



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-1693-P: Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019

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 2019.

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. 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 Physician Fee Schedule Proposed Rule.

I. The Alliance commends CMS for its streamlined and straightforward proposed implementation of the CHRONIC Care Act.

The Alliance has long supported making the home and dialysis facility originating sites for home dialysis patients' clinical assessment via telehealth, and actively supported the CHRONIC Care Act, which included these provisions and was passed earlier this year. With this change, patients will no longer have to travel to a hospital or facility-qualifying site to interface with an approved practitioner in-person on a monthly basis- a task that is often difficult for dialysis patients and may act as a disincentive to adopting home dialysis as a treatment option.

Section 50302 of the Bipartisan Budget Act (BBA) of 2018 amended sections 1881(b)(3) and 1834(m) of the Social Security Act to allow an individual with end stage renal disease receiving home dialysis to choose to receive certain monthly end stage renal disease-related (ESRD-related) clinical assessments via telehealth on or after January 1, 2019. Specifically, the BBA created the opportunity for the in-person visit for home dialysis to be completed via telehealth, after the patient has been home for 3 months and as long as the physician completes an in-person visit with the patient 1 time every 3 months.

Use of existing telehealth platforms will allow physicians to offer appropriate patients the choice of meeting in-person or having their monthly visit completed from their home setting via telehealth. The available platforms, combined with the electronic medical record, will allow

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, Gilbertson 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.

physicians to improve the patients experience and may increase access to home dialysis therapies.

The use of telehealth will better align payment with patient care needs and better ensure that clinically complex and ill beneficiaries have appropriate access to home therapies. It should also improve interdisciplinary team processes, allowing for better coordination of care and will reduce the burden on patients by eliminating the need to travel to and from office visits. This is particularly significant for those patients who live long distances from their physician, those who face transportation challenges, and for times of inclement weather. The use of telehealth, including additional data collection capabilities will further capture patient information that can be shared among providers, allow for ease of tracking and trending elements of the care, and identify treatment interruptions or other areas for potential intervention to keep patients on their home therapies.

Current telehealth platforms offer the ability for physicians to access store-and-forward data from dialysis equipment, including treatment sheets and basic physiologic parameters. Telehealth for purposes of the monthly MCP visit should also allow for patients to show or submit pictures of their access site to complement the stored data captured during treatments, in addition to the face to face video visit. Beyond optional usage in the monthly MCP visit, telehealth and similar electronic communication technologies should be permitted to occur between the care team and patient for *ad hoc* issues.

The Alliance commends CMS for its thoughtful approach to proposed implementation of the CHRONIC Care Act, which supports innovative technological advances that help patients more easily access home dialysis therapy.

II. The Alliance urges CMS to expand access to Kidney Disease Education.

Research shows that adequate education is paramount when choosing a dialysis modality, and that patients who receive appropriate education are more likely to choose a home modality. According to the International Society for Peritoneal Dialysis, education is paramount: “Of the approximately 382,000 dialysis patients in the United States, very few dialyze at home and 75% of those starting in-center hemodialysis (HD) therapy report not being aware of the option to dialyze at home. If informed of such a choice, 40% select home dialysis...”⁹

However, current uptake of the Kidney Disease Education (KDE) benefit, which provides this important patient education around dialysis modalities, has been historically low and continues to fall. According to the United States Renal Data System (USRDS), in 2011 and 2012, less than 2% of eligible Medicare beneficiaries used the KDE benefit. And MedPAC concluded that in the

⁹ Thomas A Golper et al., *Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis*, 58 AM. J. KIDNEY DIS. 879–885 (2011), <https://www.ncbi.nlm.nih.gov/pubmed/21903316> (last visited Jun 11, 2018). Emphasis added.

same years, Medicare only paid for KDE for approximately 4,200 patients; in 2013 that number fell to 3,600.

The Alliance urges CMS to take the following actions, which would increase uptake of KDE, thereby increasing uptake of home dialysis therapy:

1. CMS should consider waiving the coinsurance requirement associated with KDE.

Currently, Medicare beneficiaries are responsible for the 20 percent coinsurance requirement associated with KDE as a Part B benefit. In general, Medicare pays 80 percent of the approved amount for a Part B covered service in excess of the annual deductible, and the beneficiary is liable for the remaining 20 percent.¹⁰ For some beneficiaries, the 20 percent coinsurance is prohibitive to accessing the services. The Alliance recommends that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act with respect to KDE services for beneficiaries. Doing so would allow more beneficiaries to access KDE services.

2. CMS should designate KDE as a preventive service.

As stated above, Alliance members, particularly our physician members, are concerned that the co-pay associated with KDE disincentivizes both providers and patients from taking advantage of these services. Providers are reluctant to bill patients for a service that was provided for free in the past, and patients may not have the financial means to pay the coinsurance fee.

However, CMS has the authority to add full coverage, without co-insurance, for preventive services in Medicare through the National Coverage Determination process if the new service meets certain required criteria.¹¹ The Alliance believes that KDE meets these criteria and encourages CMS to support inclusion of KDE as a preventive service.

3. CMS should consider utilizing CMMI's Comprehensive ESRD Care Model to test other methods of expanding access to KDE, such as by expansion of provider or CKD stage, in a smaller group of patients

While changes to statute would be required to permanently broaden the clinicians allowed to prescribe or provide KDE, as well as to expand the eligible CKD stages, CMS could utilize CMMI's Comprehensive ESRD Care Model (CEC Model) to make these changes on a smaller scale, allowing for data collection and quality improvement within the model. Making these changes within the CEC Model would be impactful for the many patients and providers utilizing this model.

¹⁰ Section 1833(a)(1) of the Social Security Act.

¹¹ <https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>.

i. Expansion of clinicians eligible to refer patients to KDE services.

Currently, the relevant statute only allows nephrologists to refer patients to KDE.¹² The Alliance believes that other clinicians, specifically nurse practitioners, physician assistants, and clinical nurse specialists have the expertise and training required to prescribe KDE to patients. While we understand that an across-the-board change would require revisions to statute, CMMI could broaden the scope of clinicians eligible to refer to KDE within the ESCOs as a first step. The Alliance urges CMS to work with CMMI to do so.

ii. Expansion of providers eligible to be “qualified person[s]” for the purpose of providing KDE.

The Social Security Act requires that KDE services be furnished, upon the referral of the physician managing the individual’s kidney condition, by a “qualified person.” The statute defines a “qualified person” in paragraph (2)(A) as a:

(i) a physician defined in section 1861(r)(1) of the Act or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1848; and

(ii) a provider of services¹³ located in a rural area (as defined in section 1886(d)(2)(D)).¹⁴

The Alliance believes that other healthcare professionals, such as registered home dialysis nurses, as well as dialysis facility nurses, are qualified to provide and to receive reimbursement for KDE services. These professionals have relationships with the patients that put them in a position to communicate effectively and allow them to tailor the education services to the individual’s needs in an effective manner. In addition, these healthcare professionals may be more available to the patient than a physician, physician assistant, nurse practitioner, or clinical nurse specialist. Broadening the scope of individuals who can provide the KDE services would increase the likelihood that the services reach patients in need of KDE. The Alliance urges CMS to encourage CMMI to expand the universe of clinicians eligible to be “qualified persons” for the purpose of KDE.

iii. Expansion of CKD patient eligibility for KDE.

Section 1861(ggg)(1)(A) of the Act, establishes that in order for the KDE services to be covered by Medicare, the services must be furnished to an individual with Stage IV CKD, who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant. As implemented, all Stage IV CKD is covered because, as CMS explained, “there are

¹² Section 1861(ggg) of the Social Security Act.

¹³ CMS defines “provider of services,” consistent with the definition of “provider of services” at section 1861(u) of the Act as a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program.

¹⁴ Section 1861(ggg)(1)(B) of the Social Security Act.

currently no agreed upon accepted clinical guidelines that describe the stage IV patients who would eventually require dialysis or a kidney transplant.”¹⁵

However, all other stages of CKD were left out of the eligibility for KDE. Perhaps most problematic is the fact that Stage V CKD patients are ineligible, as these are the patients closest to needing dialysis or transplant. CKD Stage V patients, who are even closer to developing ESRD than those in Stage IV, should also be included in KDE eligibility. Specifically, Stage V patients are defined as having kidney failure with the need for dialysis or transplant and may have many complications including all applicable to Stage IV as well as bone abnormalities, swelling, and shortness of breath. These patients have an urgent need for KDE as they are likely to start dialysis imminently, and CMS should encourage CMMI to allow Stage V patients to receive KDE under the CEC Model.

III. 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.¹⁶ Patients in traditional Medicare experienced a reduction in the absolute probability of home dialysis use following payment reform.

In 2017’s rule, CMS recognized that the CPT codes related to home dialysis were misvalued. We appreciate that CMS reiterated this finding in the 2018 rule and this year’s proposed rule but are concerned to see 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 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).¹⁷ 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[]

¹⁵ 74 Fed. Reg. at 61896 (Nov. 25, 2009) (Defining Stage IV CKD as kidney damage with a severe decrease in glomerular filtration rate (GFR) quantitatively defined by a GFR value of 15-29 ml/min/1.73 m², using the Modification of Diet in Renal Disease (MDRD) Study formula).

¹⁶ 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>.

¹⁷ 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).

incentives for the increased use of home dialysis.¹⁸ Employing administrative adjustment in this instance is the most straight forward, expedient way to change the incentive and encourage home dialysis.

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The Alliance appreciates the opportunity to provide comments to the Physician Fee Schedule proposed rule for CY 2019. 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

¹⁸ 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...”



Alliance for Home Dialysis Endorsing Members

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