



April 25, 2013

Ms. Judith Kari
Technical Director, Division of Continuing Care Providers
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C2-21-16
Baltimore, MD 21244

Dear Ms. Kari,

The Alliance for Home Dialysis 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, D.C. 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 people with kidney failure and their families to the many benefits of home dialysis therapy.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers many patients significant quality of life advantages, including reduced dependence on transportation and 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 2,768 facilities and providers that are certified for PD training and 1,429 that are certified for HHD training across the country.

Members of the Alliance for Home Dialysis have identified several examples of aspects of the Medicare Survey and Certification Program that pose challenges to providing home dialysis. These challenges are not faced by all facilities, but serve as a representative sample of concerns that we wanted to bring to your attention. We would like to begin a dialogue with you on ways to address these possible barriers to access to home dialysis and to work together to ensure patient access to home modalities. The concerns can be divided into two categories: challenges with the survey and certification process and surveyor interpretation issues.

Challenges with the Survey and Certification Process

Providers report difficulty in scheduling timely surveys of new facilities and physical or service expansions of existing facilities. These delays limit the availability of home dialysis modalities.

For example, one Alliance member reports several issues in Texas including:

- A facility that provides PD/HHD waited from March 2012 to January 2013 for survey.
- Another facility that is expanding services to add home PD has been waiting since March 2012 for survey.
- A third facility that has been waiting to add home PD since January 2012.
- A fourth facility with a home program has been waiting since March 2012 for a survey to relocate the program to another facility that has better space.
- A fifth facility wants to add home services and support and has been waiting for a survey since April 2011. In this case, the Department of Health stated that the facility is licensed and certified and was last surveyed in August 2009. The Department only plans to look at the addition of services during the next recertification survey.

In the majority of these cases, the Department of Health has indicated that under the CMS Mission and Priority document, these surveys are considered to be Tier 3 work and that other facilities are being prioritized for faster review.

This problem is not limited to Texas. The same Alliance member has been waiting for a survey in Oklahoma to expand a facility to add PD and HHD training since April 2009. The nearest home training facility is 50-60 miles away.

Another Alliance member is having a similar experience in Minnesota where a facility sought to open a new home program in April 2012, and to expand a current certified dialysis unit with a home program in May 2012. The certification surveys for both of these programs occurred in February 2013. One of these facilities involved its Congressional representative to spur action. In contrast, the Alliance is aware of in-center dialysis units in Minnesota that received certification surveys in 1-2 months after opening.

We believe that CMS is aware of issues with timely surveys in other states as well which may be delaying access to home dialysis.

Surveyor Interpretation Issues

Alliance members identified standards for which the guidance from the Centers for Medicare & Medicaid Services (CMS) is appropriate for home dialysis, but surveyors have interpreted the standards in ways that frustrate use of home dialysis.

For example, V128 requires facilities have an isolation room for Hepatitis B virus (HBV)-positive patients. The interpretive guidelines are clear that an isolation room is needed only during training for home HD,

but some surveyors have insisted that facilities should have a training room for HBV positive patients at all times even though rooms can be terminally cleaned.

The regulations (42 C.F.R. § 494.100) require that home dialysis services are at least equivalent to those provided to in-center patients. The Alliance certainly supports this standard of equivalence. However, the two week time limit for the multidisciplinary meeting to format the Comprehensive Assessment and Plan of Care flowing from this requirement (and in V581) can be difficult to meet given that home patients are in the facility for only approximately one week for training, followed by monthly clinic visits. While we believe that all patients should have a plan of care, the timeframes for reassessment need to be more flexible for home patients to better coincide with the clinic visits.

Additionally, some Alliance members have raised concerns about the current water testing requirements that may be inappropriately applied to home dialysis systems. For example, a requirement that water samples be collected from taps in different parts of the water distribution system may not be appropriate for home dialysis equipment that does not have a separate water distribution system or multiple taps situated throughout the equipment. We understand that CMS may be considering a revision to the existing water standards based on those developed by AAMI, the Association for the Advancement of Medical Instrumentation, and we would appreciate the opportunity to discuss how those standards impact home dialysis.

Finally, multiple Alliance members have expressed a desire for clarification of the regulations governing the provision of home dialysis in nursing facilities. There are issues associated with surveyor interpretation and certification standards that are specific to these types of facilities and that may be impacting patient access to such alternative home modalities.

The Alliance values the validation that occurs as part of the Survey and Certification Program and believes that it is an important way to ensure safety and compliance with quality standards across facilities. We would like to work with you to establish a dialogue on these and other issues to ensure that the standards are appropriate for home dialysis and applied in a manner that is consistent with providing beneficiaries reasonable access to all modalities.

To that end, we are requesting a meeting with you at your earliest convenience to discuss these specific issues and broader survey and certification concerns for home dialysis. We would be happy to work with you or your staff to arrange a time to meet, and we look forward to beginning a dialogue on these important issues.

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