



Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: CMS-1734-P: Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021

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 2021. 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 Government Accountability Office (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

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>.

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. 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 thanks CMS for recognizing that certain HCPCS codes may complement Transitional Care Management (TCM) codes when medically necessary, instead of duplicating services.

The Alliance thanks CMS for its recent determinations that several ESRD HCPCS codes should be allowed to be paid separately alongside TCM codes. In the CY2020 Physician Fee Schedule, we requested and were pleased to see CMS allow for billing concurrent with TCM services of five codes specific to ESRD patients: 90960, 90961, 90962, 90966, and 90970. The Alliance agrees with CMS that these five abovementioned codes are distinct and complementary to the TCM codes/services. We do not believe that any of these five codes duplicate or substantially overlap TCM services, and we agree that removing the current billing restrictions around these codes may increase utilization of TCM services.

II. The Alliance thanks CMS for expanding the Kidney Disease Education Benefit (KDE) in the ESRD Treatment Choices Model (ETC Model) but urges further modifications.

While the Alliance was encouraged to see CMS broaden the availability of kidney disease education (KDE) in the recently finalized ETC Model, we continue to believe that these changes must be expanded to cover the entire country – not only cover the demonstration locations. Further, we believe that additional steps should be taken by CMS to increase access to KDE even more than was done in the draft Model.

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, 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.

As CMS has recognized, the KDE benefit is an important tool for patients and providers. However, current uptake of the KDE benefit 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 same years, Medicare only paid for KDE for approximately 4,200 patients; in 2013 that number fell to 3,600.

In its 2015 report on home dialysis, the GAO recommended that the CMS Administrator examine the KDE benefit in an effort to discern if more providers and patients should be eligible for the benefit, reflecting a deep understanding of the positive impact of KDE on modality choice. The Alliance again thanks CMS taking action on this suggestion and for expanding KDE within the ETC Model, but would also urge the following additional changes:

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.⁸ 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.⁹ The Alliance believes that KDE meets these criteria and encourages CMS to support inclusion of KDE as a preventive service.

3. CMS should allow dialysis facilities to bill for KDE.

Dialysis facilities are well-equipped to provide KDE as they typically employ the exact interdisciplinary teams necessary for an effective KDE program and patients are often present in dialysis clinics – even home patients who must see their nephrologists at certain times. Yet, dialysis clinics are currently excluded from being reimbursed for KDE provided at their facilities. CMS should therefore allow dialysis facilities to provide and bill for KDE.

III. The Alliance urges CMS to consider ways to incentivize placement of PD catheters as part of its overarching effort to increase rates of home dialysis in the US.

⁸ Section 1833(a)(1) of the Social Security Act.

⁹ <https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>.

The Alliance supports the Administration's commitment to addressing challenges facing the 37 million Americans suffering from kidney disease, and as part of that commitment, the effort to promote home dialysis. As CMS is aware, increasing the rate of home dialysis necessarily requires increasing the utilization rate of both non-facility-based dialysis modalities: PD and HHD. PD is the most common dialysis modality that permits patients to dialyze in their own home. Studies are conclusive that patients who start dialysis with PD have a 20% to 30% lower risk of death during the first one to three year after initiating dialysis, compared to those initiating with in-center HD.¹⁰

PD requires the surgical insertion of a PD catheter in order to function. However, our members report that there are currently barriers standing in the way of timely placement of PD catheters, which ultimately impacts PD initiation rates. For example, we have heard time and time again that there are not enough clinicians educated and available to place PD catheters, and compounding this problem, when an educated clinician wants to do these procedures, he or she often faces a barrier in getting adequate operating room timed booked.

The Alliance urges CMS to look into this issue and consider what the agency can do through the physician fee schedule to better incentivize PD catheter placement, especially given the lofty goals for home dialysis uptake included in the President's executive order on Advancing American Kidney Health. The Alliance would like to meet with CMS to discuss ways to collaboratively address this problem.

IV. The Alliance appreciates CMS's efforts to support home dialysis modalities, including through regulations related to remote patient monitoring (RPM), and offers the following comments.

The Alliance believes that as the standard of care for Medicare ESRD patients evolves towards more patient-centered modalities, coding for remote physiologic monitoring (RPM) services is critical to ensuring that providers may properly bill for such services. We also agree with CMS that RPM services do not create a risk of duplicative payment or overlap for TCM services; to the contrary, medically necessary RPM services complement the TCM code sets and removing billing restrictions will increase utilization of TCM services.

We applaud CMS's efforts to support this overall effort by proposing to modify certain CPT coding limitations from direct to general supervision, as reflected in the final CY2020 PFS Rule which changed the requirement for code 99457 from direct supervision to general supervision. The Alliance also thanks the agency for the acknowledgement in last year's Final Rule that CPT codes for RPM services 99091, 99453, 99454, and 99457, should be billable monthly.

The Alliance would further request that CMS allow these codes to apply for patients with chronic kidney disease (CKD), as well as acute kidney injury (AKI) who may still be dialyzing at home while recovering their kidney function. In the case of CKD patients, RPM is an important tool for providers to track the progress of disease and empower patients with the knowledge and care they need to prepare for potential kidney failure. AKI patients who may wish to dialyze at home while they

¹⁰ Kumar, et al. *Kidney Int.* 2014; 86(5): 1016-1022.
Termorshuizen, et al. *J Am Soc Nephrol.* 2003a; 14(11): 2851-2860.

recover their kidney function can benefit greatly from the option to have their physiologic information monitored remotely, negating the need for frequent in-person visits.

V. The Alliance provides the following comments on E/M codes in relation to the MCP.

The Alliance supports the CY2021 proposal to revalue the ESRD MCP codes, in recognition that the ESRD monthly services codes 90951-90961 have values closely tied to the values of office/outpatient E/M codes, and that these E/M codes (99212 and 99214) have seen multiple increases over the years without commensurate increases to the ESRD MCP code family. As such, we support the CMS proposal to increase the value of the ESRD MCP codes through a revaluing of the work, physician time, and clinical staff practice expense (PE) inputs factored into those codes.

VI. The Alliance urges CMS to use its authority to adjust the identified misvalued codes related to ESRD to increase the current rate for managing home patients to the maximum payment for managing in-center patients.

The Alliance deeply appreciates CMS's 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. As discussed in more detail throughout the letter, we are concerned that current payment structures have led to a disparity in payment for home and in-center dialysis care management. We believe that this payment disparity has led to a reduction in the probability that patients will be able to access home dialysis therapy, and urge you to consider these factors when working to increase overall home dialysis access and uptake.

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 in-center patients (90960).¹¹

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."¹² Employing administrative

¹¹ 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).

¹² 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..."

adjustment in this instance is the most straightforward, expedient way to change the incentive and encourage home dialysis.

VII. The Alliance offers the following comment on audio-only telehealth services.

The Alliance for Home Dialysis was pleased that CMS granted our request at the beginning of the PHE, to change the Physician Fee Schedule status indicators for telephone consult codes (99441-99443) from their current status of “N” for non-covered to “A” for covered.

As efforts continue to address disparities in access to telehealth technology, one interim solution would be to continue to cover these E&M services, at the current payment amount arranged under the waiver, for both new and established patients who lack access to reliable video technology or internet bandwidth. Appropriate guardrails should be in place for audio calls, including:

- Documentation should include that a good faith effort for audio-video call was inadequate to complete the visit.
- Patient’s electronic medical records available and reviewed during the call.

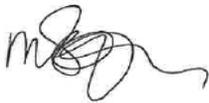
We would request that patient participation in an audio-only E&M visit be sufficient both for consent and to fulfill the patient-initiated requirements.

In instances where poor connectivity allows for some, but not all, of a visit to be conducted through video, a provider should use their best judgment as to which billing code most accurately describes the visit.

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The Alliance appreciates the opportunity to provide comments to the Physician Fee Schedule proposed rule for calendar year 2021. 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, appearing to read 'MS', with a long, sweeping flourish extending to the right.

Michelle Seger
Managing Director



American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association*
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Cleveland Clinic
DEKA*
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