

ConnectedHealthInitiative

August 22, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

RE: *Comments of the Connected Health Initiative to the Centers for Medicare and Medicaid Services on Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (87 FR 38464)*

Dear Administrator Brooks-LaSure:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) on its draft End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2023.¹

I. Introduction & Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvement in their health through policies that allow for the potential of connected health technologies to enhance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of use cases.

We are active advocates before Congress, numerous U.S. federal agencies, and states, where we seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data

¹ Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs, *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model*, 87 FR 38464 (June 28, 2022) (“Draft CY2023 HHPPS”).

interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

CHI is a longtime advocate for the increased use of digital health tools (telehealth, remote monitoring, AI, etc.) across the Department of Health and Human Services (HHS) as well as before other agencies and the U.S. Congress. CHI is also engaged in leading public-private partnerships themed in responsibly advancing the use of digital health tools, including as a current appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of 15 nationally-recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving around coding, payment, coverage, and more.²

Generally, CHI is committed to a ESRD PPS, and broader Medicare system, that serves beneficiaries effectively by leveraging the benefits of the range of digital health tools available today, consistent with other major Medicare programs.

II. Connected Health's Integral Role in the Future of Medicare

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called “telehealth,” “mHealth,” “store and forward,” “remote patient monitoring,” “remote physiologic monitoring,” “communication technology-based services,” or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device (SaMD), mobile medical apps, and cloud-based portals and dashboards, can fundamentally improve and transform American healthcare.³ Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions, and CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, there was low utilization of digital health innovations prior to the COVID-19 public health emergency (PHE), despite the ability to drastically improve beneficiary outcomes as well as to generate immense cost savings.

Further, CMS should seek to enable the use of health data and patient-generated health data (PGHD) through AI. There are varied applications of AI systems in healthcare such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value.

² <https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group>

³ This CHI resource is publicly accessible at <https://bit.ly/2MblRou>.

Payment policies must incent a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

The need for rapid modernization of Medicare incentives is more imperative considering the ongoing COVID-19 PHE in the United States. Already, remote monitoring tools have proven effective in preventing hospital admissions and improving recovery from the COVID-19 virus.⁴ As a community, we continue to support CMS' efforts to utilize advanced technology to augment care equitably, including those suffering from kidney disease. With the congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, CMS' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit use of these solutions. CMS' coverage of remote monitoring began in CY2018, when it unbundled Current Procedural Terminology (CPT®) Code 99091. In the calendar year 2019 and 2020 Physician Fee Schedules (PFS), CMS took significant steps forward in activating and paying for four remote *physiologic* monitoring codes, with further proposals made for CY2022 to support a new family of remote *therapeutic* monitoring use cases. CMS also ensured utilization of RPM in existing alternative payment models such as Medicare Advantage, where RPM has been eligible for inclusion as a basic benefit.

Building on its incremental increases of supporting for use of digital health tools in the ESRD PPS (and enhanced support for digital health tools in other key programs noted above), CMS should take all steps possible to enable the further eased use of digital health tools for those suffering from acute kidney injury (AKI). For example, remote monitoring technologies proven to enable continuous monitoring changes (e.g., turbidity of peritoneal dialysate effluent) in beneficiaries with ESRD receiving peritoneal dialysis therapy, allowing the clinical standard of care to be initiated earlier and clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier. This is just one use case demonstrating that, for the ESRD PPS, digital health tools will be helpful in (1) augmenting services in the patient's plan of care; (2) enabling clinical staff to identify changes more rapidly in a patient's clinical condition and to monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care); and (3) augmenting ESRD PPS beneficiary care in their homes. Further, CHI encourages CMS' thoughtful deliberation of the benefits of remote monitoring technologies under §§ 413.236(b)(5) and 412.87(b)(1).

⁴ <https://www.thepermanentejournal.org/issues/2021/summer/7664-description-and-early-results-of-the-kaiser-permanente-southern-california-covid-19-home-monitoring-program.html>.

While the progress described above represents important pro-digital health policy changes that are long overdue, the pace of uptake for digital health innovations in the ESRD PPS continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers (including in other Medicare payment systems). This need has become even more obvious with the COVID-19 pandemic. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient.

It is essential ESRD PPS providers and the beneficiaries they serve (ESRD Treatment Choices [ETC] Model) leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs.

CHI offers its further specific views on several provisions in the draft CY2023 ESRD PPS affecting the use of digital health technologies, particularly remote monitoring, considering the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program:

- **Quality Indicators and Program Integrity:** CHI appreciates CMS' request for comments on potential indicators of quality for patients who receive dialysis at home in order to support the use of home dialysis for ESRD patients where it is appropriate. CMS appropriately recognizes that, "while home-based dialysis may not meet the needs of every patient, home dialysis has clear benefits for those who are suitable candidates" and that it often "may be more convenient for many ESRD patients, and survivability rates for home dialysis are comparable to those of transplant recipients and in-center hemodialysis." Importantly, CMS also states that "dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center," with the main factors related to lower expenditures including "potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between peritoneal dialysis (PD) and haemodialysis (HD) services and supplies, and lower operating costs for dialysis providers for providing home dialysis." Past cost savings, we strongly urge CMS to holistically consider the broader benefits associated with the responsible use of remote monitoring, including but not limited to improved patient engagement and outcomes, as well as a better caregiver experience.⁵ CHI urges CMS to, in its consideration of quality indicators for home dialysis, ensure that the benefits of ongoing remote monitoring and its enablement of real-time trending and interventions are reflected within these quality indicators, building on general quality measurement study on remote monitoring.⁶

⁵ Pronovost PJ, Cole MD, Hughes RM. Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit. *JAMA*. 2022;327(12):1125–1126. doi:10.1001/jama.2022.2040; Coffey, J.D., Christopherson, L.A., Glasgow, A.E. *et al*. Implementation of a multisite, interdisciplinary remote patient monitoring program for ambulatory management of patients with COVID-19. *npj Digit. Med.* 4, 123 (2021). <https://doi.org/10.1038/s41746-021-00490-9>.

⁶ E.g., <https://www.appliedclinicaltrials.com/view/quality-remote-monitoring-tools-game>.

Further, CHI generally supports measures to avoid waste, fraud, and abuse in the ESRD PPS and the ETC Model. The use of various connected and digital health innovation modalities, including remote monitoring technology, does not inherently mean that such uses will translate to greater waste, fraud, and abuse; to the contrary, it is easier to ensure program integrity through real-time or near real-time data analytics provided by digital health technologies. Therefore, we urge CMS to (1) reinforce its belief about the ability of connected health technologies to improve programmatic waste in the ESRD PPS and the ETC Model; and (2) leverage existing and developing program integrity tools and metrics in the ESRD PPS and the ETC Model in a modality-neutral manner, with additional measures being implemented for specific modalities based on demonstrated heightened risks to program integrity specific to modalities.

- **ESRD Treatment Choices Model:** CMS' approach to its ETC Model, which CMS states is focused on encouraging greater use of home dialysis and kidney transplants, is a crucial part of this rule and CMS should take all steps possible to give providers the flexibility to leverage digital health platforms that are enabled by remote monitoring tools.

For example, CHI continues to support CMS giving ETC participants the flexibility to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services. CHI agrees that coinsurance payments can be burdens on patients, particularly those in America's most underserved communities. This approach to coinsurance payment requirements will advance the ETC Model's goal of increasing access to kidney disease patient education services, and to making beneficiaries more aware of their choices in preparing for kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis.

- **Kidney Disease Patient Education Services Telehealth Waiver:** CHI supports CMS' past amending of § 512.397 to add a waiver of telehealth requirements to provide qualified staff by defining, for purposes of the ETC Model at § 512.310, the flexibility to furnish kidney disease patient education services via telehealth by waiving the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) for kidney disease patient education services furnished via telehealth. CHI agrees that a kidney disease patient education services telehealth waiver would allow more Medicare beneficiaries to receive kidney disease patient education services via telehealth, advancing health equity. CHI also supports CMS' waiving the requirement in section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) so that CMS does not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) under this proposed waiver. CMS definition of "clinical staff" and "qualified staff" will provide clarity so that it is well understood that those clinicians who are authorized to furnish kidney disease patient education services pursuant to the waiver

specified at § 512.390(b)(1) fall within the existing definition of qualified person at 42 CFR 410.48(a).

III. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with CMS and other stakeholders towards realizing the most successful ESRD PPS possible.

Sincerely,



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