KIDNEY CARE PARTNERS

March 31, 2015

John Thomas
Director
Clinical Standards Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Thomas:

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments about the ESRD Conditions for Coverage (CfC). Because of the open and transparent manner in which the current CfCs were developed, we have only one substantive recommendation with regard to the regulatory text itself, which relates to updating the water standards. We also want to highlight the need to update the State Operations Manual Appendix H ESRD (SOM), which has created confusion and problems with implementing the CfCs.

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).

At the outset, we want to reiterate our gratitude for the process CMS initiated prior to the 2008 promulgation of the current CfC regulatory text. CMS provided ample opportunity to submit comments and recommendations, including participating in a KCP Board meeting to share the Agency's point of view and hear from the diverse KCP membership. This willingness to engage in a meaningful and constructive manner resulted in a set of policies that have withstood the test of time.

I. CMS should incorporate the most recent ANSI/AAMI water quality standards into the CfC.

The current CfC regulations at 42 C.F.R. § 494.40 "Condition: Water and dialysate quality," incorporate through reference the publication "Dialysate for hemodialysis," ANSI/AAMI RD52: 2004 for water quality standards. At that time, CMS noted that these more recent standards would be the "more appropriate" version to incorporate compared to the older 2001 standards.[1]

[1] 73 Fed. Reg. 20370, 20379 (Apr. 15, 2008).

Since the promulgation of the regulations in 2008, the Association for the Advancement of Medical Instrumentation (AMMI) has approved the International Standards Organization (ISO) versions of the Standards on Water for Dialysis and Dialysate, among other changes. We agree that it is appropriate to have updated standards incorporated by reference into the regulations. As such, we recommend that any update to the CfC incorporate by reference the most recently published AAMI/ANSI/ISO water quality standards. For example, AAMI has approved the ISO versions of the Standards on Water for Dialysis and Dialysate. The new international standards list a specific method – with a different time, temperature, and media for colony counts – than is currently used in the United States. This led the United States to craft a deviation to the International version that incorporated the current method of testing in the United States that was approved by ANSI/AAMI.[2] Updating these standards, and maintaining the U.S. deviation on the test method for colony counts, would better protect beneficiaries and bring the CfC guidelines in line with most providers' practices.

We recognize, however, that the most recently published ANSI/AAMI standards may not have been completely incorporated by all U.S. providers, so we encourage CMS to consider any necessary amendments to prevent undue burdens on facilities and to allow sufficient time for facilities to incorporate these new standards into their practices.

II. CMS should prioritize updating the SOM

To ensure the appropriate implementation of the CfCs, KCP encourages CMS to work with the community to update the SOM. The SOM includes the specifics as to how surveyors are supposed to implement the CfC, such as initial survey protocols; basic survey protocols; supplemental survey protocols; and specifics related to emergency procedures, environmental procedures, water and dialysate AAMI Guidelines.

Keeping the SOM updated is important because it is the primary source of guidance from CMS to contracted state agencies. It is also a critically important source of direction for dialysis facilities. They use the guidance to ensure compliance with CMS requirements.

---

[2]Approved culture methods shall include one of the following: (1) tryptone glucose extract agar (TGEA) or Reasoner's 2A supplemented with 4 percent sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d); or (2) Trypticase soy agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE), incubated at 35 °C for 48 hours. Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods. See USP <1231> for guidance on adoption of alternative methods. American National Standard ANSI/AAMI 11663:2014 (Quality of dialysis fluid for hemodialysis and related therapies).

The absence of an updated SOM has created confusion and inconsistencies in the implementation of the CfCs at the state level. One example of this problem is the ESRD Application and Survey and Certification Report (CMS Form 3427), which has been modified three times. These form changes have been in the areas of home dialysis training/support, nocturnal dialysis, dialysis in long-term care, and in-center peritoneal dialysis. Because the SOM has not been updated, CMS' intent in changing the forms is not clear. This has led to inconsistency across the country. For example, for the addition of home training, some states expect to observe a patient on training, which is difficult because providers do not know when the survey will be done, while other states are willing to survey and review the documentation of training if there is no patient in training at time of survey.

Another example of the problem can be seen in the Measure Assessment Tool (MAT), which summarizes the standards used in assessing compliance with the CfCs. For example while the CfCs require the monitoring of anemia management, it does not specify specific measures. The MAT includes the Hgb < 10 g/dL measure for evaluating facilities. This measure is also included on the FY 2015 ESRD Core Survey Worksheet. The dialysis community is committed to providing the best care possible to Medicare beneficiaries with ESRD patients, including monitoring and managing their hemoglobin levels according to current standards of care and practice guidelines. However, other Medicare quality programs, as well as the Food and Drug Administration, have removed the Hgb < 10 g/dL. Its continued use in the MAT, therefore, is outdated. This is not the only measure that is inconsistent with other programs. We, therefore, recommend that CMS update the MAT and Core Survey Worksheet to align with other Medicare quality programs.

III. Conclusion

KCP appreciates the opportunity to provide comments on the CfC and guidance documents. We look forward to working with you on these issues. Please do not hesitate to contact Kathy Lester at 202-534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners

Members of Kidney Care Partners

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
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
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
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care