence of dialysis providers, such as fluid management, access infections, etc) versus an all-cause readmission measure. However, if an all-cause readmission is used, we appreciate the exclusion of planned readmissions.

NRAA also supports excluding the deaths that occur within 30 days of a hospital discharge. The deaths may be unrelated to the patient's ESRD and therefore dialysis facilities should not be penalized for those patient deaths.

Risk Adjustment

NRAA supports adopting risk adjustments to account for differences in patient populations served by different facilities. If practical, we would support the use of an adjustment for physicians.

Anemia Management Measures

NRAA is concerned about the TEP's proposal to develop multiple additional anemia management measures. Although the NRAA agrees that ESRD patients should be monitored for anemia, the measures developed by the TEP are too numerous, especially since all the proposed measures are essentially pointed toward the same goal. Additionally, having multiple anemia measures may not account for the individualization of care. There are some patients who can thrive with a hemoglobin level of 9.5 g/DL while others require adjustment in their dosing of Epogen at those levels.

There is also not sufficient evidence based research to support some of these measures. NRAA urges the agency to support more research in this area so we better understand how to evaluate anemia management in a way that leads to the best patient care, patient safety, and outcomes for the patient.

NRAA is also concerned about the efforts to develop quality measures for dialysis facilities around blood transfusions. As the TEP discussed, there are instances where a transfusion is the most appropriate course of care. We are concerned that a blood transfusion measure would not take into account acute episodes unrelated to ESRD or an acute traumatic injury that requires blood transfusions. Also, many patients are followed by a primary care physician in addition to the care provided by a nephrologist. The primary care physician could be prescribing blood transfusions without consulting the nephrologist.

Conclusion

NRAA appreciates all of the careful consideration and many efforts CMS has dedicated to developing quality measures. We look forward to continuing working with the agency on developing these measures.

If you have any questions, please do not hesitate to contact me at (206) 915-9502 or Rich Meade at (202) 530-4841 or rich.meade@prime-policy.com.

Sincerely,

A handwritten signature in black ink that reads "Katrina A. Russell". The signature is written in a cursive style with a large initial 'K'.

Katrina Russell, RN, CNN
President, NRAA

Lana Schmidt
Kidney Patients Support Group
Quincy, IL & Hannibal, MO
1636 n703rd ln
Liberty, IL 62347
217 617 2888

Anemia Management Comments from kidney patients
Patient Comments, Chronic Fatigue and Quality
of Life

Patient #1

Having improper hemoglobin levels is detrimental to my health.
EPO is my lifeline as a kidney dialysis patient.
If my hemoglobin goes below 10, I am really struggling to keep
my nose above water. I get very depressed and begin to consider giving up,
throwing in the towel and going off dialysis. Because my quality of life is so
poor, it just doesn't seem worth it. I live alone, do daily home hemo dialysis
on my own and do not have someone there to help me prepare meals, take care of
things, get groceries, etc...
I have to have a proper hemoglobin level to function and run my
life.

All kidney
patients deal with chronic fatigue on a daily basis.
It is the
major side effect of kidney disease.
We have to
choose to push past the low energy everyday to go on.
It is unconscionable
to not have a bottom level to keep the hemoglobin in check because of the grave
impact it has on a patient's energy level and quality of life.

Patients should have a say in their medical care, treatment and medications. The government should not
be mandating
energy levels and quality of life for a patient based on the financial aspect
of providing hemoglobin medication.

There should be appropriate high and low hemoglobin levels in
place. 10-12 hbg.
Medical providers should have a responsibility and
accountability in making sure that a kidney patient's quality of life is the
best it can be.

The patient's perspective needs to be heard on the importance of
anemia management as it relates to their quality of life and the risk-benefit
tradeoff. Different patients strike that balance at different places.

It is difficult to have a statistical measure for quality of
life for kidney patients, because it varies from one person to the next.
It is objective and the best way to measure is to ask the
patients how they feel and treat the anemia accordingly.

When a kidney patient has an acceptable hemoglobin range, they are able to have a life, work, volunteer, take on family responsibilities, contribute to society, etc...

Evidence has shown that blood transfusions have gone up since the bottom level of the hemoglobin has been taken away.

When my hemoglobin gets low and I am in need of a blood transfusion to bring it up, its like I 'wake up' after being in a slump. Now I personally have so many antibodies, 100%, that I am now a difficult match for a kidney transplant. Very frustrating!

For patients with CKD, not on dialysis, they also should be treated properly for anemia.

Patient #2

When my hemoglobin drops below 10 I am non functional, no energy, cant and dont want to do anything, can barely lift my arm, sleep all the time, begin to think, 'whats the bother' and starting thinking about going off dialysis.

Patient #3

Although kidney patients fight anemia all the time to some extent I was fighting it this last six months or more with very low hemoglobin numbers. I started out at 7.2 and never went over eight point 7 . During all these months the only change that was made was to increase my Procrit shot. This wasn't working. So now were trying to get the numbers up buy iron infusion and blood transfusion. I don't know why we had to wait this long and I have to feel so bad before getting more help. I was very tired, non functional, depressed and had trouble breathing.

Patient #4

There should definitely be a lower limit. I know I really start to feel it when my hgb drops below 10. Also more transfusions make raise your pra & make it more difficult to find a match for a kidney transplant.

Patient #5

Very glad to see the discussion on bundled cost and the danger of setting a range that could drive the Clinic to set a target that is just adequate versus optimal. Dialysis in self is tiring enough without having to be on the edge of anemic as well. Your quality of life drops considerably. I thought the discussion by the panel on this issue as a whole was very good looking at the patient's well being and QOL . I appreciate their work on this important issue.

Patient #6

As a 13 years and counting in-center hemo patient this is a subject that is very near and dear to my heart. (No pun intended).

Page 18, 3.4.4

I strongly agree with the statement that says 'addresses individualization and quality of life allows for deviation of ESA therapy be started above 10.0 g/dl This is very encouraging and I am happy to see that there is a value beyond 'one size fits all'. Most patients do realize that this is being addressed.

Page 22 A.1.3

One of the metrics mentioned is 'cost of anemia management'.

I would like to know what the cutoff dollar amount is with regards to anemia management.

My final thought on the section addressing anemia management is that is a compilation of the minutes from the meeting with a lot of issues set aside for a later conversation. I would also like to see some 'Patient Input' when it comes to issues like 'Quality of life'. In my opinion the board is incomplete without patient representation on this subject.

Patient #7

A.1.3 Quality
of Life

I was very pleased to see the extent to which some of the TEP members understood the Quality of Life and Risk Benefit Tradeoff issue. I strongly support their noting the importance of QOL and patient reported outcomes AND the need for further study.

A.1.3.2 Avoidance of ESA

I really liked the recognition given to the fact that appropriate HGB targets are patient specific and that a measure of success could be keeping each patient near their appropriate target. But I was troubled by the conclusion that it was operationally impractical given the large number of patients that are seen by each physician. Even if only for reporting purposes, I don't like the idea of pigeonholing patients for ease and convenience.

A.1.4 Blood Transfusions

I really liked this topic and how it was addressed. I liked the gradations of inappropriateness. And I was very impressed with their recognition and understanding of offsite transfusions. I thought that was very well thought out and represented.

A.3. Recommended Areas for Further Research

I loved, loved, loved that they placed beginning emphasis on Quality of Life issues and hope that maybe we can be involved in the research.

Bundling often removes a patient's choice in the matter since it has a financial impact on the unit.

IF they are

looking at Patient consent for ESA treatment, then they are going to have to respect that decision and not penalize the units if the patients choose an option that does not fit into the accepted protocol.

LOVE YOUR
KIDNEYS

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Skype:Lana.Schmidt1

Check out our Facebook Page - <http://www.facebook.com/#!/pages/Kidney-Patient-Support-Group/110826278977234>

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May 2, 2013

Patrick Conway, M.D.
Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway,

The American Kidney Fund (AKF) appreciates the opportunity to comment on the draft TEP recommended measures for hospital readmission and anemia management for the ESRD population. We are committed to ensuring that kidney patients have access to safe and appropriate care. Given changes in recent years, we are especially concerned that a balanced and relevant approach to measurement of anemia management be developed and our comments support that goal.

The American Kidney Fund is the nation's leading charitable organization providing treatment-related assistance to kidney patients. Last year, AKF provided financial assistance to nearly 84,000 patients on dialysis to help pay for health insurance and dialysis treatment related expenses. Our mission is centered on works to ensure that kidney patients have access to quality health care.

The American Kidney Fund is also a member of Kidney Care Partners (KCP), a coalition of patient advocates, dialysis professionals, care providers and manufacturers dedicated to working together to improve quality of care for individuals with Chronic Kidney Disease (CKD). As such, we endorse comments submitted by KCP on these recommended measures.

AKF commends CMS for its recent efforts to put forth measures for anemia management that are intended to help ensure that clinical practices remain safe and effective. We have advocated for re-establishment of a lower level anemia measure to prevent complications of undertreated anemia, and particularly, to reduce the

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need for unnecessary blood transfusions. We applaud the inclusion of such measures for review, but echo the concerns of others that the measures, as presented, are deficient and should be modified and improved to more accurately measure appropriate anemia management. Measures must be balanced and evidence based, as well as developed in a consistent and transparent manner. Further, we support a system that is accurate and reflects the discussion and conclusions reached through the Technical Expert Panel (TEP) process without drawing conclusions that go beyond that process.

Improving Quality and Access to Care

The data that CMS uses to determine benchmarks for measures must be accurate and current. Reliance on older data does not present an accurate or clinically appropriate view of the care that patients are currently receiving. CMS should work with providers and others in the renal community to capture the most recent data when establishing benchmarks that will be used to evaluate or guide care.

CMS should also bear in mind that some people living with kidney failure who receive life-sustaining dialysis treatments will utilize the measures and benchmarks when making decisions about the source of their care.

Ensuring an Accurate and Transparent Process

AKF is concerned about the process currently used to develop measures. We support a robust measure development process resulting in proposed measures that are technically sound and relevant and that reflect the work that TEPs have done and the conclusions reached.

Moving forward, we urge CMS to provide transparency in the measure development process and the adoption of the benchmarks used to evaluate performance with these measures. CMS should open the process to the entire kidney care community and also work closely with those who are actively involved with the day to day operations of dialysis facilities. More importantly, CMS should include patients and advocates in the process to ensure that any measures developed take into consideration the concerns of people receiving dialysis services.

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The American Kidney Fund is grateful for CMS's commitment to ensuring high quality care for all individuals with kidney disease and in kidney failure. We appreciate your attention to the issue of anemia management and your consideration of our input as well as input and concerns from others in the renal community,

Thank you for the opportunity to submit comments.

Sincerely,



LaVarne A. Burton
President and CEO



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April 18, 2013

Request for Public Comment – Arbor Research: Draft ESRD Quality Measures

To Whom It May Concern,

In response to your request for public comment pertaining to the above referenced draft ESRD Quality Measures, Wheeling Renal Care LLC wishes to submit the following for consideration:

1. Anemia of chronic kidney disease: Hgb < 10 g/dL

- a. To the list of conditions to be considered as exclusions to the denominator, we suggest adding any condition causing chronic GI bleeding; e.g. intestinal angiodysplasia, chronic erosive esophagitis or gastritis, peptic ulcer disease and other conditions currently included in the list of comorbid condition adjusters used for ESRD facility billing (Addendum A);
 - i. **Rationale:** These conditions, as well as malignancy, are commonly seen in patients with CKD, including ESRD and frequently result in severe anemia that may be refractory to therapy with ESA and iron. Even documentation of a positive stool hemoccult test indicates the presence of gastrointestinal bleeding. It is assumed that such patients would be receiving iron if Tsat or serum ferritin levels are below goal; however, iron repletion may not correct Hb levels quickly. Furthermore, some patients with these conditions may be refractory to ESA, even when high doses are used (> 300 u/kg/week).
 - ii. In many instances, active bleeding may not be identified, but the mere presence of the condition (esophagitis, gastritis, duodenitis, angiodysplasia, etc.) provides good evidence for the source of GI

bleeding, particularly if studies suggest iron deficiency (low T_{sat}, serum ferritin, hypochromic, microcytic RBC indices). Again, iron repletion may take several weeks for a suitable response in erythropoiesis. Documentation of the presence of these additional conditions should be considered in determining of the number of patients in the denominator for anemia-related QIP metrics.

2. Anemia of chronic kidney disease: Dialysis Facility Standard transfusion ratio (STrR)

- a. Suggest using the number of units of blood transfused rather than transfusion events as the numerator.
 - i. **Rationale:** Patients often receive more than a single unit of blood during a transfusion setting (inpatient or outpatient); this would provide a better indicator of the extent to which transfusions are being administered. Blood bank calculations typically use the number of units of blood as a measure of blood utilization.
- b. Consideration should be given to including causes for anemia requiring transfusion as well as the physician ordering the transfusion.
 - i. **Rationale:** Many conditions resulting in the need for blood transfusion are outside the control of the dialysis facility staff, such as acute GI bleeding, surgical blood loss, drug-induced hemolytic anemia, etc. Many, but not all, transfusions are administered in the in-patient setting. Patients who are hospitalized often have multiple physicians involved in their care (primary care physician, surgeon, other consultants), not just the nephrologist. It would be unusual for a non-nephrologist to order blood transfusion for an ESRD patient in the non-hospital setting, except in the instance of oncology care. Only a small proportion of dialysis facilities permit blood transfusion in the facility setting.

The intent of this measure appears to be directed towards inappropriate ESA use, which ordinarily is the responsibility of the nephrologist and dialysis facility staff. In the situations described above, other factors leading to the decision to order a transfusion and the number of units/events actually provided should be considered. These situations may have significant impact on the dialysis facility's performance. Only those circumstances that fall under the nephrologist and dialysis facility's control should be considered in determining the numerator for this metric.

3. Anemia of chronic kidney disease: Anemia management to avoid transfusion

- a. To the list of conditions to be considered as exclusions to the denominator, suggest adding any condition causing chronic GI bleeding; e.g. intestinal angiodysplasia, chronic erosive esophagitis or gastritis, peptic ulcer disease and other conditions currently included in the list of comorbid condition adjusters used for ESRD facility billing; (Addendum A);
 - i. **Rationale:** These conditions, as well as malignancy, are commonly seen in patients with CKD, including ESRD and frequently result in severe anemia that may be refractory to therapy with ESA and iron. Even documentation of a positive stool hemoccult test indicates the presence of gastrointestinal bleeding. It is assumed that such patients would be receiving iron if Tsat or serum ferritin levels are below goal; however, iron repletion may not correct Hb levels quickly. Furthermore, some patients with these conditions may be refractory to ESA, even when high doses are used (> 300 u/kg/week).
 - ii. In many instances, active bleeding may not be identified, but the mere presence of the condition (esophagitis, gastritis, duodenitis, angiodysplasia, etc.) provides good evidence for the source of GI bleeding, particularly if studies suggest iron deficiency (low Tsat, serum ferritin, hypochromic, microcytic RBC indices). Again, iron repletion may take several weeks for a suitable response in erythropoiesis. Documentation of the presence of these additional conditions should be considered in determining of the number of patients in the denominator for anemia-related QIP metrics.

4. Standard readmission ratio for dialysis facilities

- a. The following considerations should be taken into account.
 - i. The specific reason for the patient's readmission; a condition totally unrelated to the previous admission (e.g., an acute GI bleed following an uneventful admission for pneumonia) should be excluded;
 - ii. The physician responsible for the readmission (nephrologist or non-nephrologist), and the physician who is responsible for the previous admission and, more importantly, the discharge;

1. Rationale:

- a. In many circumstances, neither the nephrologist or the dialysis facility have any responsibility for decisions made by other physicians, and often the nephrologist may not even be notified of the dialysis patients' admission, discharge, or readmission until a day later or even longer. This speaks to the overriding concern about communication and appropriate transitions of care, but these factors should not be involved in measuring a dialysis facility's readmission rates.
 - b. This is especially important when a patient may be discharged from an acute care hospital to a Skilled Nursing Facility (SNF) or Long Term Acute Care Hospital (LTACH). In the majority of instances, staff at those facilities may be unfamiliar with the patient, and depending upon local policy and practice, may decide to have the patient readmitted to the acute care hospital because of an unstable or presumably new problem. Again, the nephrologist and dialysis facility may have no responsibility or authority in directing the patient's care;
 - c. Focusing only on the dialysis facility will do nothing to improve overall coordination of care; it is essential that all transitions of care initiatives that are in place and those that are being planned include ESRD facilities. Anecdotal experience indicates that this is not occurring except for a few projects that are specifically designed to focus on dialysis patients.
- iii. It is imperative that reasons for admission and readmission be analyzed and included in this measure. Data supporting the role of inappropriate ESA dosing, metabolic bone testing, and modification of Vitamin D dosing in hospital admissions/readmissions are scant; it is doubtful that these factors contribute in a meaningful way to dialysis patient admission/readmission. Dry weight, medication reconciliation, incompletely treated pneumonia and other acute medical condition, on the other hand, are far more important.

Thank you for the opportunity to submit public comments regarding these draft ESRD quality measures.

Respectfully submitted,

Derrick Latos, MD
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Addendum A

Listing of Suggested ICD-9 codes to be added to the list of Exclusions for Anemia Quality Improvement Projects

Condition	ICD-9 Code
Positive hemoccult stool	792.1
Esophagitis	530.1
Reflux esophagitis	530.11
Acute esophagitis	530.12
Eosinophilic esophagitis	530.13
Ulcer of esophagus	530.2
Ulcer of esophagus without bleeding	530.20
Ulcer of esophagus with bleeding	530.21
Stricture and stenosis of esophagus	530.3
Perforation of esophagus	530.4
Diverticulum of esophagus, acquired	530.6
Gastroesophageal laceration-hemorrhage syndrome	530.7
Esophageal reflux	530.81
Esophageal hemorrhage	530.82
Barrett's esophagus	530.85
Gastritis and duodenitis	535
Acute gastritis	535.0
Atrophic gastritis	535.1
Gastric mucosal hypertrophy	535.2
Alcoholic gastritis	535.3

Duodenitis	536.6
Eosinophilic gastritis	535.7
Angiodysplasia of stomach and duodenum (without mention of hemorrhage)	537.82
Angiodysplasia of stomach and duodenum with hemorrhage	537.83