



August 22, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

Kidney Care Partners (KCP) appreciates that opportunity to provide comments on the “End-Stage Renal Disease Prospective Payment System [ESRD PPS], Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model Proposed Rule” (Proposed Rule). This letter addresses the proposals related to the questions concerning alternative payment models set forth in the Proposed Rule. We have provided our comments on the ESRD PPS and Quality Incentive Program in separate letters.

I. KCP continues to support efforts to improve care coordination for patients with Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) because better coordination improves patient outcomes and quality of life, while reducing overall health care spending.

The proper management and treatment of the later stages of CKD and ESRD is extremely time intensive, which usually involves dialysis three to four times a week with each session lasting three to four hours. Individuals with CKD and ESRD do not live with this disease in a vacuum, but typically have one or more serious co-morbidities, such as diabetes, high blood pressure, cardiovascular disease, and congestive heart failure.

KCP has consistently supported efforts to develop and implement other care models, such as the Special Needs Plans (SNPs) and the Comprehensive ESRD Care (CEC) model, that advance care coordination for ESRD patients. The high costs associated with patients’ care and the complexity of their clinical and non-clinical needs warrant this additional focus. In our view, the considerable time that ESRD

patients spend at dialysis facilities creates a strong rationale for care models that support dialysis facilities and clinicians with substantial kidney care expertise in assuming greater leadership and accountability roles in serving ESRD patients currently receiving care in the Medicare program.

Therefore, we are pleased that CMS continues to engage KCP and others in a dialogue about how to improve care coordination and develop alternative payment models. We have outlined our responses to the ten questions set forth in the Proposed Rule and look forward to continuing to work with the Agency as these models develop and evolve.

As a threshold matter, KCP does not support creating a mandatory model for either CKD or ESRD patients. As we have monitored the development of other mandatory models, there have been significant questions about the authority of the Secretary to use them in other settings. It is also not clear how such models will impact patient care, with the incentives being strongly focused on certain upstream providers reducing downstream costs incurred by other providers. Instead, we encourage CMS to focus efforts on getting the initial CEC Model right and expanding the options available through that model and other like models, rather than consider a mandatory model for CKD or ESRD at this time.

In addition, we recommend that as CMS works with the kidney care community to design new models, it include mechanisms to account for and support innovation.

A. KCP urges CMS to immediately improve care coordination by requiring hospitals to provide dialysis patient treatment information to dialysis facilities when they are discharged or released from an inpatient stay.

As a threshold matter, the most important first step CMS could and should take is to promote the flow of information among providers who are working with CKD and ESRD patients. KCP has consistently requested that hospitals be required to provide information about the care dialysis patients receive when they are admitted to a hospital once they are discharged or released.

Sharing hospital treatment and discharge information is particularly important to ensure the continuity of care for dialysis patients. As the preamble to the 2015 hospital discharge proposed rule notes, “[p]atients’ post-discharge needs are frequently complicated and multi-factorial, requiring a significant level of on-going planning, coordination, and communication among the health care practitioners and facilities currently caring for a patient.”¹ This statement is

¹80 *Fed. Reg.* 68126, 68127 (Nov. 3, 2015).

especially true for dialysis patients who have multiple comorbidities, require a substantial number of medications, and require dialysis treatments three to four times a week. Their dialysis facilities and nephrologists must calibrate their treatment protocols to ensure appropriate care. This includes appropriately removing volume to prevent either heart failure or hypotension; administering and dosing medications in such a way to ensure that important medications are not removed with dialysis; ensuring that medication dosing is correct for a person with no kidney function; knowing what medications need to be administered with dialysis; treating other complications and health issues (including blood pressure and nutrition); addressing important social issues that may have arisen during the hospitalization (including awareness of changes in advance directives); and managing bleeding and clotting issues that can occur with the provision of dialysis. All of these are critical to providing quality care for our patients.

Yet, for the vast majority of patients, their dialysis centers and nephrologists are never told of the care they are provided when hospitalized. This lack of sharing of information creates a black hole that places patients at higher risk of complications, unnecessary treatment, and future hospitalizations.

Despite efforts by KCP members, it has been extremely difficult to obtain discharge or other information from hospitals. We appreciate that there are many demands on hospital staff. Often, requests from dialysis facilities or nephrologists go unanswered. Thus, we are extremely pleased that the Proposed Rule would require hospitals to send to patient's other health care providers: (1) the discharge instructions and discharge summary within 48 hours; (2) pending test results within 24 hours of their availability; and (3) all other necessary information specified in the "transfer to another facility" requirements.² While some patients may tell hospitals about their nephrologists and dialysis facilities, others may forget. Therefore, we encourage CMS to clarify that hospitals must also provide this information upon request by a dialysis facility, as well as when a request is made by a nephrologist.

Having information about a patient's stay in the hospital is critically important to providing the appropriate care once he/she has been discharged or released. For example, providing erythropoietin stimulating agents (ESAs) is an essential part of a dialysis patient's treatment. Calibrating the dosage is important to ensure that patients' hematocrit levels remain within the appropriate range. Often, however, when a dialysis patient is hospitalized, neither the dialysis facility nor the nephrologists are told whether the patient received an ESA while hospitalized. Patients often do not remember what medications they did or did not receive and hospitals do not respond to requests from the dialysis facilities to obtain

²*Id.* at 68135.

the information. This lack of information could result in either over- or under-dosing of an ESA.

Similarly, it is important to understand how a patient's weight changes to assess fluid overload. Fluid overload is a leading cause of rehospitalization for dialysis patients. It is important to have sufficient data from a patient's hospitalization to allow the patient's care team to remove the appropriate amount of fluid.

Dialysis patients often require specialized care from a number of different providers across the health care system. There is no question that these patients would benefit from enhanced care coordination. Having information about what treatments/medications provided during a hospital stay, as well as discharge summaries and discharge instructions, would improve the coordination of care. Without such data, dialysis facilities and nephrologists do not have sufficient information to make sure that patients are receiving the appropriate care post-discharge.

Therefore, we ask that CMS clarify that hospitals must also provide this information upon request by a dialysis facility, as well as to a nephrologist. This information should be provided as quickly as possible, but no later than 48 hours after the discharge or release (or within 48 hours of the date of the request, if made by a dialysis facility and/or nephrologist). This timeframe would allow dialysis facilities to address readmissions, consistent with the expectation set forth in CMS's Standardized Readmissions Ratio (SRR) measure specifications, which requires dialysis facilities to assume responsibility for readmissions after 72 hours. This requirement will promote efficiency and patient safety as patients transition from a hospital to a dialysis facility.

B. Alternative Payment Models and Advanced Alternative Payment Models can advance care for beneficiaries with CKD.

More than 10 percent of adults in the United States may have some level of CKD. The chances of having CKD increase after age 50 and are most common among adults who are 70 years or older. Diabetes, high blood pressure, cardiovascular diseases, obesity, high cholesterol, lupus, and family history are all risk factors for developing CKD. Individuals with CKD who also have diabetes or high blood pressure are at higher risk of having their kidneys fail. Infections, drugs, or toxins can also lead to kidney failure, especially in patients with CKD.³ CKD patients should not be limited to only those who have yet to receive dialysis or a transplant, but should also be defined to include post-transplant patients with reduced kidney

³Centers for Disease Control and Prevention (CDC), "National Chronic Kidney Disease Fact Sheet, 2014" available at http://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf.

function. These patients may also have clinical conditions associated with CKD Stages 3 or 4 and would benefit from the same care coordination and interventions.

Yet, the vast majority of individuals living with CKD may not even know they have the diseases. Each year, more than 100,000 of individuals with CKD begin dialysis because the disease has progressed to complete renal failure.⁴ Unfortunately, tens of thousands of these individuals “crash” into dialysis.⁵ Crashing into dialysis requires emergency hospitalization, placement of temporary vascular accesses, and costly medications to treat complications. Patients experience longer hospital stays, more frequent readmissions, and higher mortality rates.⁶ We know today that 42 percent of all new dialysis patients being treated had not been followed by a nephrologist prior to their initiation of dialysis.⁷ There is no question that “substantial opportunities exist to improve care for this population.”⁸

Primary-care physicians can help monitor at-risk patients and monitor for the development of CKD. Once an individual is diagnosed with CKD, it is important that he/she manage the disease. Controlling blood sugar and blood pressure can help prevent or delay the onset of kidney failure.⁹ A nephrologist can provide the proper treatments to slow the progression of the disease and minimize complications. The NKF recommends that patients consult a nephrologist when their eGFR dips below 30 ml/min/1.73 m². Treating CKD patients requires an interdisciplinary approach. Patients can also benefit from comprehensive conservative care.

It is important to recognize that different interventions are needed at different stages of CKD. The National Institutes of Health (NIH) has indicated that “CKD is generally progressive and irreversible.”¹⁰ Yet, there are steps that can slow the progression of CKD to ESRD. The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) is currently funding the Chronic Renal Insufficiency

⁴U.S. Renal Data System (USRDS), *USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, 216 (2013) available at http://www.usrds.org/2013/pdf/v2_ch1_13.pdf.

⁵ Jeffrey L. Hymes, “Earlier Diagnosis, Patient, Education and Integrated Care Can Help Reduce the Prevalence of Dialysis Crash Starts,” *Beckers Hosp. Rev.* (July 22, 2014) available at <http://www.beckershospitalreview.com/quality/earlier-diagnosis-patient-education-and-integrated-care-can-help-reduce-the-prevalence-of-dialysis-crash-starts.html>.

⁶*Id.*

⁷USRDS, *supra* note 4, at 226.

⁸ Pradeep Arora, Peter L. Elkin, *et al.* “An observational study of the quality of care for chronic kidney disease: a Buffalo and Albany, New York metropolitan area study,” 16 *BMC Nephrol.* 199 (2015) available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669622/>.

⁹*Id.*

¹⁰National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), “Slow Progression and Reduce Complications,” *Managing Patients with CKD* available at <https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/identify-manage/manage-patients/slow-progression/Pages/slow-progression.aspx> (last accessed July 24, 2016).

Cohort (CRIC), which is examining risk factors for progression of CKD and the occurrence of cardiovascular disease among patients with CKD.¹¹ APMs and AAPMs could benefit from the results of this study that may result in new treatment trials and/or modifications to current guidelines for reducing the risk of CKD.

APMs and AAPMs have the potential to assist patients with CKD by recognizing the existence of kidney disease, implementing appropriate action step at each stage of CKD, and, if CKD does progress, preparing patients for eventual dialysis, transplantation and/or comprehensive conservative care. Early detection of CKD followed by appropriate care provision for individuals with CKD are the critical first steps toward improving the care transition. Detecting CKD earlier in patients is the first step toward improving the care transition. There are interventions that can slow the progression of the disease, but only in the early stages. For those patients who will eventually require dialysis, advanced planning is critical to improving their overall outcomes and quality of life once their kidneys fail.

APMs and AAPMs tailored to treating patients with CKD can help coordinate and provide the services necessary to successfully transition patients to dialysis, transplant or comprehensive conservative care. These services include patient education about exercise, diet, medication, as well as modality choice and vascular access. The current Medicare Kidney Disease Education (KDE) benefit, which KCP advocated for and continues to support, is woefully underutilized. APMs and AAPMs could ensure that patients are aware of this and other benefits that seek to improve patient education.

These models could also help manage the multiple comorbidities that CKD patients often have. For example, a recent study indicated that hypertension was present in 89 percent of patients with CKD, while 42.3 percent of patients had diabetes. Cardiovascular diseases are also common and increase in prevalence as the disease progresses. Other comorbidities commonly reported in CKD patients include depression (17 percent), anxiety (15 percent), and other mental illnesses (28 percent).¹²

For those CKD patients who are not on renal replacement therapy, interventions can focus on slowing the progression of the diseases and efforts to delay the onset of kidney failure. These interventions would include educating patients about ways to modify their lifestyles, addressing nutrition, as well as more effectively managing comorbidities, such as diabetes and cardiovascular disease. For patients in the earliest stages of CKD, it may be appropriate to manage them through other programs, such as those related to diabetes. Addressing these

¹¹*Id.*

¹² Arora, *supra* note 8.

comorbidities before CKD progresses is likely to be the most effective way to slow the progression of the disease. Interventions may impact not only the speed at which the disease progresses, but also morbidity, mortality, and quality of life patients experience for years after they begin dialysis.

Special attention should be paid to addressing the disparities minority populations face when it comes to CKD, as well. KCP has long-supported legislation that calls on the Secretary to complete a study on: (1) the social, behavioral, and biological factors leading to kidney disease; (2) efforts to slow the progression of kidney disease in minority populations that are disproportionately affected by such disease; and (3) treatment patterns associated with providing care, under the Medicare and Medicaid programs and through private health insurance, to minority populations that are disproportionately affected by kidney failure.

We know that in addition to the challenges of the diseases, many racial and ethnic minorities experience other barriers that can impact their ability to seek and maintain access to high quality care at all stages of the disease. Socioeconomic status likely plays a significant role in how an individual receives treatment for the precursor diseases. Enhancing educational opportunities through a variety of outlets, including schools, churches, and other local organizations, could help individuals at risk for CKD identify the risk and try to manage it earlier in the process. It is also important to provide at-risk individuals with the opportunity for earlier detection of the disease.

Insurance and the financial burden associated with it can often mean that some patients may skip treatments or not fill prescriptions to manage their underlying conditions. Often patients crash into dialysis because there were no incentives to manage them before the onset of kidney failure.

Much more can be done to address these issues. Therefore, we encourage the Secretary to undertake the study outlined in H.R. 1130 and S. 598 to begin the process of identifying the barriers to care and finding ways to eliminate them.

C. More comprehensive alternative payment models, such as SNPs, ESCOs, and other potential models, can advance care for beneficiaries with ESRD.

In the later stages of the disease, comprehensive models that include dialysis facilities, physicians, nurses, and other health care professionals can better coordinate patient care and prepare patients for receiving dialysis. These models exist today in the form of SNPs and ESCOs. Some Medicare Advantage plans also promote greater coordination among the full range of providers caring for dialysis patients. At this stage, interventions cannot halt the progression of kidney failure,

but only help the patient manage their dialysis and refer those who are eligible for transplant.

The more comprehensive models can assist patients in their transition to dialysis by providing educational opportunities to learn more about the disease and discussing treatment options. For example, it is important to expand the KDE education benefit to allow dialysis facilities, in addition to the health care professionals who are currently designated, to be able to provide the KDE education sessions and bill for them. These comprehensive models could also work with patients to identify the right modality of dialysis for them and plan for the appropriate dialysis access. They could also coordinate care to reduce infections, ensure appropriate nutrition, manage anemia and mineral and bone disorders, address mental health problems that may arise, and continue to manage patients' ongoing comorbidities. As recent studies indicate:

the positive effects of early intervention programmes suggest that multidimensional approach might improve outcome in the transition period of the start of dialysis. Next to adequate preparation of the patient for dialysis therapy including access care, individualized and targeted prescription of dialysis treatment, attention for diet and physical rehabilitation, 'just in time' starting of dialysis and adequate treatment of comorbid disease are all likely important in improving outcome during this critical period.¹³

As with CKD patients, it is critically important to better understand the disparities minority populations face when it comes to ESRD. We have long supported legislation that calls on the Secretary to complete a study that includes, as noted above, identifying treatment patterns associated with providing care, under the Medicare and Medicaid programs and through private health insurance, to minority populations that are disproportionately affected by kidney failure.

While it is true that once an individual develops ESRD, he/she may enroll in Medicare, there are still burdens that can make it difficult to consistently follow treatment protocols, including transportation problems and not having access to Medigap policies. In some instances, patients who want to remain in their private insurance because of the needs of other family members or reduced financial obligations are finding themselves being discriminated against and forced into Medicare; but again, they have not been properly managed perhaps because insurers understand they will not have to provide services to these patients after the first three months of the disease. Often racial/ethnic minority patients find themselves experiencing these problems more often than other patients might.

¹³ Natascha J.H. Broers, Anne C.M. Cuijpers, *et al.*, "The first year on haemodialysis: a critical transition," 8 *Clin. Kidney J.* 271-277, 277 (2015).

Much more can be done to understand and address these barriers. Therefore, we reiterate our recommendation that the Secretary undertake the study outlined in H.R. 1130 and S. 598 to begin the process of identifying the barriers to care and finding ways to eliminate them.

More comprehensive care coordination models can also work with patients more effectively to help them select the treatment option, including comprehensive conservative care, that is best for them. Nephrologists evaluate patients for the suitability for home dialysis, taking into account the unique situation of each patient including his/her comorbidities, ability to manage the treatment, and family/caregiver situation. It would not be appropriate to try to create a one-size-fits all approach. According to the GAO, the factors affecting the type of dialysis a patient receives include:¹⁴

- Patient preferences, such as travel distance to a dialysis facility and being able to dialyze at night;
- A patient's willingness and ability to undergo training and "assume other responsibilities that they would not otherwise have if they dialyzed in a facility";
- The availability of a spouse or caregiver to help them manage home dialyzing;
- Whether a patient has crashed into dialysis and needs an urgent start versus having been managed by a nephrologist prior to kidney failure;
- Other conditions a patient may have, such as poor vision, dexterity, previous abdominal surgeries, or multiple chronic comorbidities.

Comprehensive care coordination models can most effectively work with patients who may be appropriate candidates for home dialysis by engaging in informed decision-making. In addition, the kidney care community is already working on ways to better understand why some patients start and then stop home dialysis and evaluating what specific educational approaches may be appropriate to help patients make informed modality choices.

Another area in which these comprehensive models can improve patient outcomes is in access to transplantation. KCP supports efforts to increase access to renal transplantation. More than 375,000 kidney transplants have been performed in the United States. In 2012, 191,400 patients were living with a functioning transplanted kidney. Yet more than 100,000 patients are waiting to for a transplant.¹⁵

¹⁴GAO, "End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis" 8-9 (Oct. 2015).

¹⁵Bradley H Collins, MD, Ron Shapiro, MD, *et al.*, "Renal Transplantation," *MedScape* (Oct. 1, 2015) available at <http://emedicine.medscape.com/article/430128-overview> last accessed July 24, 2016.

There are many factors that influence whether a patient will be referred for transplant. Comprehensive care coordination models are uniquely positioned to help shepherd patients through the process, leading to more CKD and ESRD patients being referred for transplant. They can help address factors that are common contraindications for transplant. They could work to manage infections, which can be a contraindication of a transplant. Similarly, properly managing comorbidities, such as diabetes and hypertension, may allow more patients to be eligible for a renal transplant.¹⁶ Such models also help patients navigate the pretransplantation evaluation process.

CMS could also incentivize efforts to increase rates of renal transplantation. Measures assessing patient education, referrals to transplant centers, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process could be used to assess the success of these interventions. While there are positive steps comprehensive models can take to try to increase renal transplant, there are many factors that fall outside of their control, such as insurance and financial burdens, making a penalty-based approach inappropriate.

However, the Agency should recognize that one particularly difficult aspect of the transplant process is coordinating with transplant centers. It is important that transplant centers have and maintain an accurate, up-to-date list of potential transplant recipients. When properly maintained, these lists expedite the matching process, but when they are not they create an unnecessary barrier that can negatively impact patients. Standardizing data (such as tests and checklists) across transplant centers could help as well. Enhancing data sharing would improve the ability to match patients and access to transplant.

To succeed, the current comprehensive care coordination models, as well as potential future models, need to be economically stable and viable by providing adequate funding for the services provided and including appropriate risk adjusters. These models should also allow for evolution over time and permit the entrance of new providers. KCP continues to support providing multiple models that would allow facilities of all types and sizes and in various geographically diverse locations be able to participate in alternative payment models. KCP encourages CMS to work with us and others in the kidney care community to encourage innovations that can help improve care coordination.

II. Conclusion

KCP appreciates the Agency's continued willingness to engage with KCP and others in the kidney care community to develop and refine APMs and AAPMs, which can be helpful for patients in the earlier stages of CKD. We stress that for ESRD

¹⁶*Id.*

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patients especially, it is important to promote care coordination in comprehensive models that include dialysis facilities, physicians, nurses, and other health care professionals in an effort to help improve quality of life and outcomes for patients with ESRD. Please do not hesitate to contact Kathy Lester at (202) 534-1773 if you have questions about our comments or recommendations. We look forward to continuing to work with CMS on these issues.

Sincerely,

A handwritten signature in cursive script that reads "Frank Maddux M.D." with a stylized flourish at the end.

Frank Maddux, M.D.

Chairman

Kidney Care Partners

Appendix A: KCP Members

AbbVie
Akebia Therapeutics, Inc
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Baxter Gambro Renal
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners Inc.
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medicare Care Renal Therapies Group
Greenfield Health Systems
Hospira
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical, Inc.
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Health Care
U.S. Renal Care