DPC
DIALYSIS PATIENT CITIZENS

Improving Life Through Empowerment

August 31, 2012

Ms. Marilyn Tavenner
Acting 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-1352-P: Medicare Program; End Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers

Dear Ms. Tavenner:

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 Medicare Program; End Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers (CMS-1352-P). 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 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 are 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 payment and quality improvement strategy for ESRD beneficiaries.

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

Prospective Payment System

I. Incorporating Oral Only Drugs

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With oral-only drugs moving into the bundle in 2014, it is critical to start laying the groundwork for this substantial change now, so providers and patients can adequately prepare. In the final rule, CMS should provide any and all information it can to get this process moving forward appropriately. The more information that is provided as early as possible, the better the chances that providers and patients will have the time needed to safely and effectively complete this complex transition.

When it comes to including orals in the bundle, there are many challenges facing CMS and the kidney community. It is important for everyone involved, including patients, that CMS sets an appropriate payment amount. If CMS underestimates the true cost of including these medications in the PPS, it will place beneficiaries and facilities in a difficult position, as they have already seen cuts twice since the start of the new payment system. It is also important for CMS to make it a transparent process so interested parties can fully understand how the figures are determined. This will facilitate discussion and help the community better appreciate the thought that went into determining the final payment amount.

Using the most up-to-date data on the cost or utilization of these oral medications is also critical. Most patients with ESRD currently receive these drugs through Medicare Part D or private insurance plans. Moving these drugs from Medicare Part D to Medicare Part B creates a number of challenges. For example, to ensure a smooth transition, CMS must identify the appropriate payment proxies and data sets to calculate the payment amount. In addition, CMS must take into account clinical standards before shifting the coverage of oral-only drugs. Only by using the most current and accurate data can CMS ensure that a true estimate has been calculated.

There is also a need for strong patient protections. As CMS works to include these oral-only medications, it is critical that strong quality protections are in place to ensure patient care is not compromised and patients continue to have access to these necessary medications. As changes in dosing for Erythropoietin Stimulation Agents (ESAs) since the inception of the bundle have indicated, there is the potential for unintended consequences from transitions such as these, so it is critical for CMS to ensure patient care and safety isn't negatively affected. DPC recognizes that dosing reductions were due to multiple factors, but with less incentive to provide oral medications, there is always a risk to see similar results.

For CY2014, we encourage CMS to provide guidance as to how it plans to incorporate oral-only drugs into the ESRD bundle to allow for a transparent and cooperative process with the kidney care community.

II. Incentivizing High Quality 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 collected pooled funding 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. Alternatively, CMS could return the funds collected through QIP penalties to penalized facilities, but dictate that those facilities must use the money to improve care in the specific area where they did not meet the necessary standards.

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.

III. 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. Ensuring high-quality care and protecting the integrity of the bundle includes providing incentives for the development of new technologies and DPC strongly encourages CMS to consider new mechanisms for treatment innovation and implementation of new programs to reward advances in the care for ESRD patients.

DPC strongly supports the KCP position that calls on CMS to establish a new technology adjustor that would allow for additional payments in a non-budget neutral manner. Instituting this adjustor would add the new money needed to create incentives for innovation in an area that has seen few historic changes in care.

Without some mechanism to incentivize changes and innovations in dialysis care, kidney disease patients run the risk of being left behind. New technologies have the potential to lead to better diagnoses, better treatment, and better outcomes for patients, which in turn means lower costs and higher patient satisfaction. Operating under the current structure of the ESRD PPS, there is little motivation to move forward on new technologies to improve care for this vulnerable population. This adjustor would provide a mechanism to reward innovative ideas and would increase incentives for new therapies to treat kidney failure.

IV. AY modifier

DPC appreciates CMS's recognition that many dialysis facilities provide care that is not-solely dialysis related. The adoption of the AY modifier to distinguish between dialysis and non-dialysis related services provided by facilities is extremely beneficial to patients because it ensures patient access to care without requiring additional expensive doctor visits or duplicative and unnecessary lab tests.

We are concerned that the proposed rule implies that there has been abuse of the modifier. The modifier is a vital tool that eases the large burden of care place on the shoulders of dialysis patients by allowing facilities to minimize doctor visits and condense necessary care into fewer settings and fewer appointments. We are troubled with the assertion that there may be abuse of this tool, but also concerned that CMS provided little data on the exact abuses or the scope of the problem. We urge CMS to identify specific problems associated with use of the AY modifier and work with individual facilities

and providers to ensure compliance. We strongly urge CMS not to eliminate the modifier completely, as it would punish patients and do a disservice to the Medicare ESRD program. We believe a more targeted approach of addressing abuses would be better for patients and the kidney care community as a whole.

V. Timeliness of Data

We have stated this several times before, but DPC's main concern with the 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 to make it a priority to develop new ways to analyze and report the information to the public in a timelier manner. As a result, 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 the chance that QIP will become a relevant and useful resource for patients looking to make informed decisions about their care as well as for providers and the community looking for a means to track changes in treatments.

Quality Incentive Program (QIP)

I. Measures:

a. Anemia Management

We appreciate CMS' continued recognition of the importance of proper anemia management in dialysis patients. Anemia is a serious condition, which if not treated properly, causes fatigue, weakness, increased risk of hospitalization and in some cases death. Therefore, we still strongly support inclusion of the percent of clinical patients with hemoglobin greater than 12 g/dL measure for payment. Anemia management continues to be a critical aspect of patient care and patient quality of life and DPC appreciates CMS's commitment to monitor it.

We are also encouraged by CMS's decision to add the Anemia Management Reporting Measure for PY2015. With the label change made last year by the Food and Drug Administration (FDA) and the subsequent removal of the lower limit hemoglobin less than 10 g/dL measure from the QIP, there is evidence that there has been substantive changes in prescribing patterns and patient outcomes. Requiring facilities to report hemoglobin levels and ESA dosages will help to ensure that patients are not seeing negative health outcomes due to the recent t guideline and policy changes. 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 remains concerned with CMS's decision last year to remove the lower limit hemoglobin less than 10 g/dL measure entirely from the QIP. We understand the need to align the QIP with the dosing guidelines issued by the FDA, however we believe this is still a critical component of

proper kidney disease care and we reiterate our call for CMS and the kidney care community to work to develop an acceptable lower limit measure or appropriate tool to monitor lower hemoglobin levels. We hope that the new reporting measure will help gather the necessary information needed to develop an appropriate lower level anemia management measure for payment in future years of the QIP.

b. Vascular Access

DPC strongly supports inclusion of vascular access measures. The entire kidney care community has focused strongly on reducing catheter use in an effort to reduce deadly bloodstream infections. It is arguably one of the most important aspects of patient care and we are encouraged to see a vascular access measure in the QIP for payment. However, we are concerned by the potential for perverse patient outcomes that could result from the structuring of the current vascular access type composite measure.

We believe that by measuring only catheter and fistula use, and by weighting them equally, CMS will put patients who would experience optimal health outcomes with a graft at a disadvantage. Not all patients are proper candidates for AV fistulas and a synthetic graft is a substantially better option for these patients than a catheter. The structure of the measure creates a disincentive for using clinically appropriate grafts, even when it is in the best interest of patients. Therefore, we call on CMS to work with the kidney care community to develop an appropriate graft measure that takes these patients into account.

In the meantime, we join KCP in urging CMS to adjust the weighting of the current vascular access composite measure to reduce this disincentive. We suggest more heavily weighting the catheter minimization measure, making it two-thirds of the total measure score, with the fistula measure making up the final one-third. This will help minimize the incentive to use a fistula in those patients who would do better with a synthetic graft, until a proper graft measure can be developed.

c. Dialysis Adequacy

DPC supports CMS' decision to retire the URR measure and replace it with the Kt/V composite dialysis adequacy measure. The Kt/V measure more accurately reflects the metric upon which physicians rely when making treatment decisions related to adequacy. We have concerns, however, with the pediatric component of the composite measure as it is currently structured. We understand that this measure might not be appropriate for the pediatric population and we urge CMS to work with that community to make sure it is a suitable measure for young dialysis patients.

d. **Bone Mineral Metabolism**

DPC strongly supports CMS' effort to measure bone mineral metabolism and include it in the QIP. This is a very important component of kidney disease treatment and we believe that proper bone mineral metabolism should be encouraged by the QIP. We continue to support the measure for payment but are open to including the measure for reporting for a year in order to establish more robust standards. At the same time, we encourage CMS to develop more applicable measures for mineral metabolism, including but not limited to an individual phosphorous measure and or one measuring parathyroid hormone (PTH) levels, which are associated with high morbidity and mortality risk.

e. Patient Experience

DPC continues to support monitoring patient experience of dialysis care. Understanding how patients view the care they receive is critical to improving treatments and patient outcomes. Currently, we support use of the In-Center Hemodialysis Consumer Assessment of Health Providers & Systems (ICH CAHPS) Survey. However, in the future, we would like to see a new tool developed that minimizes the burden on respondents and properly gains information on the experience of home dialysis patients, which we think is a critical area that is missing from the current tool. We stand ready to work with CMS on developing a new tool to monitor patient experience of care, including adding questions from CMS to our annual patient membership survey.

f. Bloodstream Infection

DPC strongly supports inclusion of the National Healthcare Safety Network (NHSN) bloodstream infection measure. As a member of the Centers for Disease Control and Prevention (CDC) Dialysis Bloodstream Infection (BSI) Prevention Collaborative, we understand firsthand the devastating impact these infections can have on dialysis patients. Monitoring the number of patients with access-related infections will help to better understand ways to reduce infection rates in this vulnerable population.

II. Exclusion Criteria Concerns

We understand that dialysis providers and facilities cannot completely manage every aspect of a patient's care plan. Comprehensive kidney disease treatment involves not only dialysis therapy but medication regime adherence, proper diet and many other things. While the final responsibility to manage many aspects of care ultimately falls to the individual patient, it is the role of providers and facilities to fully and properly educate patients so they understand the intricacies of kidney disease treatments and the importance of following the complete prescribed care regime. This is especially true for those patients who chose to undergo their care at home. Patients who choose either home hemodialysis or peritoneal dialysis are in facilities far less frequently and have less direct interaction with their care team. This means that those times when patients do visit their assigned dialysis facility are even more crucial to ensuring that these patients are following the necessary care plan and attaining the proper health outcomes.

As a result, DPC is concerned by the recommendation to include the following language in the proposed global exclusion criteria, "beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month." We are concerned that this language has the potential to lead to discrete standards of care for in-center vs. home dialysis patients. In particular, without specific guidance regarding what is considered a "good faith effort" there is the potential for home patients to slip through the cracks. We do not wish to punish providers for patient behavior that is outside of their control; however, it is the responsibility of providers to express upon their patients the importance of making and keeping their dialysis facility appointments.

We are not opposed to having distinct exclusion criteria related to home dialysis patients, but we find the proposed language to be too broad on its own and potentially left up to individual interpretation. Therefore, we call for more detailed and prescriptive language that strikes a balanced approach of providing flexibility to facilities while ensuring home dialysis patients have proper access to the care they need. Perhaps even a detailed checklist from CMS regarding what it would consider to be a

minimum standard for what is considered a "good faith effort." We look forward to working on this important issue with CMS and the kidney care community.

III. Public Reporting

The QIP is only really useful for patients and clinics if they are able to fully understand what is being measured, how their facility is being judged and what the outcomes mean for their department or their care. While we do appreciate the effort made by CMS to make this information digestible and available to patients and clinics, there is still a need for additional clarity. Common sense dictates that the longer that it takes to understand new regulations, the less likely they will be adhered to.

DPC suggests that two sets of guidance documents are created, one set for clinics and staff that are directly impacted by scoring and one specifically for patients to understand what this means to their facility and their care. These documents should be readily available on the web and within clinics for those interested. Further, to increase awareness it would be advantageous to patients to have specific open forums with CMS where the QIP can be fully explained and questions can be answered. Through anecdotal member interaction, we have found a large disconnect between the intent of the facility's score and the interpretation by the public. Our concern is that patients without a strong understanding of the QIP could misinterpret the quality of care they are receiving at their facility and perhaps even use the score unnecessarily to move to another clinic. We would welcome the opportunity to further discuss with CMS these suggestions as well as other opportunities for patient education surrounding the QIP.

Conclusion

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,

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Executive Director