ConnectedHealth

April 6, 2020

Attention: CMS-4190-P
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-8013

RE: *Connected Health Initiative Comments to the Centers for Medicare and Medicaid Services on* Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly *(85 FR 9002)*

The Connected Health Initiative (CHI) writes to respond to the Centers for Medicare and Medicaid Services' (CMS') proposed rule.[1] We have particular interest in the proposed "additional telehealth benefits" as part of basic Medicare Advantage (MA) benefits, per the Bipartisan Budget Act of 2018, Pub. L. 115-123 (BBA). We appreciate CMS' efforts to implement the Bipartisan Budget Act of 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, and the 21st Century Cures Act; implement changes to strengthen and improve the Part C and D programs; and to advance the Patients Over Paperwork Initiative.

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 connected health technologies to improve 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 state legislatures and agencies, 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 interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

[1] 85 Fed. Reg. 9002 (February 18, 2020).

CHI is a long-time active advocate for the increased use of telehealth and remote monitoring. We maintain an ongoing dialogue about connected health modalities with the U.S. Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission (FCC). In addition, CHI engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, CHI is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG), an initiative bringing together a cross-section of 15 nationally recognized experts who identify barriers to digital medicine adoption and propose comprehensive solutions revolving around coding, payment, coverage, and more.[2] CHI is also a board member of Xcertia, a collaborative effort to develop and disseminate mHealth app guidelines that can drive the value these products bring to the market; build the confidence that physicians and consumers can have in these apps; and demonstrate how these apps have the ability to help people achieve their health and wellness goals.[3]

With approximately one in three Medicare beneficiaries enrolled in an MA plan, it is essential that MA rules allow for caregivers and beneficiaries to realize the benefits associated with leveraging patient generated health data (PGHD) collected by connected health technology. CHI appreciates CMS' recent clarifications that MA organizations may provide enrollees with access to Medicare Part B services via telehealth in any geographic area and from a variety of places, including beneficiaries' homes. Furthermore, we value that, as of CY2019, RPM's eligibility for inclusion as a basic benefit has been confirmed. These established policies in MA represent key incentives for the responsible use of digital health technologies that have, and will continue to, advance MA beneficiaries' care while maintaining flexibility needed for MA organizations seeking to innovate.

We further commend CMS for its efforts to advance the uptake of connected health innovations across other programs, including but not limited to:

- In its Physician Fee Schedule (PFS), CMS has now activated and provided payment for four Current Procedural Terminology® (CPT) codes that capture the technical and professional elements of remote physiologic monitoring (RPM);
- CMS has allowed home health agencies to include evidence-based remote physiologic monitoring expenses used to augment the care planning process as allowable administrative costs that are factored into the costs per visit under the Home Health Prospective Payment System (HHPPS);

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

[3] http://www.xcertia.org/

- CMS has put key incentives in place for the future value-based Medicare system, as well as taken steps to promote flexible use of PGHD in care coordination in the Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS). As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every American patient; and
- To address the ongoing public health emergency, CMS has taken numerous steps to bring the power of connected health technology into detection and treatment of COVID-19, including issuing information to MA organizations and Part D Sponsors to inform them of the obligations and permissible flexibilities related to the COVID-19 public health emergency.

Based on the above, CHI offers the following input to CMS specific to CMS' proposals in the proposed rule:

- CHI requests that CMS ensure its implementation of Section 50323 of the BBA aligns with CMS' established approaches in its PFS to Medicare Telehealth Services subject to the restrictions of 1834(m) of the Social Security Act, and remote physiologic monitoring and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions. Further, we urge CMS to confirm that remote physiologic monitoring technologies may be included as part of basic MA benefits and are not subject to 1834(m).
- MA plans should be encouraged to cover all visits and other services that are on the Medicare Telehealth Services list when provided through telehealth by patients' physicians.
- CHI supports CMS' proposal to codify provisions of the 21st Century Cures Act to allow all Medicare-eligible individuals with end-stage renal disease (ESRD) to enroll in MA plans beginning in 2021. CHI agrees that CMS' ESRD proposal will help improve the lives of, and empower, beneficiaries with ESRD (consistent with the President's Executive Order on Advancing American Kidney Health) by giving them choices in the type of Medicare coverage they receive, including MA plans enabling greater use of digital health technologies supporting hemodialysis and peritoneal home dialysis and remote physiologic monitoring. CMS also should ensure that ESRD patients are properly informed about their potential out-of-pocket costs and the adequacy of plan networks so that they can make good decisions as they consider switching to MA for their health care coverage.

- CHI generally supports CMS' proposal to codify existing network adequacy methodology and standards, and to permit MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth specialty providers (dermatology, psychiatry, cardiology, otolaryngology, and neurology). However, given the demonstrated benefits of digital health technologies in both the prevention and treatment of disease, CHI urges CMS to expand this credit to further specialty provider types including nephrology for home dialysis. We urge CMS to regularly consider further expansions to this list of specialties moving forward.
- CHI supports CMS' proposal to provide Programs of All-Inclusive Care for the Elderly (PACE) organizations with the ability to utilize the efficiencies of digital health technologies. Additionally, we recommend allowing PACE interdisciplinary teams (IDTs) to conduct a reassessment prior to approving a service delivery request either in-person or through the use of remote technology (if deemed necessary by the IDT and agreed to by the plan participant).
- CHI supports CMS' proposal for all Special Needs Plans to permit MA organizations' annual face-to-face visits to be conducted via a "visual, real-time, interactive telehealth encounter" within the first 12 months of enrollment within the plan.
- CHI strongly agrees with CMS that Part D must move to accommodate enrollees by enhancing the use of digital technologies used in Part D e-prescribing. We support CMS' proposals to give Part D plans a flexible way for enrollees to securely access formulary and beneficial information through smartphones and other mobile devices. We also support the development and scaling of real time benefit tools.
- CHI requests that CMS modify the MA/Part D and Accountable Care Organization risk adjustment policy to incorporate diagnoses from digital health-enabled remote encounters. Providing this clarity would resolve uncertainty as to whether connected health modalities are risk adjustable since they are not face-to-face visits.
- CHI shares CMS' goal of improving patients' access to useful information regarding drug benefits and costs; however, when considering implementation of real-time benefit technology, we urge CMS to consider the ability of such tools to support patient-physician discussions regarding treatment selection and the utility of the data for the majority of Medicare patients.
- Part D sponsors should be required to increase coverage, availability, and affordability of non-opioid treatment options, including placing non-opioid pharmacologic and non-pharmacologic options on the lowest cost-sharing tiers with minimal co-pays and benefit limitations.

- CMS should delay implementation of the provision from the SUPPORT Act pertaining to EPCS for Part D prescriptions.
- CMS should consider the inclusion of processing time, approval/denial rates, and denials overturned on appeal in prior authorization metrics in MA plan Star Ratings.

We appreciate CMS seeking input on its draft rule and for its partnership in leveraging the incredible potential of connected health technologies. We encourage CMS' thoughtful consideration of the above input and stand ready to assist further in any way that we can.

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 the its Steering Committee, which consists of the American Medical Association, Apple, Bose Corporation, Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, Otsuka Pharmaceutical, Podimetrics, Proteus Digital Health, Rimidi, Roche, Spekt, 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, visit www.connectedhi.com.