

# ConnectedHealthInitiative

February 1, 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 (86 FR 36322)*

Dear Administrator Brooks-LaSure:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) on potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.<sup>1</sup>

## 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 are developers and users of 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 and payment, privacy and security, effectiveness and quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health

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<sup>1</sup> 86 Fed Reg 68594.



data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery, among other areas. CHI is a long-time advocate for the increased use of telehealth and remote monitoring, especially in key use cases such as home dialysis. A health system that serves patients and beneficiaries most effectively must leverage the benefits of the range of digital health tools available today, consistent with other major Medicare programs.

CHI's comments to CMS are largely in response to the digital health-themed question it poses in its request for information with respect to home dialysis:<sup>2</sup>

6. *To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection of and uptake of home dialysis as a modality? What are best practices in this area that would facilitate the delivery of safe and quality care?*

## **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.<sup>3</sup> 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, 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. Payment policies must incent a pathway for the voluntary adoption and integration of AI

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<sup>2</sup> *Id.* at 68600.

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

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 crisis in the United States. Already, remote monitoring tools have proven effective in preventing hospital admissions and improving recovery from the COVID-19 virus.<sup>4</sup> As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient, 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,<sup>5</sup> with further proposals made for CY2022 to support a new family of remote *therapeutic* monitoring use cases.<sup>6</sup>

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

<sup>5</sup> These CPT codes are:

- 99453 [Remote monitoring of physiologic parameter(s) (e.g. weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment];
- 99454 [Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days];
- 99457 [Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month]; and
- 99458 [Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes].

<sup>6</sup> These CPT codes are:

- 98975 - Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes.
- 98976 - Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure).

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 use of digital health tools in the End-Stage Renal Disease Prospective Payment System (ESRDPPS) and enhanced support for digital health tools in other key programs noted above, CMS should take all steps possible to enable the use of digital health tools for those suffering from acute kidney injury (AKI). For example, remote monitoring technologies are 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 ESRDPPS, 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 monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care); and (3) augmenting ESRDPPS beneficiary care in their homes.

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 context of kidney disease (including important programs such as the ESRDPPS) 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, and only reinforces that greater access to evolving telehealth and remote monitoring technology will certainly increase the selection of and uptake of home dialysis as a modality. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient.

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- 98977 - Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment.
  - 98980 - Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days.
  - 98981 - Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days.

### III. Further Specific Connected Health Initiative Recommendations on Ways CMS Can Leverage Digital Health to Improve Kidney Care

Building on the above, CHI offers the following specific views and recommendations on several aspects of the ESRDPPS impacting the use of digital health technologies, particularly remote patient monitoring, considering the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program:

- **Kidney Disease Patient Education Services Telehealth Waiver:** CHI supports CMS' amending § 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). 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" provides 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).
- **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 supports CMS' proposing to, for purposes of testing the ETC Model, give 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. CMS' proposed 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.

- **Program Integrity:** Regarding program integrity, CHI generally supports measures to avoid waste, fraud, and abuse in the ESRDPPS and the ETC Model. The use of various connected and digital health innovation modalities,

including RPM technology, does not inherently mean that remote monitoring 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) acknowledge the ability of connected health technologies to improve programmatic waste in the ESRDPPS and the ETC Model; and (2) leverage existing and developing program integrity tools and metrics in the ESRDPPS 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.

#### IV. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input.

Sincerely,



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*The Connected Health Initiative (CHI), an initiative of ACT | The App Association, is the leading multistakeholder spanning the connected health ecosystem seeking to effect policy changes that encourage the responsible use of digital health innovations throughout the continuum of care, supporting an environment in which patients and consumers can see improvements in their health. CHI is driven by its Steering Committee, which consists of the American Medical Association, Apple Inc., Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, GoodRx, HIMSS, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, The Omega Concern, Otsuka Pharmaceutical, Podimetrics, Rimidi, Roche, United Health Group, the University of California-Davis, the University of Mississippi Medical Center (UMMC) Center for Telehealth, the University of New Orleans, and the University of Virginia Center for Telehealth.*

For more information, see [www.connectedhi.com](http://www.connectedhi.com).