

June 26, 2013

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Dear Ms. Tavenner and Dr. Gilfillan:

On behalf of the undersigned organizations, thank you for your leadership of the Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI). Together, our organizations represent the patients, physicians, nurses, scientists, and other health professionals dedicated to advancing excellence in the care of patients with kidney disease. Foremost among our shared goals is continuous improvement in the quality, efficiency, and accessibility of care available to patients with kidney disease.

Our organizations applaud the Centers for Medicare and Medicaid Services (CMS) and the CMS Innovation Center's establishment of the Comprehensive End Stage Renal Disease (ESRD) Care (CEC) Initiative. ESRD Seamless Care Organizations (ESCOs) present an exciting opportunity for the kidney care community to innovate in more patient-centered, coordinated ways to deliver kidney care and, ultimately, improve the lives of patients with kidney disease. We recognize and are grateful for your receptiveness to input from our organizations and other stakeholders in the kidney care community.

We also thank the Agency and the Innovation Center for addressing the concerns of the kidney care community by extending the deadline for submitting an application to August 1, 2013, and by reducing the minimum beneficiary threshold from 500 to 350 matched beneficiaries. The extension will allow many more nephrology practices, dialysis providers, and other Medicare providers to construct thoughtful, innovative proposals.

We write to request the opportunity for representatives from each of our organizations to meet jointly in-person with you or your staff after the August 1, 2013 application deadline. We wish to discuss how you envision the ESCO program moving forward based on the applications received, and to discuss our suggestions for strengthening the program in that context. Our organizations hope that our recommendations, outlined below in this communication, will be helpful as the CEC Initiative evolves in the coming months.

Our organizations appreciate CMS and the Innovation Center's consideration of these recommendations, and look forward to the opportunity to hopefully discuss them in

person later this summer. We believe that continued dialogue regarding the CEC Initiative will create the greatest chance of success for the program and for higher-quality care for patients on dialysis. An appendix to this letter includes contact information for each of our organizations.

Sincerely,

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Dialysis Patient Citizens
Renal Physicians Association
Renal Support Network

cc: Jonathan Blum, Deputy Administrator and Director, CMS
Sean Cavanaugh, Acting Deputy Director, Programs and Policy, CMMI
Patrick Conway, CMS Chief Medical Officer, Director for Center for Clinical Standards and Quality, and Acting Director, CMMI
David Hurwitz, Division Director, CMMI
The Honorable Tom Marino, Co-Chair, Congressional Kidney Caucus
The Honorable Jim McDermott, MD, Co-Chair, Congressional Kidney Caucus

Key Recommendations

Preferentially match patients on dialysis to ESCOs over other types of Medicare Shared Savings Programs (MSSP), reflecting the fact that ESCOs are specifically designed to improve care for this vulnerable patient population.

Our organizations concur with the Agency that ESCOs present a unique opportunity to provide comprehensive medical management of, and better care coordination for, patients on dialysis—and that ESCOs could result in improved outcomes and expenditure savings. The nephrology care team is focused entirely on the care of kidney disease patients, and therefore is ideally suited to accomplish these specific goals for this highly vulnerable patient population. The frequency of ESRD patient contact with the nephrology care team, as well as the fact that nephrologists commonly serve as primary care providers for patients treated with dialysis, means that ESCOs are in a substantially better position to provide more coordinated, patient-centered care than a traditional Accountable Care Organization (ACO) or other MSSP model, both of which are designed to address the needs of general patient populations.

Thus, the populations served by ESCOs and ACOs/MSSP models will differ in many important ways. Accordingly, we recommend that the Agency preferentially match patients on dialysis with ESCOs rather than other types of MSSPs, allowing dialysis patients to access ESRD-specific, focused care and creating the greatest opportunity for the success of the ESCO program. We believe this approach would also facilitate seamless transitions of care along a patient's disease trajectory.

Develop a plan to ensure consistent access to transplantation

For most patients, kidney transplantation is the optimal form of renal replacement therapy. The Request for Applications (RFA) states that an expected result of the ESCO model is an increased use of kidney transplantation. While recognizing that not every patient is an appropriate candidate for transplantation, our organizations believe that increased transplantation rates are essential to achieving the CEC Initiative's goals. We urge CMS to clarify how it will measure a participating ESCO's progress toward the goal of increased transplantation – or, at the very least, stable transplant rates within ESCOs.

Transplant candidates tend to be the healthiest patients and, by extension, the least costly and complicated dialysis patients. Given that patients who receive a kidney transplant are no longer attributed to an ESCO, our organizations are concerned that there is an unintended incentive to not transplant patients who would be good candidates for care through ESCOs. We recognize, however, that current quality metrics on transplant rates may not be sufficient. Our organizations urge CMS and the Innovation Center to clarify how it will address this problem, and welcome the opportunity to collaborate to develop a solution.

Establish and explain safeguards to monitor and address “cherry picking” or changes in outcomes.

While our organizations recognize that the Innovation Center will be contracting with an independent entity to evaluate ESCO programs, we are concerned that the RFA does not specify any plans to actively monitor for preferential patient selection. Given that beneficiaries may choose any provider and move freely among care environments, we recognize the challenge CMS may face in doing so. We suggest, however, that CMS assess ESCOs'

baseline population demographics over time. CMS could examine factors such as age, sex, race, socioeconomic status, employer group health insurance coverage, and comorbid illness burden over time, and identify whether any of these or other factors change more quickly than expected in a given ESCO market.

Develop dialysis-specific quality metrics in a transparent manner that allows for community input.

The Innovation Centers' assessment of whether ESCOs achieve quality measures will play an important role in ensuring that patients receive high-quality care through the CEC Initiative. Recognizing the important role of quality measurement in what is fundamentally an experiment in care delivery, our organizations strongly encourage CMS to engage the broader nephrology community in a transparent, iterative process to select and define quality measures, and establish appropriate benchmarks. Soliciting input from stakeholders—including patients, health professionals, dialysis providers, and other constituencies—will give the ESCO program the greatest opportunity for success and reinforce the kidney community's support for the program. Furthermore, we emphasize that any measures considered for the program should be based on as rigorous scientific evidence as possible, and be appropriate for this specific ESRD population. We enthusiastically offer to assist CMS in analysis and selection of metrics.

Prospectively specify the criteria that determine whether an ESCO is deemed “successful” or “unsuccessful.”

Our organizations recognize that the Innovation Center will be evaluating the extent to which ESCOs achieve certain quality measures and how successful ESCOs are at attaining cost savings. However, we strongly encourage the Innovation Center to prospectively specify the metrics it will use to determine whether an ESCO is a success overall. Given that the Agency may allow some successful ESCOs to continue operating their care delivery models beyond the five-year program window, transparency and mutual understanding regarding the definition of success is imperative. Our organizations request clarification of this definition prior to the start date of the ESCO program.

Facilitate investigation into and understanding of dialysis care by sharing de-identified ESCO patient data with the research community.

We believe that the ESCO program represents a prime opportunity to foster innovation in nephrology care delivery and commend CMS and the Innovation Center for creating this opportunity for the ESRD community. To build upon this benefit, our organizations strongly encourage the agency to make all data it collects from ESCOs available (in de-identified form) in the public domain for qualified investigators. We recognize that the Innovation Center will be contracting with an independent entity to evaluate the ESCO program overall, but would like to emphasize that making this data available would greatly facilitate research in dialysis care delivery. This step would follow a precedent established by the National Institutes of Health (NIH), which mandates that all data from NIH-funded research be made public within 12 months following the conclusion of investigation.

Allow nephrologists to both participate as specialists in an ACO and own an ESCO in the same market.

For patients with kidney disease to receive optimal care, it is crucial that nephrologists have the opportunity to participate in all forms of shared savings programs in a given market. Our

organizations suggest that nephrologists be allowed to both participate as specialists in an ACO and be a co-owner of an ESCO in the same market. This approach would ensure that patients with all stages of kidney disease—acute kidney injury, pre-dialysis chronic kidney disease (CKD), on dialysis, and living with a kidney transplant—in a given market would have optimal access to the expertise of nephrologists. At the very least, nephrologists should be permitted to be a co-owner of an ESCO and contract with an ACO in the same market.

Continue to emphasize the leadership role of the nephrologist or nephrology practice.

Our organizations are grateful that CMS and the Innovation Center emphasized the importance of nephrologist leadership in ESCOs numerous times in the RFA, and especially how establishment of nephrologist-led interdisciplinary care teams may be the best mechanism for ESCOs to meet the complex care needs of beneficiaries. We request clarification whether, on page 22, the Agency intended that the “providers” who comprise at least 75% of the ESCO board are to be nephrologists, advanced practice registered nurses, registered nurses, or other health professionals, rather than being representatives of owners or administrators of dialysis facilities.

Incorporate the use of waivers as a tool to improve patient care.

ESCOs’ access to waivers for certain elements of care or services that improve patients’ overall experiences and outcomes is an important, unique feature of the CEC Initiative. Waivers have already proven that they can be an effective method to improve the quality of care: One example is the recent removal of the barrier to providing nutritional supplements to applicable patients in dialysis facilities. Studies have demonstrated that providing these supplements to dialysis patients may result in up to a 20% reduction in hospitalizationsⁱ and improved survival.ⁱⁱ Our organizations recognize the legal challenges and importance of working with other federal agencies to make waivers available. However, we believe that waivers are a crucial component of the success of the ESCO program and urge the Innovation Center to provide more specific details regarding the type of waivers it will be making available in the program, and necessary requirements to secure such waivers.

Reconsider the goal of rebasing the program in years four and five.

Our organizations recommend that CMS and the Innovation Center reconsider the proposal to rebase ESCOs in years four and five. A key goal of the ESCO program is to encourage innovation and new ways of delivering care; rebasing the program midstream would likely impede participants’ ability to adopt new technologies and practices. We are concerned that the plan to prematurely rebase jeopardizes the likelihood of success for the CEC Initiative overall, as it may deter potential participants from joining in the first place. The current rebasing schedule will particularly penalize those ESCOs who, during the first three years, are exceptionally successful in reducing spending, as they will need to generate even greater savings in the fourth and fifth years. Moreover, our organizations are not aware of rebasing being done partway through any other MMSP. The rationale for rebasing in the ESCO program is unclear, and we suggest that CMS allow the program to operate for the full five-year window before rebasing.

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ⁱ Cheu Christine, Pearson Jeffrey, Dahlerus Claudia, et al. Association between oral nutritional supplementation and clinical outcomes among patients with ESRD. *Clinical Journal of the American Society of Nephrology*. 2012. Retrieved from <http://cjasn.asnjournals.org/content/early/2012/10/17/CJN.13091211.full>.

ⁱⁱ Lacson Eduardo, Wang Weiling, Zebrowski Barbara, et al. Outcomes Associated With Intradialytic Oral Nutritional Supplements in Patients Undergoing Maintenance Hemodialysis: A Quality Improvement Report. *American Journal of Kidney Diseases*. 2012 Oct;60(4):591-600.