

August 30, 2011

Dr. Donald Berwick  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1577-P: Medicare Program; Changes to the End Stage Renal Disease Prospective Payment System for CY 2012, End Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014

Dear Dr. Berwick:

Dialysis Patient Citizens (DPC) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Proposed Rule for the Changes to the End Stage Renal Disease Prospective Payment System for CY 2012, End Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014. As America's largest dialysis patient organization, DPC's membership consists of more than 23,000 dialysis and pre-dialysis patients and their families. We seek to ensure that the patient's point of view is heard and considered by policy makers on a wide variety of issues so 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 end stage renal disease (ESRD) does not mean the end of life. Dialysis patients can lead long, productive lives, in many ways because Congress and Medicare is committed to ensuring patients have access to quality kidney care. It is for these reasons that we respectfully submit comments on the latest evolution in Medicare's quality improvement strategy for ESRD beneficiaries.

As a member of Kidney Care Partners (KCP), DPC strongly supports the comments submitted by the coalition, and would like to take this opportunity to highlight a few points and emphasize several key priorities.

### **1. Timeliness of Data**

DPC's main concern with the Quality Incentive Program (QIP) continues to be the lack of timeliness of data. In order for the QIP to be a truly useful tool for patients, the data used to evaluate the quality of care delivered must be current. It should not be acceptable for patients to rely on data that is more than two years old, which is compared against much older baseline data.

With claims data coming into CMS in real-time, we strongly urge CMS make it a priority to develop new ways to analyze and report the information to the public in a timelier manner. DPC would like to see no more than a 6 month lag between data submission and public reporting. Further delays reduce the value of such information to patients and providers. DPC hopes that CROWNWeb will soon provide more timely data and encourages CMS to continue to develop tools for more rapid reporting.

The more current the data that CMS can provide, the greater chance that QIP will become a relevant and useful resource for patients looking to make informed decisions about their care and for providers and the community looking for a means to track changes in treatments.

### **2. Anemia Management Measures**

DPC is greatly concerned with CMS's decision to remove the lower limit hemoglobin less than 10 g/dL measure entirely from the QIP.

DPC understands that with the Food and Drug Administration (FDA) label change, the below 10 g/dL measure may no longer be an appropriate measure to include in the QIP for payment. That said, this change could be dramatic on patient care, and its potential impact on patient quality of life cannot be underestimated. As a result, it is absolutely critical for CMS to provide information about patient hemoglobin levels as soon as possible. And if such timely reporting could be provided through the QIP, DPC would support its inclusion.

The new bundled payment system coupled with the recent FDA label change is already exerting downward pressure on hemoglobin levels in dialysis patients. Recent data from the DOPPS Practice Monitor is already showing a decline in hemoglobin levels, particularly in African American patients. The data shows a greater rise in the percentage of patients with hemoglobin levels less than 10 g/dL and a larger decline in mean hemoglobin levels in African American patients compared to other hemodialysis patients. The report calls for additional monitoring of these trends and evaluation of their potential consequences.<sup>1</sup> Clinical data has demonstrated an increased association between hemoglobin less than 10 g/dL and increased transfusions and morbidity. Because of this critical patient safety issue, DPC supports timely reporting of hemoglobin below 10 g/dL.

With clinical data already demonstrating a drop in hemoglobin levels, DPC also strongly supports public reporting of the full range of hemoglobin levels below 10 g/dL. We believe patients should have access to information regarding all hemoglobins below 10 g/dL, stratified by 1 gram increments (e.g., percentage of patients with hemoglobin levels 9-10 g/dL, 8-9 g/dL, etc.) as well as the national average for each gradation. This data should be published both on Dialysis Facility Compare and made available in individual facilities. This information will not only allow the kidney care community and CMS to better understand how the label change impacts care outcomes, but it will provide patients with up-to-date

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<sup>1</sup> "Latest Findings from the DOPPS Practice Monitor (DPM) during Implementation of the Prospective Payment System (PPS) for Hemodialysis: August 2010 – February, 2011" DOPPS Practice Monitor, page 2  
[http://www.dopps.org/DPM/July2011\\_DPM\\_highlights.pdf](http://www.dopps.org/DPM/July2011_DPM_highlights.pdf)

information regarding the quality of care each facility delivers. However, this information is only meaningful to patients if it is timely. DPC recommends CMS make data available from the most recent six months from the date of posting and update the data regularly, including all dialysis patients, not only those who receive ESA treatment.

By monitoring and publically reporting hemoglobin levels on a timely basis, CMS and patients will have a more meaningful understanding of the impact recent changes have made on standards and quality of care. At the same time, DPC urges CMS to develop appropriate anemia management measures for payment in QIP. Such measures could include transfusions, patient quality of life, or perhaps a higher percentage of patients at the hemoglobin 10 g/dL level.

### **3. Additional Clinical Measures**

DPC would also like to take this opportunity to comment on the other proposed clinical measures.

#### **a. Dialysis Adequacy**

While DPC supports CMS' decision to move from a URR to Kt/V dialysis adequacy measures, it is acknowledged that Kt/V does not accurately reflect the status of patients who do daily, more frequent or nocturnal hemodialysis. DPC strongly urges CMS to encourage the development of an adequacy measure for hemodialysis patients who dialyze more than 3 times per week, either at home or in a clinic.

#### **b. Vascular Access Type Measure**

DPC strongly supports the inclusion of a vascular access measure because of the importance of vascular access choice on other components of care included in the QIP. At the same time, DPC is concerned that the current measure falls short because it does not take into account patients who are not good candidates for placement of an AV fistula and would be better served by the placement of a synthetic graft.

#### **c. Standardized Hospitalization Ratio (SHR) Admissions Measure**

DPC urges CMS to focus the SHR Admissions measures on hospital admissions that could be prevented by interventions by dialysis facilities. A measure of this kind will both help to monitor the rate of hospitalization for dialysis patients while reducing the incentive for providers to avoid the sickest patients who may require hospitalizations that are not a direct result of their kidney failure.

### **4. Additional Reporting Measures**

DPC would like to provide comments on the reporting measures proposed in the QIP.

#### **a. Patient Experience of Care**

DPC is greatly encouraged by CMS' desire to improve efforts to evaluate the experience of care dialysis patients receive. DPC looks forward to working with the Agency to further develop this measure and determine new ways to increase patient response rates for the current Consumer Assessment of Healthcare Provider and Systems (CAHPS) survey.

#### **b. Bone Mineral Metabolism**

DPC strongly supports CMS' effort to measure bone mineral metabolism. At the same time, in addition to calcium and phosphorus, this measure should be expanded to include PTH. Due to high morbidity and mortality risks associated with extreme PTH levels, it is critical to monitor these patient values as well.

#### **5. Put Funds Removed by QIP Back into Incentivizing Care**

DPC is also troubled by CMS' interpretation of the Medicare Improvements for Patients and Providers Act (MIPPA), specifically with its decision to turn the Quality Incentive Program into a Penalty Program. The name alone – Quality Incentive Program – emphasizes Congress' objective to reward providers for improving care. Therefore, DPC is concerned that CMS has interpreted the program to only act as a penalty for those providers who fail to meet the quality standards. DPC strongly urges CMS to establish a means to also reward those providers who deliver the highest quality of care.

Establishing a program that purely acts as a penalty diminishes the ability of some facilities to achieve high standards. By continually removing dollars from the system, it has the potential to increase the burden on many facilities and reduce patient access to care. DPC believes the best way to preserve access and encourage improvement is to reinvest the funds collected by the QIP payment reductions back into the system. DPC recommends that CMS use the dollars saved to provide facilities that show the greatest improvement and deliver the highest quality of care with higher payments. This will further incentivize providers to strive to deliver high quality care and will ensure that dialysis patients do not suffer due to the removal of funds from the ESRD program.

DPC strongly believes the Quality Incentive Program should act as a true incentive for providers and we urge CMS to take the steps necessary to make the QIP an "incentive" program.

#### **4. Incentives for Innovation**

In conjunction with the call for the addition of incentives into the program, DPC urges CMS to consider new ways to promote innovation in ESRD treatment. With the implementation of the bundled payment system for the ESRD program, there are limited mechanisms for introducing new therapies in the short-term. As it stands, it takes at least a couple of years for payment revisions and updates to take place, which potentially reduces the ability of innovative technologies and therapies to be quickly introduced to ESRD beneficiaries. DPC strongly encourages CMS to consider new mechanisms for treatment innovation and implement new programs to reward advances in the care for ESRD patients.

One mechanism for CMS to consider is the implementation of a pass-through payment program modeled after the current program in place for the Hospital Outpatient Prospective Payment System (OPPS). Under the current program, Medicare provides transitional pass-through payments for the additional costs of new and current medical devices, drugs, and biologicals. As mandated by Congress, the pass-through status was created to provide temporary additional payments for certain innovative medical devices, drugs and biologicals. The pass-through status applies to "new" drugs and/or non-implantable biologicals only. It does not apply to existing products on the market or those products seeking pass-through status based on new clinical trials. Under the program, a new drug and/or non-implantable biological is eligible for a pass-through status for at least two years, but not more than three years beginning on the date that CMS establishes the category.

Implementing a similar pass through system in the Medicare ESRD program could enable new technologies and therapies to be available to ESRD Medicare beneficiaries for a set period before inclusion into the bundle. This type of a system would provide a mechanism to reward innovative ideas and would increase incentives for new therapies to treat kidney failure. The funds collected from the penalties in the QIP could also be placed into such a program to help get it going, which would also enable the money to remain in the ESRD program and improve patient care and quality of life. DPC would also welcome any additional creative solutions or adaptations of relevant existing policies to

ensure that the ESRD program has a mechanism to encourage the development of innovative therapies to treat kidney failure.

In summary, DPC would like to thank CMS for its continued efforts to improve patient care and patient quality of life for ESRD beneficiaries. DPC hopes that CMS will continue to develop new and timelier means for disseminating the information in the QIP to the public, because the more current the information becomes the more useful a tool the QIP will be for everyone. Additionally, DPC strongly urges CMS to report timely data on the hemoglobin less than 10 g/dL measure and develop future anemia management measures for payment. DPC appreciates the opportunity to weigh in on additional clinical and reporting measures and strongly suggests creating a new incentive program within the QIP to reward high quality care. DPC also urges CMS to consider new ways to incorporate innovative care methods into the QIP in the short term.

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  
Executive Director