



September 6, 2016

Mr. Andrew Slavitt
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-1654-P: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017

Dear Administrator Slavitt:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare & 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 2017.

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, 10.2 percent of incident dialysis patients and 11.5 percent of prevalent dialysis patients receive treatment at home.¹

As CMS recognizes in this year's rule, a recent GAO report found that experts and stakeholders indicate that home dialysis could be clinically appropriate for at least half of ESRD patients.²

¹ United States Renal Data System (USRDS), 2015 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>.

Those patients who are able to elect home modalities have shown improved clinical outcomes, including reduced cardiovascular death and 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. 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 make the choice and access this modality.

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

Section II. C. Medicare Telehealth Services

The Alliance commends CMS for its proposal to add additional home dialysis ESRD services (CPT codes 90967-90970) to its telehealth list. We believe that physician management of ESRD patients, which can involve the complex monitoring of comorbidities, can be effectively delivered via telehealth when part of an overall care plan that maximizes patient benefit. We are pleased to see CMS recognizing this capacity and the potential for evolving technologies to improve and expand the care available to home dialysis patients.

However, as the agency recognizes, a patient's home and dialysis facility are not yet authorized as originating sites for telehealth, and authorizing either location as an "originating site" for purposes of telehealth payments would require an act of Congress. Congress is currently considering several proposals in this area. The Medicare Telehealth Parity Act of 2015 (H.R. 2948),⁹ sponsored by Representatives Mike Thompson (D-CA) and Gregg Harper (R-MS), designates the home as an originating site for the purposes of the monthly clinical visit for home dialysis patients. The Chronic Kidney Disease Improvement in Research and Treatment Act of 2015 (H.R. 1130),¹⁰ sponsored by Representatives Tom Marino (R-PA), John Lewis (D-GA) and Peter Roskam (R-IL), designates the renal dialysis facility as an originating site. The Senate

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 See Section 2(b)(2) of H.R. 2948 (Medicare Telehealth Parity Act of 2015), 114th Congress (2015-2016)

¹⁰ See Section 203 of H.R. 1130 (Chronic Kidney Disease Improvement in Research and Treatment Act of 2015), 114th Congress (2015-2016).

Finance Committee's Chronic Care Working Group is considering both options, as published in its Policy Options Document released earlier this year.

We strongly encourage the agency to work with these and other policymakers in Congress who are exploring the potential addition of originating sites for the purposes of treating home dialysis patients; the agency can be a vital source of support around the technical aspects of these proposals. For example, CMS could verify that, given the capitated structure of the monthly capitated payment, changing the location of the service would not increase Federal spending. In addition, we encourage CMS to support the critical safeguards that the Alliance has previously endorsed, including face to face interaction with a physician at least once every three calendar months. CMS can also provide insight into existing Conditions for Coverage, which provides guidance relating to the regularity with which home dialysis patients see their nurses and facility staff for inspections of catheter access sites and other issues.

The Alliance is encouraged by lawmakers' interest in ensuring that home dialysis patients can reap the benefits of emerging telehealth technologies, and hopes that CMS will continue to work with all interested stakeholders to help these policies move forward.

Section II.D. Potentially Misvalued Services 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. In the proposed rule, CMS recognizes that far more patients could be clinically appropriate for home dialysis than are currently utilizing the modality, and that the GAO specifically looked at Medicare payment issues that could change this pattern.¹¹ We support CMS' efforts to comply with the GAO recommendation to CMS

to examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients, and revise them if necessary to ensure that policies are consistent with our goal of encouraging the use of home dialysis among patients for whom it is appropriate.¹²

In particular, we support CMS' proposal to identify CPT codes 90963 through 90970 as potentially misvalued codes so that the Agency can evaluate the physician services under these codes and adjust the Medicare payment as needed.

In a recent study published in the American Journal of Managed Care, researchers found that transition to fee-for-service payment for in-center hemodialysis had the unintended consequence of reducing home dialysis use. Patients most affected by the policy experienced a reduction in the absolute probability of home dialysis use following payment reform. "These findings highlight both an area of policy failure and the importance of considering unintended

¹¹ See 81 Fed. Reg. at 46189.

¹² Id.

consequences of future efforts to reform physician payment," the authors wrote.¹³ Again, we commend CMS for considering this issue in this year's proposed rule.

Because we strongly agree with the goal of using all policy tools available to 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).¹⁴ 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."¹⁵ Employing administrative adjustment in this instance is the most straight forward, expedient way to change the incentive and encourage home dialysis.

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 Elizabeth Lee at elee@homedialysisalliance.org or 202-466-8700 if you have any questions or would like additional details.

Sincerely,



Stephanie Silverman
Executive Director

¹³ Erickson, K.F., Winkelmayr, 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>.

¹⁴ 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).

¹⁵ 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..."



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