KIDNEY CARE
PARTNERS

March 29, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, NW
Washington, DC 20201

Dear Administrator:

On behalf of Kidney Care Partners (KCP), I am writing to applaud the Agency for developing the Comprehensive ESRD Care (CEC) Initiative (Initiative). It is a positive step forward and extremely important to beneficiaries with kidney failure because it recognizes the unique nature of the care they receive. KCP shares and supports the Agency's goals to improve care through better coordination. Thus, we seek to provide you with our recommendations as to how the Initiative could be improved to ensure its success. We urge the Agency to address these recommendations as quickly as possible to allow the Initiative to move forward.

KCP is an alliance of members[1] of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD).

As a threshold issue, we want to thank the Agency for extending the deadline for submitting an application to July 1. This important step will provide those organizations that would like to participate more time to develop their proposal. We also hope that it will allow CMS to take into account and provide some of the refinements to the requirements that we highlight in this letter.

Because KCP members view the CEC Initiative as a way to allow those who care for beneficiaries with kidney failure to provide innovative care strategies, we urge the Agency to re-examine certain aspects of the Request for Application (RFA) and refine it so that the Initiative will provide participating organizations with the best opportunity possible to provide patient-centered, high-quality care. In sum, KCP recommends that the Agency:

[1] *See* Appendix A for list of members.

- Protect beneficiaries with kidney failure by ensuring that they receive care from those providers best able to provide it by matching ESRD beneficiaries to an ESRD Seamless Care Organization (ESCO) preferentially even if they had previously been matched to an Accountable Care Organization (ACO) or a dual demonstration project.

- Refine the economic framework so that ESCOs would be subject to similar rules and methodology as the majority of ACOs and would be permitted to operate with fewer than 500 beneficiaries so that all types and sizes of facilities may participate in the Initiative.

- Measure quality performance using metrics tailored to the unique nature of beneficiaries with kidney failure, which means that measures should be ESRD specific and supported by a community-based, evidence-driven consensus-based process established to develop quality metrics specifically for the CEC Initiative and that includes patients, facilities, physicians, and other stakeholders.

- Allow for ESCOs to be formed and participate after the first year.

I. The CEC Initiative should protect beneficiaries with kidney failure by ensuring that they receive care from those providers best able to provide it by matching ESRD beneficiaries to an ESCO preferentially

The kidney care community is well situated to accomplish the goal of providing patient-centered, high-quality, integrated care to patients with kidney failure. As the principal providers for patients with kidney failure, dialysis facilities and nephrologists are in the best position to determine how to establish integrated care models that improve quality and increase efficiencies for this unique patient population. Thus, we believe that to be successful the CEC Initiative must permit beneficiaries enrolled in ACOs or one of the dual demonstration projects to be matched to an ESCO preferentially.

For patients, being matched to an ESCO means having the opportunity to work with a team of providers whose expertise is in caring for individuals living with kidney failure and implementing new and innovative strategies for delivering disease-specific care. Dialysis facilities and nephrologists, not hospitals or primary care physicians, are in the best position to promote accountability for the population of patients with kidney failure, as well as to coordinate Parts A and B services for these patients. Dialysis facilities and nephrologists engage directly with beneficiaries with kidney failure much more frequently than hospitals or primary care physicians because most ESRD beneficiaries receive dialysis treatments in facilities at least three times a week. Nephrologists see patients between one and four times each month. This frequency of direct patient contact, which is necessary

and unique within the Medicare program, allows providers the opportunity to work closely with their patients to educate them about their disease, co-morbidities, and treatment options. It also provides for closer patient monitoring. Thus, restricting access to the ESCOs based upon previous assignments to ACOs or other demonstration projects will disadvantage beneficiaries. Indeed, having recognized that the unique needs of this patient population are better addressed through a renal-specific integrated care program like the CEC Initiative rather than through primary care-focused ACOs, CMS is ill-served by an attribution model that excludes tens of thousands of ESRD patients from accessing the benefits of the CEC Initiative's innovative model.

For physicians and providers seeking to participate in the initiative, the matching restriction may make it difficult to meet the minimum number of beneficiaries required to participate. In fact, the matching restriction places physicians and providers in the difficult position of having to apply to form an ESCO without even knowing whether there are sufficient Medicare beneficiaries in a given market to satisfy the minimum beneficiary requirement. Also under the current framework, beneficiaries within a single facility could be divided between an ACO, duals demonstration project, and an ESCO – all of which could be focusing on different care strategies. Trying to administer different care models would be extremely difficult and quite possibly, unnecessarily burdensome. While a facility could decide not to participate in an ESCO to avoid this problem, such an alternative may not be the most appropriate for patients, especially if the ESCO would allow for better disease-specific care and outcomes. Thus, it would be far more effective and efficient to match ESRD patients with ESCOs and remove these patients from other demonstration projects to which the patients have previously been assigned.

II. The Agency should refine the economic framework so that ESCOs would be subject to similar rules and methodology as the majority of ACOs and would be permitted to operate with fewer than 500 beneficiaries so that all types and sizes of facilities may participate in the Initiative

We appreciate the Agency's focus on an ESRD-specific integrated care model. However, there are a few refinements that we believe are necessary to address the unique nature of this population. Most importantly, the framework sets the bar higher than that set for most of the Medicare Shared Savings Program (MSSP) ACOs when, in fact, the frameworks should be similar. We applaud the Agency's recognition that all types and sizes of facilities should be allowed to participate, but as a practical matter the current 500 beneficiary minimum requirement will not allow for this goal to be achieved and will unnecessarily limit beneficiary access to ESCOs.

First, the proposed economic model does not account for the unique nature of ESRD patients, who often have multiple co-morbidities. Specifically, the benchmark methodology should take into account increasing patient morbidity and

other unique features of the ESRD population. It should also not penalize providers and dialysis organizations for historically high-quality performance.

Second, the economic framework of the CEC Initiative should be consistent with that used to establish the average ACO. For example, like ACOs (including the Pioneer ACOs, which purportedly have the most experience in integrated care models), there should be no guaranteed discount and a minimum savings rate. Also like most ACOs, ESCOs should not be subject to a rebasing in subsequent years. Similarly, we request that the Agency provide clear guidance on the process for an ESCO to follow to determine whether a waiver can be obtained. Finally, like the ACOs, the ESCO models should not be tied to ownership type. Doing otherwise would run counter to how Medicare reimburses providers generally.

The ACO models also focus on providers/organizations directly related to the care of the beneficiaries. The CEC Initiative's requirement to have "other providers" participate in the risk sharing structure beyond dialysis facilities and nephrologists breaks from the ACO model. Not all beneficiaries with kidney failure see a primary care provider and in those cases facilities and nephrologists fill the primary care role. While other entities may play a role in the care of certain patients, they may not be directly linked to all or even a majority of the patients in an ESCO and, therefore, likely unwilling to participate in risk sharing. Requiring such "other providers" to participate in the risk sharing model only makes sense if they too have a consistent, ongoing relationship with the patients and could serve as a barrier to forming ESCOs if "other providers" are unwilling to participate as an owner. In sum, KCP is concerned that the more restrictive requirements of the ESCO model will create unnecessary barriers that will make it less likely for the innovative models developed by the ESCOs to demonstrate improvement in care and efficiency over time.

Third, the Agency should clarify the participation by nephrologists in the various integrated care models underway. For patients living with chronic kidney disease (regardless of the Stage), having access to a nephrologist to guide his/her care is critically important. Under the current models, nephrologists may treat patients who are pre-dialysis through an ACO and others who are Stage V and receiving dialysis through an ESCO. If nephrologists are forced to pick a model in which to participate (whether as a caregiver or an owner), then his/her patients will be forced to change doctors at a time when consistency of care is most important. Thus, we encourage the Agency to clarify that nephrologists may participate in both ESCO and ACO models.

Finally, we applaud the Agency for repeatedly indicating that all types and sizes of providers should be able to participate in ESCOs. As a practical matter, however, the 500 minimum patient requirement will create an unnecessary barrier that will prohibit many smaller dialysis facilities and nephrology practices from participating in the Initiative. We understand that the actuaries have indicated that 500 is the minimum number of patients that will allow the Agency to report

statistically valid results. Based upon the experience of our members who participate regularly in research projects and trials, there appears to be sufficient statistical validity for results if an ESCO included less than 500 beneficiaries.

The Agency and the community share the common goal of testing innovative care models that may be more effective and efficient. We would welcome the opportunity to talk with the actuaries. Together, we may find a more appropriate minimum number or identify additional models that could include less than 500 matched beneficiaries that would address this concern to ensure that all who would like to participate in the Initiative have the opportunity and are not barred by the size of the population they serve.

In sum, KCP urges CMS to revise the economic framework presented in the RFA so that it takes into account the unique health status of the ESRD patient population, is more aligned with the average ACO framework, and practically allows various types and sizes of providers to participate.

III. An independent evidence-driven, consensus-based process that includes patients, facilities, physicians, and other stakeholders should be established to develop ESRD-specific quality metrics used in the CEC Initiative

Because the reporting of quality metrics will be a key mechanism the Agency will use to verify clinical improvements, assess patient outcomes and the appropriateness of the coordination of care, and ensure continued quality of care for beneficiaries within ESCOs, it is crucially important that these metrics be tailored to the ESRD population, even if measures are not limited to more traditional ESRD metrics such as adequacy, vascular access, and anemia management. Thus, as a first step, CMS should clarify how the domains listed in RFA will be specifically developed and tailored into measures for the Initiative. Consistent with KCP's comments regarding measure adoption in the Quality Incentive Program (QIP), we urge the Agency to recognize that it is not appropriate to apply measures developed for other health care settings, such as hospitals, to the ESRD setting in a wholesale manner. The metrics established should be based upon data that are available to ESCOs and actionable by ESCOs.

As it defines these quality measures, the Agency should rely upon an evidence-driven, consensus-based process that includes participants representing the complete array of stakeholders in the kidney care community, including dialysis facilities, patients and patient advocates, nephrologists, nurses, and others. It is important to make sure that the measures reflect the clinical priorities of the community and are consistent with high-quality standards of care and clinical practice. It is also important to have these measures and the benchmark spelled out clearly and consistently prior to the application deadline so that ESCOs are well informed and can make appropriate decisions in designing their proposals.

Therefore, it would be necessary to engage with the community quickly to begin this process.

As we have also learned from members' experiences with the ESRD QIP, there should be a clear sequence of events when rolling out measures. First, the metrics must be clearly identified and defined to allow for standardized reporting. Second, the Agency should establish clear benchmarks prior to the application of measures so that ESCOs will know the targets and be able to adjust behavior if needed to meet them. We applaud the Agency for recognizing that the data needed to set the benchmarks for new measures should be obtained through a reporting phase in the first year of the ESCO. A reporting phase provides an opportunity to address any clarification or submission problems. Only after these steps are completed should the measures be linked to the sharing savings eligibility.

This process would not require slowing down the implementation of the CEC Initiative. There are already valid, ESRD tailored measures that could be considered by a community-based consensus group to establish a starter set of metrics for the Initiative distinct from those already applied in the QIP. Other metrics could be developed and integrated in subsequent years after a reporting phase as well. CMS would be able to monitor performance, but until the testing phase ended, the measure results would not be linked to eligibility for shared savings.

Once implemented, it is important to ensure that facilities already subject to the QIP would not be penalized twice for the same metrics – once through a QIP penalty and a second time by not being eligible for shared savings through the ESCO. The RFA does not explain the interaction of the two programs. Thus, we encourage the Agency to clarify how the measures selected will not result in a double penalty.

In sum, we urge the Agency to look outside of its existing technical expert panel processes and work with the kidney care community to develop a limited set of appropriate quality metrics and benchmarks for the CEC Initiative. KCP would welcome the opportunity to discuss in more detail how the community could support this process in a timely manner.

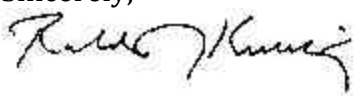
IV. CMS should allow for ESCOs to be formed and participate after the first year

The CEC Initiative provides those who care for beneficiaries with kidney failure the opportunity to break the existing care silos and to work together more closely in ways that KCP believes will improve care for beneficiaries. Given this belief, we encourage the Agency to allow organizations that might not be able to develop the necessary infrastructure to operate an ESCO by the application deadline with the opportunity to participate in subsequent years. This approach would maximize the ability of beneficiaries to benefit from the innovative models being tested. Such flexibility would seem to support the overall goals of the Agency is seeking to achieve through the Initiative as well.

V. Conclusion

As always, we appreciate the Agency's willingness to engage with the community. We also recognize that the CEC Initiative is the result of multiple conversations and meetings with the community. As noted, we share the same goals in wanting the CEC initiative to succeed. With the refinements we have outlined, we believe it can. Please do not hesitate to contact Kathy Lester at 202-457-6562 or klester@pattonboggs.com to discuss our recommendations or to answer any questions that you might have. She will be following up with you as well.

Sincerely,



Ronald Kuerbitz
Chairman
Kidney Care Partners

cc: Jonathan Blum
Richard Gilfillan

Appendix A: KCP Members

AbbVie Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
National Kidney Foundation
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care