



July 14, 2021

Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General
US Department of Health and Human Services
330 Independence Ave SW
Washington, DC 20201

Dear Ms. Grimm:

The Alliance for Home Dialysis (Alliance) is a coalition of kidney community stakeholders representing patients, clinicians, providers, and industry. Through the Alliance, we promote policies and programs 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. We have long supported the important work that HHS has done in the interests of patients with kidney disease, particularly efforts to increase access to home dialysis. We have provided regular input in the context of relevant annual rulemaking cycles and have broadly supported the Advancing American Kidney Health Initiative (AAKHI) program and corresponding models developed by the Centers for Medicare and Medicaid Innovation (CMMI).

In an effort to ensure that these models work as successfully as possible in increasing home dialysis, we are writing to you today seeking clarification on a point related to the four voluntary payment models falling under the Kidney Care Choice (KCC) umbrella. More broadly, we would also appreciate clarification as to whether provision of staff assisted home dialysis would be considered an inducement for a dialysis facility enrolled in any voluntary or mandatory value-based payment model.

The Alliance supports policy and programmatic efforts to facilitate staff assistance, or assistance by a professional in the home, for home dialysis patients who require such support. This assistance, even if provided for a time-limited period at the initiation of home therapy, is shown to make an important therapeutic or quality of care difference for patients who want to get the benefits of home dialysis, but who may need extra help to do so. Recent research has shown that providing home assistance can open up access to home dialysis therapy for patients who would benefit from additional support, reassurance, or ongoing training to be successful dialyzing at home, instead of having to resort to in-center dialysis. This type of assistance can also provide a “bridge” for a patient who dialyzes at home, but is faced with an intervening illness and needs help for a period of time, allowing that patient to stay home instead of

revert to in-center dialysis.¹ Further, patients who move from one care setting to another, such as hospital to home or long-term care facility to home, can also benefit from extra support.

Unfortunately, Medicare does not pay for staff assisted home dialysis, and as such, it is not commonly available in the United States other than for patients who can afford to pay out-of-pocket for professional home dialysis assistance² or in limited circumstances through commercial payors. This reality exacerbates pre-existing disparities in access to home dialysis therapy by race, economic status, and even location.

As related to the AAKHI, our members believe that increased availability of staff assistance can help providers participating in the KCC model to more easily reach the goals of the models for increased numbers of patients on home therapy. However, there is some confusion currently in the HCP and provider community regarding the desire among many to provide staff assistance and whether doing so might run afoul of existing anti-kickback rules which prohibit offering free goods or services. Clarity is needed on this matter, and we therefore ask that OIG provide clarifying language on the following question:

Would OIG consider provision of staff assisted home dialysis by a dialysis facility or clinician (nephrologist, nurse, etc.) to be an inducement as defined by the Physician Self-Referral Law or the federal Anti-Kickback Statute?

Thank you in advance for your attention to this matter. Should you have any questions or wish to talk with a member of the Alliance staff, please contact Michelle Seger at michelle@homedialysisalliance.org.

Sincerely,



Michelle Seger
Managing Director

CC: Elizabeth "Liz" Fowler, Deputy Administrator & Director, CMMI; Robinsue Frohboese, Acting Director and Principal Deputy, HHS OCR

¹ <https://www.asn-online.org/education/distancelearning/curricula/geriatrics/Chapter23.pdf>

² <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf>