Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: CMS-1676-P: CY 2018 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B

Dear Ms. Verma:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on its proposed rule updating payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS) for calendar year 2018.

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

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

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 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 are able to access this modality.

The Alliance offers the following comments to the Physician Fee Schedule Proposed Rule.

I. Misvalued Codes Under the Physician Fee Schedule

The Alliance deeply appreciates CMS' commitment to incentivizing home dialysis, and its consideration of all factors within its control to help ensure that patients have access to dialysis treatments in their homes. Research has shown that the 2004 transition from capitation to tiered fee-for-service payment for in-center hemodialysis has had the unintended consequence of reducing home dialysis use by creating a payment disparity for home and in center care management.[9] Patients in traditional Medicare experienced a reduction in the absolute probability of home dialysis use following payment reform.

In last year's rule, CMS recognized that the CPT codes related to home dialysis were misvalued. We appreciate that CMS restates its finding from last year's rule that CPT Codes 90963 through 90970 are misvalued, but are concerned that the agency does not outline plans for reevaluation of these codes. Because we strongly agree with the goal of using all policy tools available to

---

[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.

[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] Erickson, K.F., Winkelmayer, W.C., et al: Effects of Physician Payment Reform on Provision of Home Dialysis. AJMC. Published online, available at: http://www.ajmc.com/journals/issue/2016/2016-vol22-n6/effects-of-physician-payment-reform-on-provision-of-home-dialysis.

incentivize the use of home dialysis, and believe this should be accomplished in the most expedient manner possible, we urge CMS to use its authority to adjust Medicare payments for physicians' services to increase the current rate for managing home patients (90966) to the maximum payment amount for managing center based payments (90960).[10] CMS has used its administrative authority in the past to adjust values for CPT codes, and has specifically done so to achieve the Congressional mandate to develop renal reimbursement mechanisms that "…provide[] incentives for the increased use of home dialysis.[11]" Employing administrative adjustment in this instance is the most straight forward, expedient way to change the incentive and encourage home dialysis.

II. Clinically Accepted Care Practices and Telecommunications Technology for Access Site Examinations

The Alliance is concerned with the highest standards of clinical care for home dialysis patients. As such, we appreciate the opportunity to provide comments on clinically accepted care practices for access site examinations, specifically regarding how telecommunications technology could be employed to examine the access site.

Complications related to the access site are dangerous, and can lead to infection and hospitalization. In order to prevent such complications that can have significant health impacts, clinicians and patients must ensure that access site is regularly evaluated. At a minimum, the clinician must have a clear picture of the access site. The Alliance believes that, when clinically appropriate and agreed upon by the provider and the patient, monthly access site evaluations could take place with the help of high resolution image transfer to the provider.[12] When

---

[10] See Social Security Act § 1848(c)(describing the determination of relative values for physicians' services and directing the Secretary to determine the work relative value units for each physicians' service or group of services based on the relative resources incorporating physician time and intensity required in furnishing the service). In addition, § 1848(c)(2)(K) of the Act provides CMS with the explicit authority to identify services as being potentially misvalued and "to review and make appropriate adjustments to the relative values established . . . ." CMS has the authority to establish work RVUs for new, revised and potentially misvalued codes on its own without working through the RUC as part of the three year review process (CMS' review "generally includes, *but is not limited to*, recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC)"). 80 Fed. Reg. at 70889 (Nov. 16, 2015).

[11] See Social Security Act § 1881(b)(3)(B) which directs the Agency to develop within the Physician Fee Schedule a mechanism "which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis…"

[12] The Alliance urges CMS to be consider how HIPAA regulations interact with telecommunications technologies, particularly regarding secure transmission and storage of patient electronic protected health information, when making any change to monthly access site examination requirements. HIPAA 45 C.F.R. § 164.530(c) allows covered health care providers to communicate electronically with their patients provided they apply reasonable safeguards. These reasonable safeguards include protecting information through encryption and data security, and must abide by HIPAA compliance, healthcare industry standards, and compliance with various state laws. Under Privacy Rule 45 C.F.R. § 164.522(b), individuals have the right to request and have a covered health care provider communicate by alternative means or at alternative locations, if reasonable. Pictures and Videos are considered Protected Health Information (PHI). HIPAA Standard 164.306(b): Flexibility Approach, permits photos to be used

possible and necessary for the provider and patient, real time video can also provide meaningful assessment opportunities. However, we believe that CMS should require an in-person access site examination once per quarter, as well as an in-person visit for any patient who exhibits signs of infection or experiences symptoms that are signs of infection (including bleeding, swelling, and pain) or other problems during the telehealth check.

We urge CMS to consider permitting these technologies to maximize the value of telehealth. By allowing monthly access site examinations to take place through telecommunications technologies, patients would no longer have to travel to a hospital or facility-qualifying site to interface with an approved practitioner. This task is oftentimes difficult for dialysis patients and may act as a disincentive to adopt home dialysis as a treatment option.

The Alliance appreciates the opportunity to provide comments to the Proposed Rule. We look forward to continuing to work with CMS to advance policies that support appropriate utilization of home dialysis.

Please feel free to contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions or would like additional details.

Sincerely,

Stephanie Silverman
Executive Director

---

while implementing reasonable and appropriate security measures. These measures abide by the same reasonable safeguards as HIPAA 45 C.F.R. § 164.530(c).
https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/adminsafeguards.pdf

Submitting Members

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Pediatric Nephrology
Baxter
Cleveland Clinic
DaVita
DEKA
Dialysis Clinic, Inc.
Fresenius Medical Care
Home Dialyzors United
ISPD North America
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
NxStage Medical
Satellite Healthcare
The Rogosin Institute
TNT Moborg International Ltd.