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Deputy Administrator Acting Director
Centers for Medicare and Medicaid Services Center for Medicare and Medicaid
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Dear Mr. Blum and Dr. Gilfillan:

The undersigned organizations, representing physicians, scientists, nurses, and other health professionals are writing to offer comments on the Agency’s request for application (RFA) to develop end-stage renal disease—ESRD—Seamless Care Organizations (ESCOs) as part of the Comprehensive ESRD Care (CEC) Initiative. It is our opinion that CMS has taken a logical step forward in seeking to allow Medicare beneficiaries with ESRD to benefit from the innovative health care delivery strategies currently being tested in other accountable care organizations (ACOs) and Medicare Shared Savings Programs (MSSPs). Our organizations have long advocated for the development of an ACO-like care delivery model for ESRD patients, and given that stance, we commend the Agency, and in particular the staff from the Center for Medicare and Medicaid Innovation (CMMI), for their efforts in this area.

We believe that there is a solid policy rationale behind developing ESCOs, and we appreciate the degree to which CMMI has taken into account many of our recommendations along the way. However, we also believe that the process for developing the RFA and some of the specific policies outlined within it could benefit from refinement. In that spirit, this letter offers comments and suggestions that we believe would facilitate the effectiveness of ESCOs.

**Rebasing**

The undersigned organizations believe that CMMI should reconsider its decision to rebase payments to participating entities in years four and five of the program. It is our understanding that a design feature of this nature is not included within the initial period in the majority of other MSSP ACO products, and we would contend that it is inappropriate to rebase in the initial period of the ESCO model as well.

We are concerned that inclusion of the plan to rebase for years four and five will negatively affect the potential participation of major stakeholders in the kidney care community, and thus run the risk of defeating the purpose of developing the ESCO proposal itself. Further, for those groups choosing to participate, the ability to invest in innovation and new technologies will be severely curtailed if not eliminated, which seems counterintuitive to the broader goal of ESCOs. **Our organizations recommend that rather than rebasing these last two years, CMMI should allow the entire five-year program to run its course before considering rebasing.**
Allow ESCOs as the First Option for ESRD Patients

The RFA states that “to be eligible for matching to an ESCO (a beneficiary) must NOT have already been matched to a Medicare ACO or another Medicare program/demonstration/model involving shared savings at the date of initial matching for the CEC Model.” Our organizations believe that this specific criterion is not in the best interests of ESRD patients and should be removed from the list of beneficiary criteria.

While we recognize the complexities with attribution that arise from implementation of care delivery models such as ACOs and ESCOs across large patient populations, we are concerned that the unique needs of ESRD patients may not be addressed in non-kidney disease specific ACOs, and that these patients will be exposed to a care delivery model lacking the unique degree of nephrology expertise that would exist in an ESCO. While we are not advocating that ESRD patients already enrolled in a general ACO be required to leave that model, we believe that they should have that option.

Matched Beneficiary Minimum and CBSA Limitation

We believe that the combined impact of the 500 matched beneficiary minimum and the limitation on the size of markets to no more than two Medicare core-based statistical areas (CBSAs) will unnecessarily and artificially constrain the ability of potential applicants to serve as ESCOs. The undersigned organizations are sympathetic to the need to have a minimum number of ESRD patients in an ESCO to appropriately account for risk, and we do not specifically disagree with 500 as the threshold per se. However, when the geographic catchment area is limited to two CBSAs, the ability of kidney care providers to form a partnership and develop a legitimate application to serve as an ESCO is significantly compromised.

Alternatively, our organizations recommend that within a geographic region, CMS/CMMI remove the limitation on the number of CBSAs that can serve as a market, and the requirement that they be contiguous. It is our belief that such a change would broaden and enrich the applicant pool in a specific region. Further, the ability to form larger ESCOs would substantially increase the number of Medicare beneficiaries with ESRD who could benefit from the comprehensive care models that ESCOs are intended to provide.

Quality Measure Selection Process

Our organizations recognize the fundamental role that quality measurement will play in assessing the success of the ESCO care delivery model as implemented by participating groups. As such we believe both the process generally, and the selection of measures specifically, must be pursued as systematically, openly, inclusively, and in as evidence-based a manner as possible. The input of all stakeholders, including patients, nephrology practitioners, dialysis providers and other stakeholder groups should be meaningfully considered. We join others in the kidney community in urging CMMI to adhere to a step-wise process that begins with identifying and defining measures, establishing benchmarks, and ensuring that the ESCOs are aware of the benchmarks prospectively to maximize the opportunity for success. While these concepts seem
self-evident, recent experience in the quality measure development milieu leads us to emphasize
the importance of openness and utilizing a process that is as evidence-based and consensus
driven as possible.

Further, it is of paramount importance that the measures selected are appropriate for use with the
ESRD patient population (as noted in the RFA), and we suggest that the numerous ESRD-
specific measures that have been approved through the National Quality Forum (NQF) process
would be a good place to start in the search for appropriate measures.

Use of Waivers

In the RFA, CMMI sets forth the legal requirements and considerations that the Agency must
account for in issuing waivers from existing regulation, and we also appreciate that in their
interactions with other federal agencies CMS and CMMI must navigate the course of allowing
waivers carefully. However, we also believe that the availability of waivers is the design feature
that distinguishes innovative payment models like ESCOs from existing models such as fee for
service. Further, the use of waivers is critically important to the care improvements and cost
savings that are the goal of ESCOs.

For these reasons, our organizations strongly urge CMMI to provide greater clarity on the type
and scope of waivers that may be available to ESCO applicants. This clarity would provide
potential ESCOs with a more precise idea of what products and services they can provide to their
matched beneficiaries while remaining compliant with existing laws and regulations.

Success Metrics for Overall ESCO Project

We urge CMS/CMMI to provide more specificity on how the success of the ESCO project
overall will be determined. Acknowledging that the general goals of the triple aim (better health,
better health care, and lower Medicare per capita costs for matched beneficiaries) should be
achieved, we are concerned that absent greater clarity, the perceptions of success by
CMS/CMMI and the ESCOs themselves may be different. If this were to occur, an ESCO entity
could invest five years’ worth of time and resources into developing a model that they believe is
successful in terms of reducing costs and improving care, but if CMS/CMMI doesn’t agree, their
program could be discontinued and their efforts could be for naught. To address this concern, we urge CMS/CMMI to be more specific in defining how an ESCO will be judged to be a success.

Transparency of ESCO RFA Process

Our organizations believe that there must be a greater degree of transparency in the policy
development process pertaining to ESCOs. We acknowledge that CMMI has been reviewing the
benefits and challenges of developing an ACO-like care delivery model for kidney patients over
the last several years, and that the release of the RFA was an effort to be responsive to renal
community calls for a tangible proposal in this area. Further, we recognize that the full-blown
rulemaking process would likely be too unwieldy and unrealistic to use for a project of the
limited scope proposed for ESCO development and implementation.
However, it is also our opinion that the process thus far has been marked by limited transparency. While the RFA is a fairly comprehensive document that addresses a broad range of issues associated with developing an ESCO proposal, it is in essence the only source of information on the project. Subsequent conference calls and the CEC FAQ page offer only information already included in the RFA, or refer the user to the CEC questions in-box. Given the level of uncertainty in the kidney care community on issues such as the minimum size of an ESCO, quality measures to be used, and rebasing, we urge CMMI to have a more robust and interactive dialogue with the community prospectively, rather than seeking to correct issues later in the process.

As always, we welcome the opportunity to work collaboratively with CMS and CMMI in their efforts to improve the quality of care provided to the nation’s kidney patients, and we believe that the release of the ESCO RFA is an important step forward in this regard. Our organizations stand ready as a resource to CMS and CMMI in the further refinement of the ESCO proposal, and in all other future endeavors.

Sincerely,

American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Renal Physicians Association

cc: Sean Cavanaugh, Acting Deputy Director, Programs and Policy, CMMI
    Representative John Fleming, MD, Vice-Chair, Congressional Kidney Caucus
    Representative Tom Marino, Co-Chair, Congressional Kidney Caucus
    Representative Jim McDermott, MD, Co-Chair, Congressional Kidney Caucus
    Marilyn Tavenner, Acting Administrator, CMS