



March 31, 2015

John Thomas
Director, Clinical Standards Group (CSG)
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Thomas:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide comments on the Conditions for Coverage (CfC) for ESRD facilities. As the Centers for Medicare & Medicaid Services (CMS) Center for Clinical Standards and Quality (CCSQ) recently noted in its request for comments, the regulations for CfC for ESRD facilities were last revised in 2008.¹ We appreciate the invitation to submit suggestions with respect to updating these regulations. The Alliance believes there are several areas in particular in which updating the regulations would help to assure alignment with current industry standards and that facilities are providing patients with safe and appropriate care.

The Alliance is a coalition of kidney dialysis stakeholders -- representing patients, clinicians, providers and industry -- that came together following the first-ever National Summit on Home Dialysis Policy held in March of 2012 in Washington, DC. The goal of the Alliance is to promote activities and policies that will facilitate treatment choice in dialysis care while identifying and addressing systematic barriers that limit access for patients and their families to the many benefits of home dialysis therapy.

¹ Conditions for Coverage for End-Stage Renal Disease Facilities are located at 42 C.F.R. Part 494; last revised in CMS, Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities, Final Rule, 73 Fed. Reg. 20370 (Apr. 15, 2008).

Home dialysis -- peritoneal dialysis (PD) and home hemodialysis (HHD) -- is an important treatment option that offers many patients significant quality of life advantages, including meaningful improvements in physical and mental health. Currently, about 10% of U.S. dialysis patients receive treatment at home, and according to Dialysis Facility Compare, there are approximately 3,174 centers that are certified for PD training and 1,741 centers that are certified for HHD training across the country.

The Alliance commends CMS' engagement with the dialysis community, as we share the goal of maintaining the highest quality facilities utilizing the most up-to-date quality standards in the field. The current CfC, though almost seven years old, reflect a productive dialogue between patients, providers, and the agency.

In response to your request for comments, we have identified two specific areas that we believe would provide increased clarity and standardization for facilities wishing to provide home services, and would modernize the regulations to better reflect updated practices. **We recommend that CMS (1) publish an updated State Operations Manual (SOM) to provide additional guidance to states in the survey and certification process, and (2) incorporate current Association for the Advancement of Medical Instrumentation/American National Standards Institute (ANSI/AAMI) hemodialysis water standards into the CfC regulations.**

Below we provide further details on each of our suggestions.

(1) CMS should publish an updated State Operations Manual (SOM) to clarify the survey and certification process for facilities wishing to provide home services.

Alliance members are concerned that states have taken varying approaches in conducting the survey and certification process in relation to home dialysis patients. We believe the process should be standardized across states to ensure that all facilities are providing the same quality services to their patients and that facilities are not required to undertake unnecessary, duplicative measures to meet standards that are inconsistently applied across facilities. An additional negative consequence of the varying approaches is that dialysis providers cannot share best practices across states or effectively support less-resourced facilities plan for the process. The lack of standardization would be significantly alleviated if CMS published an updated SOM to provide state surveyors with clear guidelines on what must be provided for home certification.

When CMS published its initial interpretive CfC guidance in 2008,² the agency stated that it intended to publish an updated SOM. However, an SOM has not yet been published and the

² See CMS, ESRD Surveyor Training Interpretive Guidance Interim Final Version 1.1 (October 3, 2008), at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>.

lack of a clear standard has led to considerable confusion for facilities, with state surveyors and providers relying on a system of patchwork methods to certify facilities seeking to provide home dialysis services. Dialysis facilities and state surveyors have had to rely upon the CMS Form 3427 and its occasional changes to determine which documentation must be provided to surveyors for certification.

Furthermore, various states have reached differing conclusions on how to enforce the current CfC. For example, V589 requires facilities to provide documentation of a home visit at the initiation of home treatment and “whenever a problem is identified with either patient health or equipment that could be related to treatment at home.”³ While the interpretive guidance specifically states that home visits should not “necessarily” be mandated for periodic routine replacement of equipment, some states have interpreted this to require yearly documented home visits.

In addition, while V583 and V584 only require that facilities demonstrate an ability to train patients and qualified staff, some states have interpreted these V-tags as requiring facilities to separately certify all forms of home dialysis, and sometimes to have a patient in each modality for certification. These interpretations are unsupported, we believe, and in addition, are duplicative, adding an unnecessary administrative layer for facilities that could reasonably demonstrate proficiency in multiple modalities simultaneously.

By publishing an SOM, CMS would create reliable standards across regions and would provide state surveyors with much-needed clarity. The Alliance believes that publishing an SOM is the most efficient method to enable stability and predictability for providers within the certification process.

(2) CMS should incorporate the most recent ANSI/AAMI hemodialysis standards into the CfC.

Current 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. When CMS published the 2008 standards, it noted that the more recent water quality would be the “more appropriate” version to incorporate, compared to the older 2001 standards.⁴

Since the promulgation of the regulations in 2008, the Association for the Advancement of Medical Instrumentation (AAMI) has approved the International Standards Organization (ISO) versions of the Standards on Water for Dialysis and Dialysate, among other changes. We agree

³ CMS, ESRD Surveyor Training Interpretive Guidance Interim Final Version 1.1 (October 3, 2008), at p. 231.

⁴ 73 Fed. Reg. at 20379.

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 U.S. This led the U.S. to craft a deviation to the International version that incorporated the current method of testing in the U.S. and which was approved by ANSI/AAMI.⁵ Updating these standards, and maintaining the U.S. deviation on the test method for colony counts, would better protect beneficiaries and bring the CfC 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 for facilities to incorporate these new standards into their practices.

We also urge you to consider the differences between home practices and those based in-center, as some guidelines may be unnecessary or accomplished in other ways for patients treated in the home setting.

The CfC and survey and certification process play an important role in ensuring that dialysis facilities meet the highest standards of patient care. We thank you for your consideration of our comments and look forward to continuing to work with CMS to promote the highest caliber of care possible for home dialysis patients. If you have any questions, please contact Elizabeth Lee at (202) 466-8700.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephanie Silverman", with a long horizontal flourish extending to the right.

Stephanie Silverman
Executive Director

⁵ Approved culture methods shall include one of the following: (1) tryptone glucose extract agar (TGEA) or Reasoner's 2A supplemented with 4 % 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)



Membership List

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American Society of Pediatric Nephrology
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