September 27, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1674-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: Dialysis in Nursing Home Draft Guidance and Exhibit IV: "Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes."

Dear Administrator Verma:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on two draft guidance documents, "Dialysis in Nursing Homes," and "Exhibit IV: 'Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes.'"

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. HHD, for example, allows for more frequent and/or longer lasting dialysis sessions. Studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment and fewer side effects[1]; improved cardiac status[2] and survival rates[3]; and increased opportunity for rehabilitation.[4] PD patients often experience fewer negative side effects, such

[1] Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.
[2] Culleton, B et al. Effect of Frequent NHD vs.CHD on Left Ventricular Mass and Quality of Life. *JAMA 2007;*11
[3] Foley, R.N, D.T. Gilbertson et al. Long interdialytic interval and mortality among patients receiving hemodialysis. *New England Journal of Medicine. 2011* 365, no.12:1099-1107
[4] Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22- 28. Web. 12 Apr 2012. http://www.aami.org/publications/HH/Home.Blagg.pdf.

as nausea, and dietary restrictions than in-center patients.[5] Additionally, home dialysis offers significant quality of life advantages, including greater autonomy and flexibility in dialysis scheduling, and reduced dependence on transportation. In 2014 (the most recent year for which data is available), 11.6 percent of prevalent dialysis patients received treatment at home.[6] However, recent studies, including the Government Accountability Office, have found that home dialysis could be clinically appropriate for up to half of the dialysis population.[7]

Approximately 10-15% of the dialysis population is in a skilled nursing facility, long-term care facility, or rehabilitation facility at any given time. Furthermore, patients aged 80 and older are one of the fastest growing segments in the dialysis population. Some patients will be admitted to a long-term care setting on a home modality, and should be given accommodation to continue their treatment; others may be accustomed to an in-center regimen, but prefer to receive dialysis in their institutional home setting; and still others may develop the need for renal replacement in the long-term care setting and, together with their physician, elect home dialysis as their modality of choice. In all circumstances, the Alliance believes that CMS has a responsibility to ensure that patients retain the rights detailed in the ESRD Conditions for Coverage, and maintain access to the appropriate treatment modality and setting of their choice.

Therefore, the Alliance is deeply appreciative of CMS's efforts to issue clear guidance for dialysis care in long-term care settings. We are especially encouraged by the agency's clear guidance that dialysis providers do not need to seek approval to begin dialysis services in a skilled nursing facility (SNF). As you may know, especially in states with a backlog of survey responsibilities, this lack of clarity has hindered access to home modalities. However, we do have some specific suggestions that we believe will improve the guidance, and offer the following comments:

I. Peritoneal and Home Hemodialysis

a. The Alliance Recommends that CMS Consider Separating Guidance Applicable to Peritoneal Dialysis from Guidance Applicable to Home Hemodialysis.

The Alliance appreciates CMS's recognition of the fundamental differences in the delivery of PD and HHD through appropriate distinction in standards and requirements. Currently, requirements and recommendations for PD and HHD are made throughout each guidance document. While some of the guidance documents can apply to both modalities (e.g. requirements of a written agreement; policies and procedures), the Alliance respectfully requests, for ease of understanding by all relevant stakeholders and compliance with the guidance, that CMS consider separating the recommendations on PD and HHD in distinct sections of the guidance.

II. Staffing Requirements

a. The Alliance Recommends that CMS Clarify the Section "Dialysis Supervision and Administration."

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[5] "A Brief Overview of Peritoneal Dialysis." DaVita, Inc., Web. 16 Jul 2012. http://www.davita.com/treatment-options/home-peritoneal-dialysis/what-is-peritoneal-disease-/a-brief-overview-of-peritoneal-dialysis/t/5483.

[6] United States Renal Data System (USRDS), 2016 Annual Data Report: Epidemiology of Kidney Disease in the United States.

[7] End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis," October 2015. https://www.gao.gov/assets/680/673140.pdf

i. Differentiating the levels of competence required by a Dialysis Supervisor and Hands-On Caregiver

The Alliance agrees with the general outline of the staffing requirements outlined in the "Dialysis in Nursing Homes" guidance, but has specific recommendations to increase clarity and ensure continuity of patient care.

First, we urge CMS to further differentiate the required levels of training and competency required for the nurse that provides dialysis supervision in a nursing home, and the staff providing daily hands-on care of the dialysis patient. Currently, many facilities train hemodialysis care partners, or those helping a home hemodialysis patient complete therapy. This training is rigorous, but would not meet the standard required of a permanent dialysis nurse, for whom additional services and knowledge may be expected required. For example, the dialysis supervisor for these home dialysis patients could be a home dialysis nurse from the partnering ESRD facility, where a trained nurse is required by the ESRD Conditions for Coverage to be available on call 24/7/365. This nurse must be extremely competent in all dialysis modalities and able to assist in medically complex situations or emergencies. We agree with your proposal that this nurse would not necessarily need to be physically present with each patient at all times.

On the other hand, the Alliance would consider staff directly supervising the patient as equivalent to the typical home dialysis caregiver who has been through an ESRD facility home training program.

The Alliance respectfully requests that CMS edit the proposed guidance by more clearly outlining the expectations of the supervising nurse from the home dialysis facility, the LTC or on-site nurse and administering care partners.

Second, the Alliance seeks clarity from the agency as to whether a patient with an "existing personal caregiver" as outlined on page 5 would also require the nurse supervision and administration outlined earlier in the guidance. In the case of patients who are trained to perform their dialysis without the requirement of a care partner, we recommend that the nursing home keep record of the nephrologist's recommendation as to whether they recommend the patient perform their own treatment or receive care with their treatments from trained care partners.

ii. Allowing for Accommodations for Patient Centered Care

The Alliance appreciates CMS's commitment to patient safety, as evidenced by the requirements for adequate patient monitoring included in the draft guidance. However, the Alliance also understands that within the nursing home patient population, there is a significant range in the factors that contribute to whether or not a patient requires constant supervision during a dialysis treatment; these factors can include acuity, experience with dialysis, and capacity for personal decision making. Therefore, the Alliance recommends that the decision as to the level of monitoring and direct visual contact be determined as part of the ESRD Plan of Care, with input from the nephrologist and the rest of the Interdisciplinary team. As an example, the plan of care may be permitted to make adjustments for patients who have been trained to dialyze with or without a care partner prior to long-term care facility admission and have maintained the physical and mental acuity necessary to apply that training and dialyze without direct visual contact with their nurse throughout the duration of their

treatment, when approved by the nephrologist. All patients would still be expected to have staff checks at routine intervals throughout the treatment.

iii. Allowing Additional Staff to Initiate Dialysis

The Alliance recommends allowing patients, trained care partners or certified patient care technicians to initiate dialysis, under the supervision of an LPN, LVN or RN. Specifically, in addition to the patients or their trained care partner, we recommend that CMS align this guidance with the "Guidance to Surveyors for Long-term Care Facilities," published in July of 2017, which states "An RN, LPN/LVN, a nurse aide or a trained technician can provide dialysis treatments if not in conflict with the States Nurse Practice Act/Scope of practice and only if the individual has received training from a qualified dialysis trainer from a certified dialysis facility for the individual resident receiving HHD/PD" (page 363).

iv. Dialysis Supervision and Administration: Point Two

The guidance document "Dialysis in Nursing Homes" outlines the supervision necessary for dialysis. Point #2 of the section "Dialysis Supervision and Administration" states, "…qualified dialysis administering personnel (HD or PD) are present in the room…" The Alliance recommends that CMS clarify that this section pertains only to HHD, not PD, given that delivery of PD does not have the same requirements.

b. The Alliance Recommends that CMS Require all Patient Plans of Care to Include Who Performs Dialysis for the Patient.

The Alliance is encouraged that CMS addressed the needs of patients who come into the nursing home setting already on a home dialysis modality, and potentially already working with a preferred care partner. However, the Alliance acknowledges that there are potential occasions where existing personal care partners may not be available to assist in performing the patient's dialysis treatment. Therefore, the Alliance respectfully requests that CMS require all patient plans of care to include primary care partners as well as employees of the nursing home who may perform or assist in performing dialysis for each patient.

III. The Alliance Recommends that CMS Clarify Which Nursing Home Settings are Allowable for the Purposes of Providing Home Dialysis.

The Alliance noted a lack of guidance addressing the appropriate settings for nursing home dialysis in the draft. As CMS recognized in its State Operations Manual for Long-term Care Facilities Surveyors, some nursing homes provide dialysis for multiple residents at a time, such as up to 4, in a single area/den setting. The Alliance would appreciate CMS providing clarity within the context of this guidance that such a setting is permissible, and what requirements the facility must follow in order to maximize patient safety and access to treatment of their choice. Specifically, we recommend that current guidance on the use of a centralized den setting be allowed. For some patients, this interaction with other patients is important. It also allows for staff efficiency in this setting that may allow increased access to home dialysis in the LTC setting. Flexibility to evaluate various models of care in this setting will permit facilities to identify and offer the setting that best meet the needs of each individual patient across all types of LTC.

IV. The Alliance Requests that CMS Add a Question on Quality of Life to the Interview Questions with Residents.

The Alliance appreciates CMS's inclusion of interviews with residents who receive dialysis in nursing homes in "Exhibit IV: 'Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes." The Alliance has long advocated for the creation and implementation of patient experience metrics that would reflect the experiences of home dialysis patients, not only those dialyzing in a center setting. Accordingly, the Alliance is pleased to see so many questions aimed toward gauging patient experience in the nursing home setting, and would propose adding one more question measuring nursing home dialysis patient quality of life, such as, "How has receiving dialysis in your facility improved your quality of life?"

The Alliance appreciates consideration of our comments. To truly achieve the effect that we hope the guidance is intended to deliver, we must urge the agency to issue a complete and updated State Operations Manual for ESRD Certification without delay. This guidance is long overdue; in the wait for additional clarity, we believe that patients have experienced barriers to home modalities that could have been prevented.

The Alliance appreciates the opportunity to provide comments on the two draft guidance documents, "Dialysis in Nursing Homes," and "Exhibit IV: 'Survey Process for ESRD Surveyors Reviewing Dialysis in Nursing Homes'" and looks forward to working with CMS in the future to advance policies that support appropriate utilization of home dialysis. For any questions you may have, please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700.

Sincerely,

Stephanie Silverman
Executive Director

Submitting Members

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