



Ms. Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0803-N
Cohen Building, Room 5513
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0803-N: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on its Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP.

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 improved clinical outcomes, including reduced cardiovascular death and

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>.

hospitalization^{3,4} lower blood pressure⁵, reduced use of antihypertensive agents⁶, and reduced serum phosphorus⁷. Studies have also shown that patients have better mental health outcomes, including social function, which is vitally important for overall well-being⁸. 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.

The Alliance offers the following comments to the Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP.

1. Definition of “Telehealth Technologies”

Section 50302(c) of the Bipartisan Budget Act of 2018 created a new exception to the definition of “remuneration” in the beneficiary inducement civil monetary penalty (CMP) statute for “telehealth technologies” provided on or after January 1, 2019. Congress directed the Secretary to establish a definition for “telehealth technologies,” and the OIG solicits comments on how “telehealth technologies” should be defined.

The Alliance for Home Dialysis supports a definition of “telehealth technologies” that promotes improved patient access to quality care while reducing costs. The Center for Medicare & Medicaid Services (CMS) has recognized that telehealth technologies can achieve these dual objectives either as a substitute for professional in-person visits, or as a clinical decision-making support tool. Accordingly, we urge the OIG to adopt a definition of “telehealth technologies” that accommodates both purposes.

Under certain circumstances, Medicare separately pays for certain “telehealth services” that serve as a substitute for professional in-person visits.⁹ In order for these “telehealth services” to be reimbursed by Medicare, the telecommunications system in question must be an “interactive” telecommunication system with audio and video equipment that permits two-way, real-time interactive communication between the patient and distant site physician or

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 Weinhandl 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 See § 1834(m) of the Social Security Act.

practitioner.¹⁰ CMS adopted this definition of a qualifying telecommunication technology because it viewed that in order for a telehealth service to be a “substitute” for an in-person visit, the underlying technology must enable the physician or practitioner to conduct a medical examination of the patient.¹¹

In addition to supporting telehealth visits, “telehealth technologies” could enhance clinical decision-making in other ways as well, even if not directly reimbursed by Medicare. CMS recognized most recently in the CY 2019 Home Health Prospective Payment System proposed rule that some telecommunications system enable “remote patient monitoring” (RPM), which CMS described as “digital technologies [that] collect medical and other forms of health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment and recommendations.”¹² RPM allows patients to collect and transmit a myriad of important clinical data, such as blood pressure, blood sugar, blood oxygen levels, heart rate, and electrocardiograms, all of which could support providers in the delivery of patient care and reduce the number of hospitalizations, readmissions, and lengths of stays in hospitals.¹³ CMS succinctly summarized the value of RPM technologies when it stated:

“Surveillance and case management are frequently occurring interventions in home health, and remote patient monitoring leverages technology to encourage patient involvement and accountability in order to improve care coordination.”¹⁴

In summary, we urge that the OIG’s definition of “telehealth technologies” take into consideration the full spectrum of telehealth technologies that serve to improve patient care through enhanced care coordination and case management.

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¹⁰ See 42 C.F.R. § 410.78.

¹¹ 63 Fed. Reg. 58814, 58880 (Nov. 2, 1998).

¹² 83 Fed. Reg. 32425, (July 12, 2018).

¹³ “Remote Patient Monitoring,” Center for Connected Health Policy (last accessed on Sept. 24, 2018), <http://www.cchpca.org/remote-patient-monitoring>.

¹⁴ See 83 Fed. Reg. at 32425.

The Alliance appreciates the opportunity to provide comments to the Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP. 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,

A handwritten signature in black ink that reads "Stephanie Silverman". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Stephanie Silverman
Executive Director



Alliance for Home Dialysis Endorsing Members

**American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
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