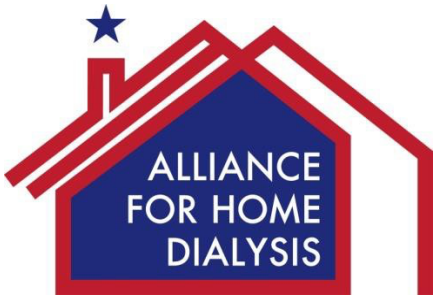

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-1751-P: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

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 (CY) 2022.

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote and advance 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.

We appreciate that CMS has long recognized home dialysis – peritoneal dialysis (PD) and home hemodialysis (HHD) – as an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental

Health. The most recently available data show that in 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients.[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 and hospitalization, lower blood pressure, and reduced overall mortality.[3,4,5,6] Studies have also shown that patients have better mental health outcomes, including social function, which is vitally important for overall well-being.[7]

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 CY22 Physician Fee Schedule proposed rule:

I. The Alliance applauds CMS for revaluing ESRD monthly capitated payment (MCP) codes in the CY 2021 PFS final rule.

The Alliance appreciates CMS's decision in last year's final PFS rule to revalue certain 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 CMS's decision to increase the value of the ESRD MCP codes

[1] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.
[2] Government Accountability Office. Medicare Payment Refinements Could Promote Increased Use of Home Dialysis. November 16, 2015. 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] Rydell, H., Ivarsson, K., Almquist, M. et al. Improved long-term survival with home hemodialysis compared with institutional hemodialysis and peritoneal dialysis: a matched cohort study. BMC Nephrol 20, 52 (2019). https://doi.org/10.1186/s12882-019-1245-x
[7] Masterson R. The advantages and disadvantages of home hemodialysis. Hemodialysis International, 12: S16-S20, 2008. https://doi.org/10.1111/j.1542-4758.2008.00290.x

through a revaluing of the work, physician time, and clinical staff practice expense (PE) inputs factored into those codes.

II. The Alliance appreciates CMS's efforts to expand telehealth and remote patient monitoring (RPM) services, and urges additional action to increase access to these beneficial services.

As new technologies – like telehealth and RPM – have emerged to help improve a patient's quality of, and access to, a wider array of kidney care modalities, the Alliance has advocated for broader access to these innovations. Many of our member organizations are investing in new telehealth and RPM capabilities because we know that patients can benefit from the option to receive some of their dialysis care remotely. However, underserved patients living in both urban and rural communities some patients continue to experience poor access to necessary technologies and are not able to fully benefit from new digital tools or expanded access to telehealth. For example, lack of access to high-speed internet or appropriate communication devices keeps some of our member organizations' patients from leveraging the benefits of telehealth and RPM technology. Unfortunately, these challenges have only been accentuated during the pandemic.[8]

The Alliance does appreciate CMS's efforts to alleviate pressures on patients by expanding access to telehealth and RPM. First, we want to thank you for the rapid and necessary changes you have made to allow dialysis patients to stay in their homes as much as possible during the public health emergency (PHE). Specifically, we appreciate CMS's work in implementing the Coronavirus Aid, Relief, and Economic Security (CARES) Act provision that would remove the once a quarter in-person visit requirement under the MCP for home dialysis patients during this time.[9] In addition, we appreciate that CMS relaxed the barriers to providing telehealth services over rural state lines.[10] Furthermore, we appreciate the HHS sent a letter to state governors seeking to remove other barriers to telemedicine, including state licensing requirements and scope of practice laws.[11]

The Alliance strongly believes that seeing patients remotely can preserve resources, promote social-distancing, and provide more convenience for patients, and we appreciate CMS's attention to these important issues. We recommend that additional steps be taken to increase access to these necessary technologies.

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[8] Tummalapalli SL, Warnock N, Mendu ML. The COVID-19 Pandemic Converges With Kidney Policy Transformation: Implications for CKD Population Health. *Am J Kidney Dis*. 2021;77(2):268-271. doi:10.1053/j.ajkd.2020.10.004

[9] Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act, Pub. L. No. 116-136 § 3705.

[10] CMS. COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. May 24, 2021. https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

[11] Azar A. HHS Secretary Letter to States Licensing Waivers. March 24, 2020. https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf

A. The Alliance encourages continued access to phone evaluation and management (E&M) services for home dialysis patients.

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 "N" for non-covered to "A" for covered.

In our response to the CY 2021 PFS proposed rule, the Alliance advocated for continued coverage of 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. As you are aware, the 2021 PFS final rule did not extend coverage of these codes, so that they will be removed from the Medicare telehealth services list as of the date that the PHE for COVID-19 ends.

We strongly encourage CMS to reconsider this decision and grant codes 99441-99443 a Category 3 status. These E&M services will continue to be important for patients with ESRD or acute kidney injury (AKI), especially as the pandemic continues to provide an obstacle for patients to meet with their physician. Furthermore, covering these services aligns with President Biden's *Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. Phone consultation with physicians is an important lifeline for home dialysis patients in underserved communities with unreliable broadband or access to technology. The Alliance believes that this category 3 designation and the continued coverage of these telephone consult codes will ultimately demonstrate that these E&M services deserve to be permanently included in the Medicare telehealth list.

The Alliance understands and stresses that appropriate guardrails should be in place for audio calls, such as:

- Documentation should include that a good faith effort for an audio-video call was inadequate to complete the visit.
- Patients' relevant electronic medical records and patients' dialysis treatment flowsheets were 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.

B. The Alliance appreciates CMS's efforts to support home dialysis modalities 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 Transitional Care Management (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 CY 2020 PFS final rule, which changed the requirement for code 99457 from direct supervision to general supervision. The Alliance also thanks the agency for the acknowledgement in that rule that CPT codes for RPM services 99091, 99453, 99454, and 99457 should be billable monthly.

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. As such, we support the determination in the CY 2020 final rule that CPT codes for RPM services 99091, 99453, 99454, and 99457 should be billable monthly. In addition to our request that CMS allow the use of these codes for ESRD patients, we would like to reiterate our request that CMS allow these codes to apply for patients with AKI who may still be dialyzing at home while recovering their kidney function and so can benefit greatly from the option to have their physiologic information monitored remotely, negating the need for frequent in-person visits.

Furthermore, we commend CMS's effort to expand remote therapeutic monitoring (RTM) capabilities to more providers through the proposed introduction of remote therapeutic monitoring (RTM) codes (989X1 – 989X5) in this year's proposed rule. We encourage CMS to consider adding codes for use by ESRD patients.

C. The Alliance urges CMS to extend remove originating site and geographic restrictions for all dialysis patients.

The Alliance for Home Dialysis has long supported the designation of both a patient's home and dialysis facility as originating sites for home dialysis services, without geographic restrictions. We were pleased to see Congress grant this request in the 2018 Balanced Budget Act, which included the CHRONIC Care Act and its provisions to waive these requirements for home dialysis patients. We thank CMS for temporarily allowing both these venues to serve as originating sites for all dialysis patients regardless of modality during the COVID-19 public health emergency. Our members report that the benefits have redounded to the benefit of the broader kidney patient community:

- CKD patients need regular care to properly manage their disease, including education on their modality options if and when they enter kidney failure. Many of the challenges that CKD patients face in receiving that care can be ameliorated by allowing them to receive some care through telehealth or RPM.
- Kidney transplant patients require extensive evaluation and education before and after their transplant surgery, as well as continued monitoring post-surgery to evaluate organ function, medication adherence, and so on. Accessing this care requires regular visits with medical staff located at kidney transplant centers, which are often urban institutions that require patients to travel a long way to seek care. Many of these visits can be conducted by telehealth, saving patients time and expense.
- Providers who may be called upon to serve in an acute care setting can use telehealth or RPM capabilities to provide dialysis care to patients in a dialysis center or at home.

We therefore call on CMS to permanently remove Medicare's geographic and originating site restrictions, to open these opportunities to all ESRD patients across the country, regardless of modality.

III. The Alliance provides the following comments on data collection efforts to promote greater health equity in ESRD care.

Existing data and ongoing research paint a picture of troubling disparity in ESRD care and ensuing outcomes. We encourage federal policymakers to leverage their unique access to large and comprehensive databases (e.g., Medicare claims data, Hospital Consumer Assessment of Healthcare Providers and Systems survey, etc.) to learn lessons about patient experience and outcomes in the present, as well as conduct real-time evaluation of new models such as the ESRD Treatment Choices Model, to ensure that communities of color reap the benefits. Following are some suggestions on how further data collection and research might be operationalized:

- Some data is available on home dialysis retention by modality, but more information about what leads patients struggling with home dialysis to give it up entirely would help policymakers effectively target sources of inequity.
- CMS should consider a survey of in-center patients, organized demographically, to determine patient's understanding of the perceived barriers to dialyzing at home. One pathway to conducting this survey would be through the ESRD Networks.[12] Another approach would be to focus on specific geographic regions using existing classifications like the Hospital Referral Region (HRR).

[12] CMS. ESRD Network Organizations. October 4, 2017. https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations

- Dialysis claims are an opportunity to gather more information about individual patients, their circumstances, and social determinants of health that may inform future policy targets. For example, reporting "Z" codes on dialysis claims would enable CMS to better understand what non-clinical barriers patients are facing that might be dissuading otherwise-qualified candidates from home dialysis.
- While in-center hemodialysis patients can report their experience using the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey, there is no patient-reported experience measure for assessment of patient experience of care for peritoneal dialysis or home hemodialysis. We encourage CMS to consider development of such a measure, informed by ongoing work in the academic community.[13]
- According to a clinical expert in the field of kidney care, measuring the impact of innovative care models in real time will be instrumental in understanding their impact on disadvantaged communities and will help ensure that these models promote health care delivery in an equitable manner.[14]

Conclusion

The Alliance appreciates the opportunity to provide comments to the Physician Fee Schedule proposed rule for calendar year 2022. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Should you need any further information, please contact Kelly Ferguson at kferguson@homedialysisalliance.org.

Sincerely,

Kelly Ferguson
Policy Director

[13] Neumann M. Researchers develop tool to assess satisfaction with home dialysis. *Healio.* April 5, 2021. https://www.healio.com/news/nephrology/20210405/researchers-develop-tool-to-assess-satisfaction-with-home-dialysis
[14] Overview of Health Disparities and Inequity in Dialysis: Framing the Discussion (Roundtable Panel). 2021 Home Dialysis National Policy Roundtable: A Dialogue on Disparities, Systemic Inequities, and Access. February 25, 2021.

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