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August 30, 2013

Marilyn Tavenner
Centers for Medicaid and Medicare Services
Department of Health and Human Services
Washington, DC 20515

**RE: CMS 1526-P- Medicare Program; End-Stage Renal Disease
Prospective Payment System, Quality Incentive Program, and Durable
Medical Equipment, Prosthetics, Orthotics and Supplies**

Dear Ms. Tavenner,

The American Kidney Fund (AKF) appreciates the opportunity to comment on Proposed Rule [CMS-1526P] Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies. We thank CMS for considering the input and feedback from individuals and organizations, including the American Kidney Fund that are committed to ensuring that individuals with kidney failure receive quality care.

The American Kidney Fund is the nation's leading patient organization providing financial assistance to individuals on dialysis. We provide grants to patients with End Stage Renal Disease to assist them in paying health insurance premiums as well as to help them obtain medications, transportation and other treatment related services that insurance will not cover. We see firsthand some of the financial challenges individuals with kidney failure face as they attempt to access treatment and care. For these reasons, we continue to advocate for access to adequate and quality care for patients.

The American Kidney Fund is also a member of Kidney Care Partners (KCP). The mission of KCP is to ensure that individuals with kidney disease receive optimal care. In addition to our comments, we support the comments submitted by KCP.

AKF commends CMS for its commitment to ensuring that Medicare remains a viable health care option for patients with ESRD. Through implementation of the Prospective Payment System (PPS) and the Quality Incentive Program (QIP), CMS has made great progress in developing a system that puts patients first and links payment to quality care.

AKF understands the budget challenges that face our nation. We understand that the Department of Health and Human Services must find savings within the health care delivery system to help address our nation's deficit. However, considerable reductions have already been made in the Medicare ESRD payment system over the past several years and these reductions make substantial

contributions to reducing the national deficit. Therefore, AKF recommends that the Administration and Agency take caution as they move forward with the ESRD PPS Final Rule, as we believe that the progress made over the past several years to improve quality is in danger of being reversed, and access to high quality services under the PPS could be compromised. The following represent AKF's key concerns with the Proposed Rule, which we hope that CMS will consider as the rule is being finalized:

I. AKF opposes the proposed \$30 cut from the PPS payment rate for CY2014

The American Kidney Fund is extremely concerned about the proposed cut to the ESRD PPS. We believe such a cut would have negative consequences for beneficiary access to dialysis treatment and services as well as quality outcomes. CMS should use caution as it moves forward to finalize the payment amount. There are several issues that concern us and that we believe must be addressed.

AKF is concerned about the methodology used to calculate the ATRA reduction

The American Kidney Fund understands that CMS has been mandated to re-evaluate the ESRD PPS to reflect the change in drug utilization. We remain concerned, however, that CMS has not provided any analysis or explanation of the methodology used to calculate the change in drug utilization from 2007-2012. In August 2012, CMS posted new drug utilization data on the website; however, it did not include several variables, such as how the treatments were counted, data on injectables and the inclusion of oral equivalents, and overall, a basis to validate the calculations. AKF recommends that CMS provide data and information to support the methodology it is using in its calculations. We believe that the proposed cut would result in the payment rate not covering the cost of providing care. CMS should provide access to the claims data used to calculate the reduction.

AKF believes that CMS has not complied with the statutory obligations and legal obligations under section 1181(b) (2) (B)

We know that CMS has authority and must comply with ATRA; however, CMS also has responsibility and authority to adjust the PPS and avoid cuts that would destabilize patient care. Further, CMS must ensure that the PPS covers the actual costs for providing care. The Moran Company, a health care research and consulting firm, analyzed Medicare payments and provider costs based on 2011 data and found that the mean Medicare margin for dialysis service was 3.6 percent. They also projected the impact of the recently proposed cut, which reduced the mean margin to -6.4 percent. With the sequester taken into account, the mean margin would be -8.11 percent.¹ Based on these calculations, it does not appear that the proposed payment for CY2014 will cover the actual treatment costs. AKF believes CMS should exercise its full authority to prevent a drastic cut from placing access and quality at risk.

AKF is concerned about the phase-in approach

AKF appreciates that CMS has asked for comments on the possibility of phasing in the proposed payment reductions. However, we believe that the phase-in would not change the risks associated

¹ U.S. Renal Data System, 2012 Annual Data Report.

with the cut. Specifically, it would not relieve the pressure on facilities to close, nor would it eliminate the need to make staffing changes, reduce hours of available care, or other options for care that are currently available to patients. According to the Moran Company, an analysis of the 2011 cost report data concluded that 35% of dialysis center profit margins were below the break-even point before the implementation of additional cuts. Moreover, after applying the 12 percent cut to the baseline as set forth in the FY2014 Proposed Rule and applying the 2 percent sequester to Medicare, the Moran Company projects that 78 percent of dialysis center margins will be below the break-even point. AKF believes that CMS should work to ensure that the payment amount is adequate before considering whether a phase-in or even a delay in implementation is warranted.

CMS also should take into consideration that the impact of the reductions among small dialysis providers will be even greater. Many of these centers, especially those located in inner city and rural areas, are already under severe financial pressure and may not survive the additional cuts.

II. AKF believes high quality service and access to care could be compromised under the proposed PPS

Eighty-four percent of dialysis patients rely on Medicare for their health care coverage. The original goal of the QIP and PPS was to improve quality and patient care for those beneficiaries who rely on Medicare. There have been impressive strides in the quality of care rendered to dialysis patients over the years as science and technology have evolved. AKF believes the reductions in the Proposed Rule will have a detrimental impact on quality of care and will threaten access to care moving forward.

AKF believes that there could be limited patient access to care

The Rule will likely cause consolidations and closures resulting in patients having fewer options for treatment and increased transportation costs. Some providers have expressed a likelihood that they may begin to close and consolidate facilities, reduce operating hours, and/or staffing. This poses a great risk for patients in rural areas who may be forced to travel even longer distances to receive their care. Long travel time reduces patients' quality of life, and patients may experience increased transportation costs associated with longer drives to treatment. It also increases the possibility of missed appointments, thus jeopardizing quality outcomes for patients as well as the economic balance for dialysis center operations.

The Proposed Rule will likely result in reduced staff hours, meaning that patients will have less flexibility for scheduling treatment and greater potential for loss of employment. Individuals in kidney failure rely on dialysis to survive. Any interruptions in their care or access to care will be detrimental to both their health and quality of life. If a patient is not able to schedule treatment during a time that is convenient for their work schedule, or if they have to spend more time getting to and from dialysis, they are at risk of losing their job. Moreover, a reduction in staff hours may hinder a patient's ability to receive care, posing a risk for increased mortality rates. Some patients have already indicated that as a result of previous changes to the dialysis payment system, they have begun to experience negative changes as it relates to hours available for scheduling treatment at their dialysis center. Below are a few quotes from patients:

“If you cut the Medicare ESRD program as proposed, many of the senior citizens I know from my previous center may not be able to get the care they need as transportation has already been cut there. This can actually be a life or death situation for these patients”

“I ask that you please not make your cuts on the backs of chronically ill and vulnerable people. This is a life and death service and you are going to make it that much harder for patients to receive the proper care they need. Dialysis is devastating enough just to adjust your life around.”

“I am a 32 year old female who has lived with End Stage Renal Disease since birth and have been on dialysis for the last eight years. Already, the financial burden is more than a single woman in her early 30s is able to bear, but with Medicare's help, I know I am able to get the care that I need to maintain a healthy lifestyle. My life depends on the care that dialysis provides for me, and I do worry about the upcoming cuts I keep hearing about. Already, there are not enough social workers and not enough clean, quiet clinics for dialysis patients to feel as if they still have dignity in life, and cuts through Medicare will make matters worse. People on dialysis are human beings who deserve quality care and dignity.”

Impact to overall health care costs due to increased hospitalizations

Over the years, improvements in patient care and quality, including a decrease in hospitalizations, have occurred. AKF believes reductions in payment for dialysis could halt or reverse progress made in this area, as well as increase the risk of patient mortality. If quality-focused outpatient dialysis care is not accessible in a patient's community, they may be forced to be admitted to hospitals to receive their treatments, driving up overall health care costs.

III. AKF supports the goals of the Quality Incentive Program, but a number of administrative and technical issues must be addressed with the proposed measures for PY 2016

The American Kidney Fund appreciates the opportunity to offer comments on the QIP provisions in the Proposed Rule. We appreciate the efforts made to date to ensure that payment is linked to quality outcomes and support the clinical topics chosen for measure inclusion to date. However, we continue to have concerns about the quality and appropriateness of the QIP measures, as well as the ability of many of the measures to have a positive impact on patient care and outcomes.

As it relates to the QIP and quality measures enacted or suggested to date, we support the following principles:

1. All measures used in a quality incentive program must be based on science and strong consensus that the measures indeed improve patient morbidity, mortality, patient experience with care and quality of life.
2. If a measure has demonstrated evidence base and consensus on improving patient outcomes or experience with care, then specifications and data collection must be appropriately tested and evaluated prior to inclusion in the QIP.

3. If a measure is used in the QIP, it should not divert human or financial resources to the extent that other aspects of quality care are jeopardized.

4. The number of measures in a QIP must be manageable and must not distract from other aspects of holistic patient care.

Review of the proposed measures, as well as discussions with members of the renal professional community, has led us to conclude that there are a number of measure issues, i.e., lack of evidence base as well as technical and/or administrative problems, that must be addressed and corrected before the ESRD QIP measures can truly affect the goal of the QIP, i.e., improved patient outcomes and satisfaction with care.

We urge CMS to give serious consideration to thoughtful comments made by KCP and professional organizations about the very real issues with measures already in the QIP as well the current proposed measures.

The ICH CAHPS measure is a prime example of the concerns surrounding many of the proposed measures.

While we recognize the importance of and strongly support evaluating patients' experiences when receiving dialysis, we are concerned about the burden of ICH CAHPS on patients and providers as well as the deviation of administrative specifications from AHRQ's tested approach.

First, we are very concerned about the length of the survey, as well as the requirement to answer 29 core items in order for a survey to be complete. Patient survey fatigue is likely to result in incomplete surveys that will benefit no one. We continue to support the recommendation that CMS allow the vendor to divide the survey into AHRQ's three independently verified domains when administering it, so that patients will answer one-third of the survey plus the core demographic questions. If a facility's patients would be divided into thirds, each receiving a different component of the test, a valid assessment of performance could be obtained.

Second, CMS proposes that the ICH CAHPS survey be administered twice yearly. AKF strongly urges CMS to reduce the requirement to annually, as in PY 2015, utilizing the single-domain administration approach discussed above. This would reduce administrative cost and burden, while allowing facilities the time needed to analyze survey results and subsequently develop and implement action plans for needed improvement.

Third, the specifications for this measure should clearly state that aggregate responses will be provided to facilities so that appropriate quality improvement actions based on the data can occur. We understand that reporting individual patient responses would be inappropriate.

Fourth, CMS's proposed revised administrative specifications for ICH CAHPS include homeless persons as eligible for surveying. This population is excluded from the AHRQ administrative specifications. Because of the hardships that homeless persons may face in accessing the survey and that facilities and vendors may face in surveying this patient population, we recommend that, consistent with the AHRQ administrative specifications, individuals who are homeless should be removed from the list of eligible patients.

Fifth, we believe it is important for the CMS administrative specifications to provide an opportunity for facilities to ensure that the primary survey and/or any follow-up is delivered to the most current contact (phone or mail) given the penalty that applies for non-responsiveness.

Finally, AKF continues to be concerned that the CAHPS survey does not address experience of care for patients other than those on in-center hemodialysis. The experience of care for all patients on dialysis should be assessed by CMS.

In summary, AKF urges CMS to address the expressed concerns about the ICH CAHPS survey as well those expressed about the other modified and proposed measures before their incorporation into the QIP 2016 final rule.

IV. AKF recommends that CMS continue to work with the kidney care community to develop future measures and strategic goals for the QIP

As noted in past comments, CMS should develop a more transparent and inclusive approach to measure development. CMS should consider not only the input of outside entities but that of all stakeholders within the kidney care community to ensure that moving forward the process for measure development is inclusive. CMS should also provide continuing monitoring of the measures to ensure that they are updated based upon science and practice.

Thank you for your consideration of our comments.

Sincerely,



LaVarne A. Burton
President and CEO