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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-G2
200 Independence Avenue, SW
Washington, D.C. 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; Proposed Rule

Dear Ms. Tavenner:

The American Kidney Fund is our nation's leading charitable health organization fighting kidney disease through direct financial support to patients in need; health education; and prevention efforts. We appreciate the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System. As a patient advocacy organization, we focus on policies that improve the quality of life and care for patients with kidney disease.

The American Kidney Fund is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies to improve the quality of care for individuals with both chronic kidney disease (CKD) and ESRD. KCP has submitted comments on the rule and AKF supports those comments.

The American Kidney Fund supports CMS and the rule-making process. We are pleased that CMS recognizes the need to provide an update to the base rate, as well as maintain the transition adjuster at zero. At a time when the Medicare ESRD program is undergoing significant changes and facing the strong possibility of additional cuts as part of the sequestration process, it is important to retain savings where applicable. We do, however, remain concerned about a few specific aspects of the ESRD PPS that the Agency has not addressed.

I. Case Mix Adjustors

Race Adjustor

AKF has commented in previous letters about the correlations that exist between race and cost. Racial and ethnic disparities in ESRD persist, with 2009 incident rates in the African American and Native American populations 3.5 and 1.9 times greater, respectively, than the rate among whites. African Americans represent 13 percent of the U.S. population, but make up 37 percent of those on dialysis. Among those individuals of Hispanic background, the ESRD rate is 1.5 times higher than among non-Hispanics.¹

CMS has noted that required utilization and spending levels are higher on some separately billable drugs for minority patients. Nonetheless, the proposed payment system will include these drugs in the bundle without adequately accounting for the higher cost of minority patients. If CMS reimbursement to cover the cost of racial minorities is inadequate, it could have a negative financial impact on facilities that treat a large number of such patients and subsequently limit access to care.

Under the Medicare Improvements for Patients and Providers Act (MIPPA), there is a requirement that the ESRD payment system include an adjustor that may include the race of a patient. CMS has a great deal of data regarding race provided by the Medicare Enrollment Database (EDB) and the Renal Management Information System (REMIS); however, CMS has repeatedly cited challenges in evaluating data needed to establish race as an adjustor.

The American Kidney Fund believes that these two data sources provide sufficient data to inform decisions regarding race and that CMS currently has the means to implement a case-mix adjustor based on race. AKF also believes that the Medicare data surrounding race is just as reliable as the data used to implement other case mix adjustors that CMS has incorporated.

The American Kidney Fund believes that CMS should evaluate the most current data available in order to incorporate race as an adjustor in the final rule.

II. Oral Drugs

The proposed rule does not indicate how CMS plans to implement the inclusion of oral drugs in the payment bundle in 2014. Consistent with our previous comments, the American Kidney Fund remains concerned that including oral drugs without an IV equivalent in the payment bundle may limit patient access to the most clinically appropriate drugs and threaten optimal outcomes. We are also concerned that CMS has not put forth any measures or recommendations for tracking usage and monitoring outcomes.

To help ensure that Medicare beneficiaries have access to high-quality dialysis care, the Government Accountability Office (GAO) recommended that the Administrator of CMS assess the extent to which the bundled payment for dialysis care will be sufficient to cover an efficient

¹ U.S. Renal Data System 2011 Annual Data Report

dialysis organization's costs to provide such care when the bundled payment expands to cover oral-only ESRD drugs. In addition, in order to ensure effective monitoring of treatment of mineral and bone disorder, GAO recommended that the Administrator of CMS continue collecting data for quality measures related to this condition from sources such as the Elab Project until CROWNWeb is fully implemented. GAO recommended that assessment of this data should be completed before implementing the expanded bundled payment.

The American Kidney Fund remains opposed to including Part D oral drugs that do not have intravenous equivalents in the payment bundle until CMS addresses issues of access, quality measures and outcomes, and disbursement. As the process moves forward, we encourage CMS to use the most recent data available and an appropriate methodology to calculate the bundled payment when oral-only drugs are incorporated into the bundle in CY 2014.

We recommend that CMS include a position in the final rule on how it plans to incorporate oral drugs in 2014.

III. PY2014 and PY2015 QIP

The Medicare benefit has provided access to care that has extended and improved the lives of many ESRD patients. We applaud CMS for its commitment to efficiency and high quality of care for individuals living with ESRD, particularly through the development of the Quality Incentive Program (QIP). For over 30 years, CMS has made monitoring the quality of care provided to ESRD patients and provider/facility accountability important components of the Medicare ESRD payment system. As such, it is important to continue to focus on the original intent and major goals of the program:

a. Continue to establish performance periods that align with incentives and the basic principles of quality improvement.

AKF has commented in previous letters that basing payments on retroactive performance data does not achieve the basic purpose of the QIP, which is to change performance and drive quality. We were pleased that, for the first time in the brief history of the QIP, the PY2014 performance measures were finalized prior to the start of the PY2014 performance period, CY2012. With the proposed PY2015 QIP performance period set as CY2013, AKF encourages CMS to finalize the performance measures and performance standards in a timely manner to ensure that facilities continue to be given appropriate targets and guidelines on the performance measures that will impact future payments.

b. Ensure transparency in the further development of the QIP process.

As CMS develops additional performance measures for the QIP, it is important to work closely with advocacy groups and others within the kidney care community. The American Kidney Fund believes that CMS and the kidney community should agree prospectively on the

process and timeline for development of future performance standards. There should not be surprises or changes that could adversely affect patient care.

c. Ensure that the primary purpose of QIP is to drive quality improvements for patients rather than a method to cut program spending.

CMS should continue its work to develop quality-based incentive programs to reward facilities for meeting and exceeding national performance standards as well as making defined strides in improving quality of care. Facilities that perform below national standards should be penalized, but those that consistently meet or exceed performance standards should receive incentives. On balance, funds should not be taken out of the system. They should remain in the system so that patient care is further improved.

d. Ensure that measures selected are the best determinants of quality of care and that patients have continued access to quality care.

MIPPA requires the Secretary to select performance measures for the QIP. As such, the American Kidney Fund believes that the selection of these performance measures should be based on what best determines increased survival, decreased hospitalizations and improved quality of life; that monitoring should be provided to ensure appropriate levels of care; and that patients should be neither under treated nor over treated.

While AKF appreciates the addition of the anemia management reporting measure in PY2015 and beyond, we remain very concerned that having a bundled payment system that imposes an upper ceiling on medications that treat anemia without a clear minimum standard of care could adversely affect patients by, among other things, increasing the need for transfusions. Therefore, we ask CMS to take actions to provide patient protections. While hemoglobin less than 10 is not included as a pay metric at the current time, setting a lower level standard is still very important to patient safety. Therefore, CMS should continue to monitor anemia management indicators and trends and should make such data publicly available on a current basis. Furthermore, CMS should work with the American Kidney Fund and others in the kidney care community to determine the feasibility of including a clinically appropriate lower hemoglobin measure in the QIP for payment.

IV. Bad Debt

The proposed rule seeks to implement the new bad debt requirements established in the Middle Class Tax Extensions and Job Creation Act. The American Kidney Fund continues to be concerned about the stream of reductions imposed on the ESRD payment system. With reductions associated with the implementation of the ESRD payment bundle and Quality Incentive Program, and potential cuts as a result of the Budget Control Act, we believe that quality and access could be hindered.

Thank you for your consideration of our comments. We look forward to continuing to work with CMS and the Department of Health and Human Services to ensure that Medicare beneficiaries with ESRD continue to have access to necessary health services.

Sincerely,



LaVarne A. Burton
President and Chief Executive Officer