Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-3366-PN
P.O. Box 8013
Baltimore, Maryland 21244-8013

**RE: CMS-3366-PN: Medicare and Medicaid Programs: National Dialysis Accreditation Commission (NDAC) for Approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program**

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 the application from the National Dialysis Accreditation (NDAC) for recognition as a national accrediting organization (AO) for End Stage Renal Disease (ESRD) Facilities that wish to participate in the Medicare or Medicaid programs.

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. Currently, 11.6 percent of dialysis patients receive treatment at home.[1]

Though the uptake rates for home dialysis have increased incrementally over the years, a 2015 GAO report found that experts and stakeholders indicate that home dialysis could be clinically appropriate for at least half of ESRD patients.[2] Those patients who are able to elect home modalities have shown

[1] United States Renal Data System (USRDS), 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States.
[2] Government Accountability Office, "Medicare Payment Refinements Could Promote Increased Use of Home Dialysis," published November 16, 2015. Available at http://www.gao.gov/products/GAO-16-125.

improved clinical outcomes, including reduced cardiovascular death and hospitalization[3],[4] lower blood pressure[5], reduced use of antihypertensive agents[6], and reduced serum phosphorus[7]. Studies have also shown that patients have better mental health outcomes, including social function, which is vitally important for overall well-being[8]. The Alliance believes that more patients than are currently receiving home dialysis are suitable for, and could benefit from, home dialysis. We believe that dialysis providers, health professionals (including physicians), and policymakers all play an integral role in ensuring that patients have access to the modality of their choice. Our comments identify opportunities for CMS to ensure that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis can access this modality.

The Alliance offers the following comments to the NDAC application.

**I. CMS should continue to recognize the value of home-only programs.**

Since 2013, CMS has recognized the value that home dialysis only facilities, including those that only offer one modality of home dialysis, provide to patients. The Center for Clinical Standards and Quality (CCSQ) released an updated survey and certification memo stating, "Therefore, ESRD Home Dialysis Only facilities may provide HHD or PD or both modalities."[9] The Alliance is pleased with the presence of a new AO application for ESRD facilities but asks CMS to continue to follow survey and certification policy in their consideration of these proposals. Specifically, the Alliance reminds CMS that per 42 CFR 405.2102, the definition of an ESRD facility is, "A facility which is approved to furnish at least one specific ESRD service…" We respectfully ask CMS to factor in how new AOs will view home dialysis only facilities in their accreditation process.

The Alliance has previously commented on the necessity of allowing home dialysis only facilities the ability to be certified for ESRD patients to provide one or both modalities. Denying certification of facilities that offer one home dialysis modality, but not the other could limit a patient's access to all home modalities, thus undermining the long-standing intent of Congress and CMS to encourage the use of home dialysis for appropriate patient populations. We believe that as long as an ESRD facility is in compliance with all of the Conditions for Coverage and properly informs patients about any service modalities that are not provided, the facility should be able to be certified as a home dialysis provider that offers only HHD, only PD or both.

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[3] Weinhandl ED, Liu J, Gilbertson DT, Arneson TJ, Collins AJ: Survival in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. J. Am. Soc. Nephrol JASN 23: 895-904, 2012.
[4] Weindhandl ED, Nieman KM, Gilbertston DT, Collins AJ: Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am. J. Kidney Dis. Office. J, Natl Kidney Found. 65: 98-108, 2015.
[5] Kotanko P, Garg AX, Depner T, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials. Hemodial Int. Int. Symp. Home Hemodial. 19: 386-401, 2015.
[6] Jaber BL, Collins AJ, Finkelstein FO, Glickman JD, Hull AR, Kraus MA, McCarthy J, Miller BW, Spry LA.; FREEDOM Study Group: Daily hemodialysis (DHD) reduces the need for anti-hypertensive medications [Abstract] J Am Soc Nephrol 20: SA-PO2461, 2009.
[7] FHN Trial Group, et al: In-center hemodialysis six times per week versus three times per week. N. Engl J Med, 363: 2287-2300, 2010.
[8] Finkelstein FO, Schiller B, Daoui R et al: At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int. 82: 561-569, 2012.
[9] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-40.pdf

## II. The Alliance welcomes the opportunity for third party accreditation of dialysis facilities, as allowed under the CHRONIC Care Act.

The Alliance appreciates the congressional intent of the CHRONIC Care Act, which was included in the Bipartisan Budget Act of 2018. As stated in the background of this request for comment, "section 50403 of the Bipartisan Budget Act of 2018 amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program. Accreditation by an AO is voluntary and is not required for Medicare participation."[10]

Home dialysis providers deserve flexibility to offer the dialysis modality or modalities best suited to their experience, their patient base, and the capacities of their facilities. Such flexibility will ultimately improve access to essential care for dialysis patients by allowing home dialysis providers to structure their offerings in a manner that preserves their ability to provide home dialysis services.

The Alliance recognizes the need for consistent and quality accreditation of ESRD facilities. We are pleased that Congress chose to include third party accreditation for ESRD facilities in the CHRONIC Care Act. This change is likely to increase access for ESRD patients as accreditation will keep pace with facility openings. ESRD facilities will now receive parity with other Medicare providers.

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The Alliance appreciates the opportunity to provide comments to NDAC's AO application. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

Stephanie Silverman
Executive Director

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[10] https://www.federalregister.gov/documents/2018/08/07/2018-16871/medicare-and-medicaid-programs-national-dialysis-accreditation-commission-ndac-for-approval-of-its

**Alliance for Home Dialysis 2018 Members**

**American Association of Kidney Patients**
**American Kidney Fund**
**American Nephrology Nurses Association**
**American Society of Nephrology**
**American Society of Pediatric Nephrology**
**Baxter**
**Cleveland Clinic**
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**Northwest Kidney Centers**
**NxStage Medical**
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