Kidney Care Partners (KCP) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Statement of Work (SOW) of the End Stage Renal Disease Network Organizations. KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both chronic kidney disease (CKD) and irreversible kidney failure, known as End Stage Renal Disease (ESRD). In sum, we appreciate many aspects of the SOW, but are concerned that too many of the proposed activities overlap with existing quality initiatives, specifically the ESRD QIP, and if the SOW were adopted as proposed could undermine the effectiveness of both the QIP and the Networks efforts related to continuous quality improvement.

First, we appreciate the Agency’s extension of the filing deadline. We understand that review of the SOW will be a recursive process. Thus, KCP respectfully requests that future comment periods provide a longer window to allow for a more thoughtful set of comments and recommendations on the document. We appreciate having the opportunity to comment, but it is important that the activities and tasks of the Networks be the result of a meaningful dialogue between the community, CMS, and the Networks. Network activities have serious implications for patients, providers, and other stakeholders. Providing only 5 business days to review and comment on this broad document is not sufficient time for a thorough review.

While we have provided some additional comments in this letter, a more thorough review would likely have resulted in not only more specific comments, but also more specific recommendations to assist CMS and the Networks in accomplishing their missions. For example, it is extremely difficult to engage with patients in a meaningful way on such short notice given that they have other competing obligations, including employment, families, and of course, their treatment schedule. Yet, many of the activities listed seek to improve patient engagement,
clinical outcomes, and understanding. As with other ESRD-related policies, CMS should provide at least 30 days for a review and comment period. This approach would be more consistent with the stated network goal of “serving as a partner in improvement with other health care organizations, beneficiaries, health care providers, practitioners, and stakeholders.”

The relationship between the Networks and the kidney care community should be a partnership with the common goal of fostering continuous quality improvement that has a meaningful impact on patient outcomes. This partnership should begin with a consensus-driven set of performance objectives, activities, and tasks. Providing the opportunity for comment on the SOW moves in the right direction, but the lack of detail presented in the document, along with the broad language used throughout raises serious concerns. Therefore, KCP recommends that CMS streamline and focus the Networks on areas where there are gaps in current quality initiatives.

For example, the SOW requires Networks to “encourage” the use of the ICH CAHPS tool and to report the information “as directed by CMS” with the goals of tracking provider participation, assisting facilities with the interpretation of results and the development of an action plan, and helping with trend analysis. The SOW does not define what constitutes such encouragement. For example, does it mean establishing a benchmark of participation and sanctioning facilities that do not meet it? The SOW requires Networks to establish benchmarks, but with a limited exception in the vascular access management section, the SOW does not define the benchmark, the process for setting them, or when they are appropriate to use and enforce. If encouragement would occur through such a process, it is not clear whether the Network would be bound to follow the existing metrics, measure specifications, data collection requirements, and benchmarks established for the administration of this tool through the ESRD QIP. If encouragement means something else, it is difficult to evaluate the value of this activity without more specific detail.

Even in areas that appear to provide some specificity, the clinical support for the stated goals are not identified. For example, the SOW requires a Network prevalent AV fistula rate of 68 percent. Not only is there no clinical explanation for why this percentage versus another was selected, but there is also a hidden, yet extremely dangerous, clinical assumption inherent in it – namely, that AV fistulas are always appropriate for every dialysis patient. While there is attention paid to reducing catheter rates, this metrics in this domain and benchmark ignores the clinical reality that some patients cannot maintain an AV fistula. In these patients, grafts are often the best option. As structured, the Network goal entirely ignores grafts and establishes incentives to place AV fistulas even if it is known that the patient is not an appropriate candidate for this type of vascular access. Such an incentive does not promote appropriate patient care.

1Statement of Work of the End Stage Renal Disease Network Organization (SOW) 5.

2Id. at 18-19.

3Id. at 20.
One of the more troubling examples of the lack of clarity arises in the section describing the sanctions (C.3.12). First, the section does not define the specific sanctions that the Networks can leverage against facilities. Would they go beyond the current authority to report problems through the survey and certification process, consistent with the Conditions for Coverage? If so, what is the authority for doing so? Second, it is not clear what constitutes a “recalcitrant” facility. The list of actions for which a Network must consider recommending a sanction are extremely vague. For example, how is an “inappropriate practice pattern” defined? Would these be practice patterns related to the domains outlined in the SOW or any practice pattern? As noted above, many KCP members would view favoring an AV fistula in all circumstances as an inappropriate practice pattern; yet, such a practice would be consistent with the incentives created by the metrics and benchmarks for vascular access management (C.4.1.D). A similar question arises as to the decision of a facility not to accept a Network’s offer of technical assistance. How would discrepancies between the Network and the clinical judgment of a medical director, physician, or other medical authority fit into this potential offense? Finally, it is not clear what would constitute an “effective Quality Improvement activity” that would allow a facility to escape sanctions. Who would define “effective”? Would it need to be based again on a benchmark, clinical evidence, observational evidence, or some other standard?

Given the questions raised by the lack of specificity, KCP strongly encourages CMS reconsider the SOW. As noted below, streamlining and focusing the Networks on areas where there are gaps in current quality initiative would to a great degree address the problems outlined above.

While KCP agrees that the domains outlined in the SOW should be the focus on quality improvement efforts, more quality improvement activities, metrics, and standards in these areas will not necessarily lead to quicker improvements in quality or attainment of quality goals. In fact, more activities create the very real risk that limited resources will be divided over many projects and lessen the overall ability of the community to improve patient outcomes. Specifically, KCP is extremely concerned that the domains outlined, the general benchmark authority delegated to the Networks, and the potential sanctions duplicate and are/could be inconsistent with the ESRD QIP. Thus, we strongly urge CMS to review both the Network activities and the QIP requirements to ensure alignment and eliminate any activities and tasks in the SOW that duplicate the ESRD QIP.

For example, the majority of domains highlighted in the SOW overlap with the metrics CMS promulgated through rulemaking as part of the ESRD QIP. Specifically, the QIP includes ICH CAHPS and NHSN structural measures and vascular access management outcomes-based measures. The SOW not only does not describe the interaction between the contemplated

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4 See id. at 12-13.
Network activities, but also fails to acknowledge the potential overlap. There is no requirement that the Networks set their metrics or benchmarks to align with the QIP.

Even if that requirement were present, it is not at all clear that the Networks could legally implement what amounts to a parallel value-based purchasing program in that Congress clearly spoke as to how CMS was to incentivize quality improvement through the specific process outlined in statute for measure adoption, the establishment of benchmarks, and application of sanctions.⁵ One of the most troubling aspects of the overlap comes in the discussion of sanctions that provides Networks with the authority to determine their own benchmarks against which to evaluate facilities and requires the Network to consider sanctioning a facility (in an undefined manner) if a facility does not meet these benchmarks.⁶ If Congress had intended for another type of program to penalize facilities for not meeting quality metrics based upon defined benchmarks, it would have provided for such authority in the statute. Congress did not do so.

KCP is also concerned that each Network would be tasked with explaining the results of a facility’s QIP performance score certificate to beneficiaries. As we have indicated in our comment letters on the ESRD QIP through rulemaking, KCP believes that there needs to be a standardized, easy-to-understand format used to disseminate facility QIP performance score report certificates so that patients are empowered to understand the results in a way that acknowledges data shortcomings, changes in clinical practice patterns, and also allows for an open dialogue with their health care providers. At first glance having the Networks take on this role might seem appropriate; however, this approach would likely lead to 18 different interpretations that could be confusing to patients who travel between facilities and result in dialysis facilities—especially those operating in multiple Networks—being given conflicting requirements.

A related problem exists if the Networks serve as the primary point of contact and resolution for questions regarding CROWNWeb, as described in AIM 4.3. KCP has engaged in productive ongoing technical dialogue with the Office for Clinical Standards and Quality technical team to identify concerns with measure specifications and data collection requirements so that when resolved there is a clear, precise, national standardized approach. Such standardization is critically important to ensuring validity of the QIP or other data collection efforts. Without it, there is no legitimate way to compare metrics between facilities or to establish national benchmarks. We are concerned that delegating this responsibility to the Networks will lead to numerous different interpretations with no single arbiter. Even if CMS clarified it would ultimately resolve any conflicts, having the Networks stand in between the facilities and CMS technical staff would only lengthen the time to resolve the problems and jeopardize data collection.

In addition, KCP is concerned that the SOW inappropriately links lowering cost with facility performance improvement measures (such as anemia management, dialysis adequacy, and

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⁵See 42 U.S.C. § 1395rr.

⁶SOW, supra note 1, at 12-13.
There is no evidence that improvement in the specific measure areas identified is related to lower cost; nor that compliance with QIP procedures are related to increased efficiency. By focusing on specific measure areas, the SOW could be quite damaging to patient care. By attempting to tie these measures to efficiency, it appears that the SOW is creating de novo efficiency measures that have no evidence base and have not gone through either the rulemaking or National Quality Forum processes identified by the Congress as the path for adopting measures.

The quality objectives outlined in the SOW are important goals, but to address them, the kidney care community must establish through a collaborative and transparent process a single, consistent way to measure, evaluate, and address them. More data systems, layers of review, and penalties are not the answer. Limited resources should be used to fill gaps in existing system, not to duplicate current efforts.

For the Networks to achieve their mission, it is important that their obligations, authority, and activities are clearly and precisely set forth in the SOW. Networks should not be placed in the position of developing programs that duplicate other ESRD quality initiatives, nor should they become a barrier to effectuating quick resolution of important technical questions. To that end and given the limited time during which we have had to consider the options, KCP recommends that CMS focus the Networks activities in three core areas:

1. Providing technical assistant to facilities requesting assistance for quality improvement and sharing best practices (developed in a consensus process with the kidney care community);

2. Promoting coordination of care by assisting facilities with obtaining data required to coordinate care, including working with hospitals and physicians’ offices to provide the diagnostic information related to co-morbid conditions and requiring hospitals to provide complete discharge records to dialysis facilities upon the patient’s discharge, that will ensure that facilities have the information they need to coordinate care and that, at least to date, the vast majority of other providers have refused to share with facilities; and

3. Utilizing existing educational materials developed by the kidney care community to better inform beneficiaries.

KCP applauds those aspects of the SOW that highlight the need for a resource that facilities can access to help them improve quality. Use of this resource, however, should not be mandatory, but rather established as a cooperative relationship that allows medical professionals, patients, and others to work together to identify strategies and tactics to improve performance. KCP has long supported the inclusion of a

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7Id. at 26-28.
technical assistance option as part of the ESRD QIP. The Networks could provide this assistance by working with the community to develop materials and activities that facilities could consult. Just as every patient has unique needs, every facility has its own unique strengths and weaknesses. A one-size-fits-all approach will not work. However, working together with the community, the Networks could fill the current gaps in the QIP and fulfill their mission of achieving national quality improvement goals (as defined and implemented through the QIP).

There is no question that better coordination among the various providers who care for individuals receiving dialysis treatments will improve patient outcomes. Expanding data collection requirements in the area of health care that already has one of the richest sources of patient-related outcome data is not the best approach to driving quality improvement. Instead, we recommend that the Networks assist dialysis facilities with obtaining data from other providers who often refuse to share it so that there are fewer gaps in patients’ medical records that could compromise their outcomes. KCP members have experienced this problem historically as they tried to obtain information about patients who were hospitalized. During such visits, a patient with kidney failure might receive dialysis treatments, multiple drugs or biologicals, or red blood cell transfusions, that could affect their care on a going-forward basis. Yet, hospitals do not regularly share this information with dialysis facilities, even though HIPAA permits such disclosures. The problem has become even more prominent with the introduction of co-morbidity case-mix adjustors in the ESRD PPS. While CMS found some correlation between the adjustors and the amount of care required, facilities often do not have the diagnostic information to know whether or not a patient has a particular co-morbid condition. Clearly, this situation is not ideal for coordinating care. Rather than adding more administrative burden through collecting outcomes data yet a different way, Networks could serve as an intermediary to promote care coordination through appropriate data sharing.

KCP supports efforts to improve patient awareness and understanding of kidney disease. Our members lead many efforts individually and together to educate patients. We believe the Networks can assist with these efforts as well. Working with the kidney care community and utilizing existing resources developed by its members, the Networks should identify priority areas and disseminate appropriate materials in a meaningful way to patients.

While these three areas address gaps in current quality improvement goals, there may be others that if given additional time we would be able to recommend.

Again, we appreciate the opportunity to provide these limited comments and sincerely hope that you will provide the community with additional time to provide a more thoughtful response. In the meantime, KCP strongly urges CMS to refine the SOW to allow Networks to play a specific and meaningful role that fills existing gaps in existing quality initiatives, data collection efforts, and expand the reach of current patient education efforts, rather than risk inconsistent metrics, benchmarks, and guidance by having Networks focus in areas already being addressed.
KCP looks forward to continuing a meaningful and productive dialogue with the Agency as it continues the work of the Networks, as well as through other quality initiatives. Please do not hesitate to contact me or our counsel, Kathy Lester at (202) 457-6562 or klester@pattonboggs.com, if you would like to discuss our comments or recommendations further.

Sincerely,

Ronald Kuerbitz
Chairman
Kidney Care Partners

Abbott Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses’ Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology Centers for Dialysis Care
DaVita, Inc.
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Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
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Nephrology Nursing Certification Commission
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