DPC
DIALYSIS PATIENT CITIZENS

Improving Life Through Empowerment

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 ERSD 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,

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