March 31, 2015

John Thomas  
Director  
Clinical Standards Group  
Center for Clinical Standards and Quality (CCSQ)  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244  
ESRDCSG@cms.hhs.gov

Re: Recommendations for Future Updates to the Conditions for Coverage (CfCs) for ESRD Facilities

Dear Mr. Thomas:

On behalf of the American Nephrology Nurses’ Association (ANNA), I am writing to share our comments on the current Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage (CfCs) for End-Stage Renal Disease (ESRD) facilities. We appreciate the opportunity to offer our suggestions with respect to revising these regulations. ANNA believes regular updates are required to ensure the regulations stay current with advances in practice and to ensure ESRD facilities provide patients with high-quality, comprehensive health care.

ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 10,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis facilities, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.
ANNA is a member of Kidney Care Partners (KCP) and the Alliance for Home Dialysis and supports their comment letters. The following comments are in addition to the comments submitted to CMS by KCP and the Alliance for Home Dialysis.

**Governance**

ANNA strongly supports continuing the requirement that a registered nurse (RN) be present in an ESRD facility at all times that in-center dialysis patients are being treated. (42 C.F.R. §494.180(b)(2)). Registered nurses provide professional assessment and care, coordinate the patient experience, educate patients and their families/caregivers, and provide advice and emotional support. ANNA believes very strongly that this RN requirement is crucial to the safe delivery of dialysis and applauds CMS for implementing this fundamental standard. CMS should not make any changes to this requirement.

**ESRD State Operations Manual**

Patient safety is “indistinguishable from the delivery of quality health care.” To ensure ESRD facilities are properly equipped to deliver quality dialysis care to patients, ANNA strongly encourages CMS to publish an updated ESRD State Operations Manual (SOM). Both state agencies and providers require uniform guidance and direction in the survey and certification process. A standardized SOM is necessary to ensure state surveyors employ consistent methods when conducting the survey and certification process. Such guidance also would expand facility staff members’ comprehension and accurate interpretation of the requirements, resulting in improved care outcomes and greater patient satisfaction. ANNA urges CMS to publish a comprehensive SOM to help ensure ESRD facilities understand the certification requirements and properly interpret CMS regulations, thus increasing the level of compliance with CMS’s health and safety standards. Standardized guidelines that can be consistently applied by state agencies and providers will allow for improved communication between providers, state agencies, and the CMS Regional Offices, and decreased confusion and inconsistent application of requirements. These improvements in communication will enhance the environment of ESRD facilities in ways that keep patients safe while improving the overall delivery of dialysis care.

**Culture of Safety**

We applaud the emphasis on “culture of safety” that CMS has placed in the Core Survey for each facility. This emphasis in the Core Survey supports the encouragement of patient and staff reporting of adverse events; complaints and near misses without fear of reprisal; a robust program for the identification of medication

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and treatment errors; and patient engagement and participation in their health care. ANNA suggests that any revision of the ESRD CfCs consider the culture of safety model as part of the Quality Assessment and Performance Improvement (QAPI) CfC.

**Telehealth**

Telehealth services enable health care professionals to improve access to care, empower patients to participate in their care, reduce overall health care expenses, and assist with communication between patients and their treatment team. While telehealth is not currently addressed in the CfC regulations, ANNA believes that telehealth, a cost-effective alternative to the face-to-face delivery of medical care, is an extremely beneficial service that if permitted in ESRD facilities, would result in improved outcomes for patients.

Telehealth creates a more convenient and accessible environment for patients, allowing patients to interact in real-time with physicians and/or advanced practice professionals (APPs) during in-center dialysis as well as part of the home therapy delivery model. Telehealth also facilitates social connectedness between patients and their providers. Recognizing telehealth as a method to deliver some aspects of care would allow ESRD facilities to use telehealth services to improve the ability of the interdisciplinary team to furnish care as needs arise and enable providers to remotely monitor patients. The use of telehealth also would allow for faster response times and result in fewer office/clinic visits. ANNA strongly urges CMS to recognize telehealth as a method to deliver care in the ESRD program.

**Measures Assessment Tool**

The Measures Assessment Tool (MAT) is a useful reference tool that offers guidelines from current professionally-accepted standards and core indicator values for listed clinical elements in the CfCs for Patient Assessment, Plan of Care, and QAPI. ESRD surveyors and facility staff members use the MAT on a regular basis to ensure compliance with regulatory requirements. The MAT has been modified at least 10 times since 2008, with no notice to alert the ESRD community of these modifications. Notifying facilities when the MAT is updated would facilitate rapid compliance with the revisions. A possible method of notification includes the use of a notice posted on the Medicare Learning Network. ANNA believes that implementing a system to notify the ESRD community when the MAT is revised would demonstrate transparency and result in improved communication by CMS.

**Dialysis Furnished in a Nursing Home Environment**

In the February 4, 2005 proposed rule entitled *Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities*, CMS requested input on whether current home dialysis regulations should be modified to protect hemodialysis patients receiving dialysis within nursing facilities (NFs) and skilled nursing
facilities (SNFs). In the April 15, 2008 final rule (CMS 3818-F), CMS stated “a regulation regarding NF/SNF dialysis would be premature.” Since that time, the provision of dialysis in nursing homes has grown rapidly across the United States. Given the lack of guidance on dialysis furnished within NFs and SNFs, ANNA is very concerned about the safety of this most vulnerable population of dialysis patients and encourages CMS to publish regulations to govern dialysis provided within a NF/SNF in a proposed rule and allow the community to provide comment and feedback.

**Infection Control**

ANNA is committed to safeguarding patients from infections and applauds CMS for including in the CfCs by reference the Centers for Disease Control (CDC) infection control protocols and guidelines. We have noted that the most frequently cited deficiency since the implementation of these regulations continues to be Tag #V113, cited when there are identified breaks in hand washing protocols and/or changing gloves.

ANNA encourages CMS to work with the CDC to develop surveyor guidance to define more clearly when this tag should be cited. While we agree that a single break in technique may present a risk, in many cases this regulation has become “low-hanging fruit,” that is, very easy to cite without thought or consideration of whether a single instance constitutes a pattern or trend.

**Water and Dialysate Quality**

In 2008, the CfCs incorporated by reference the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) RD52:2004 guidelines. The CfCs also require that preconfigured hemodialysis systems be maintained and operated in accordance with manufacturers’ instructions, and ANNA commends CMS for addressing these newer systems within the CfCs. However, the ANSI/AAMI standards have been updated since the regulations were last revised, leading to differences between the ANSI/AAMI standards and the CfCs. This has resulted in two different sets of documents governing fluid quality, water treatment, and dialysate preparation and delivery, confusing ESRD facilities and state surveyors as to what standard should be followed.

To properly address this issue, ANNA encourages CMS to:

- Revise the current water quality regulations (42 C.F.R. §494.40) and incorporate by reference the 2014 editions of the ANSI/AAMI hemodialysis water standards, specifically incorporating the following:
  - 23500 (Guidance for the preparation and quality management of fluids for hemodialysis and related therapies);
  - 13958 (Concentrates for hemodialysis and related therapies);
  - 13959 (Water for hemodialysis and related therapies);
o 11663 (Quality of dialysis fluid for hemodialysis and related therapies); and
o 26722 (Water treatment equipment for hemodialysis and related therapies).

- We note that the referenced ANSI/AAMI documents permit continued use of the culture methodology from AAMI RD52:2004, while requiring the current International Standard Organization (ISO) lower levels for microbial contamination and endotoxins.
- ANNA believes that incorporating the current ANSI/AAMI standards into the regulations will promote improved outcomes and ensure the safety of dialysis patients.

**Physical Environment**

ANNA encourages CMS to revise the Physical Environment regulations (42 C.F.R. §494.60) to reflect the July 12, 2013 Center for Clinical Standards and Quality/Survey & Certification Group letter that limits the application of the Life Safety Code requirements to facilities in hazardous locations and those without exits to grade level. Revising the physical environment regulations to reflect the Survey & Certification Group letter would add clarity for providers and surveyors as to the Life Safety Code requirements for ESRD facilities.

**Patient’s Rights**

ANNA is committed to improving the quality of outcomes for patients and providing greater health care efficiencies through care coordination that is centered on the needs and preferences of patients and their families. ANNA supports CMS’s emphasis on patient engagement, as ANNA believes the engagement of patients and families is essential to improving patient outcomes and the quality of care and support.

ANNA greatly appreciates the opportunity to share our recommendations on future updates to the CfCs for ESRD facilities. As the leading professional association representing nephrology nurses, we look forward to continuing to work with your Agency on these important issues. Please feel free to contact me directly if you have any questions or would like to discuss these issues in greater detail.

Sincerely,

Sharon Longton, RN, BSN, CNN, CCTC
2014-2015 National President