

April 9, 2020

The Honorable Alex Azar  
Secretary  
United States Department of Health and  
Human Services  
Washington, District of Columbia 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, District of Columbia 20201

Dear Secretary Azar and Administrator Verma:

We applaud your continued leadership in declaring a public health emergency (PHE) and vigorously responding to the COVID-19 (“coronavirus”) pandemic. The U.S. Department of Health and Human Services (HHS) must continue to lead in diagnosing and treating Americans with COVID-19, while taking further measures to flatten the infection curve using the most innovative and effective solutions available to them. A cornerstone of HHS’ efforts to address the COVID-19 crisis must be the use of internet connected digital health technologies, including telehealth, remote physiologic monitoring (RPM), and artificial/augmented intelligence (AI), among others.

The Connected Health 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 improvements in their health through policies that allow for connected health technologies to advance 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 promote 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](http://www.connectedhi.com).



In follow up to the previous recommendations we provided to HHS and Congress on how to fully realize the benefits of digital health tools in addressing the COVID-19 PHE, we offer the following further steps that HHS can and should take as soon as possible, without congressional action:

- **CMS should provide needed Anti-Kickback Statute relief for digital health.** As clinicians remotely monitor patients at home who may have COVID-19, there are ongoing concerns that any equipment or access to software platforms provided free of charge may inadvertently trigger liability under the Anti-Kickback Statute (AKS). We request that HHS Office of the Inspector General (OIG) provide clarity that providing access to software-based platforms for patient generated health data (PGHD) analytics or telemedicine at no/low cost does not violate the AKS. Additionally, the operative definition for “remuneration” in this statutory provision, at 42 U.S.C. 1320a–7a(i)(6), is broad, and we recommend that the HHS OIG also provide clear guidance that giving patients a device to communicate with a care team is not considered a beneficiary inducement. These clarifications will enable the provisioning of RPM, telehealth, and other tech-driven healthcare tools without triggering AKS liability.

Further, we call on OIG to clarify, via an AKS safe harbor and revisions to the Civil Monetary Penalties (CMP) rules, that utilization of a device with multiple functions, such as a smartphone or e-tablet, does not violate the AKS and the CMP when it is primarily used for managing a patient’s healthcare, including the social determinants – e.g. finances, scheduling, and transportation – that impact a patient’s health. Multi-function devices are essential in the successful and responsible application of connected health technology to improve outcomes and reduce costs. However, many existing interpretations of the AKS regulations and guidance prohibit such devices from reaching the patients who need it most. Multi-function devices offer the ability in clinical trials to validate the identity of trial participants and allow health care functionality to be integrated into the other digitized aspects of a patient’s life, such as their email and text message communication, personal finances, or navigation, making patients more likely to use a multi-function device, while also giving providers real-time information about a patient’s status (e.g., blood pressure or heart rate).

- **CHI urges CMS to extend enforcement discretion to eliminate face-to-face requirements for home international normalized ratio (INR) monitoring services (HCPCS G0248 and G0249) services.** While CMS has indicated that it will use enforcement discretion to eliminate face-to-face requirements for telehealth, communications-based technology services (CBTS), and RPM, we believe that such an allowance for home INR monitoring services will also be crucial in addressing the COVID-19 PHE.
- **CMS should clarify that Independent Diagnostic Testing Facilities (IDTFs) are permitted to bill the CPT codes 99453 and 99454 RPM codes.** While CMS has already provided unofficial guidance to permit such billing, Medicare Administrative Contractors (MACs) are not allowing IDTFs to bill these codes currently.

- **CMS should enable CPT codes for solely “telephone evaluation and management (E/M) services” for physicians and non-physicians.** CMS has clarified that Medicare will not pay for telehealth services that do not include both audio and visual interactive means. However, it should reassess and enable CPT Codes (physician – 99441, 99442, and 99443) (non-physician – 98966, 98967, 98968) to serve those Americans who may not have access to an audio-visual device or those who do not understand how to utilize these types of technologies.
- **CMS should ensure that Federally Qualified Health Centers (FQHC) and rural health clinics (RHC) are able to furnish RPM services.** FQHCs and RHCs need the ability to monitor key PGHD metrics for those being treated for COVID-19. CHI suggests that the same fee-for-service carve out FQHCs and RHCs already enjoy for Chronic Care Management (CCM), Transitional Care Management (TCM), and Behavioral Health Integration (BHI) services be applied to COVID-19 services furnished by RHCs and FQHCs.
- **CHI requests that CMS modify the Medicare Advantage (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 urges HHS to take further needed steps to provide certainty with respect to HIPAA’s application to various remote technology modalities during the PHE.** Recently, HHS’ Office of Civil Rights (OCR) announced enforcement discretion with respect to the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations. Importantly, the enforcement discretion clarifies that the use of private, secure telehealth tools that are not part of the provider’s official offerings will not draw a penalty, as long as the provider alerts the patients to the risks. CHI urges OCR to issue guidance clarifying that certain telehealth, CBTS, and RPM tools that are fully end-to-end encrypted are mere “conduits,” and therefore do not require business associate agreements (BAAs). The guidance should clarify that the providers of such telehealth services should only store electronic protected health information (ePHI) on a temporary basis incident to the transmission service.
- **CHI calls on HHS to leverage artificial and augmented intelligence (AI)-enabled technology to combat the COVID-19 PHE.** AI, powered by streams of data and advanced algorithms, has incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and improve patient engagement. Not surprisingly, public health experts are leveraging AI in a variety of ways to combat COVID-19 and its spread, including by analyzing large data sets to identify infection clusters, spread patterns, and high-risk patients.<sup>1</sup> Additionally, scientists are using AI for natural language-processing in a White House supported effort to mine research papers related to COVID-19 to assist with the development of a vaccine. Providers are also using AI-driven decision support and triaging tools to manage their services and patients. Yet, applications of AI in healthcare have also given rise to a variety of potential opportunities and challenges for U.S. policymakers to consider, including notice/consent,

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<sup>1</sup> See <https://thehill.com/opinion/technology/490005-enlisting-ai-in-our-war-on-coronavirus-potential-and-pitfalls>.

bias, inclusion, transparency and digital due process, and law enforcement access to data, among others. Representing the leading developers of AI, we recognize that the design of healthcare AI systems must be informed by real-world workflow, human-centered design and usability principles, and end-user needs, facilitating the “Quadruple Aim.”<sup>2</sup>

As healthcare AI innovations continue to be developed and even start to enter today’s regulatory processes, policymakers at the legislative and regulatory levels are considering whether policy changes are needed. To inform these discussions, CHI’s AI Task Force has developed a set of healthcare AI policy principles that address the range of opportunities and challenges associated with AI in healthcare and propose the appropriate role of government regulation that we urge you to consider.<sup>3</sup> Notably, given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as a steward of significant amounts of patient data, CHI calls for the development of a federal government-wide healthcare AI strategy. This strategy will be vital to achieving the promise that AI offers to patients and the healthcare sector. We call on HHS to bring about such a strategy consistent with the CHI Health AI Task Force’s policy principles and to examine necessary authority changes needed for key agencies to appropriately regulate AI in the healthcare context as part of a comprehensive response to COVID-19.

Further, AI-driven tools are poised to combat the COVID-19 public health emergency in countless ways, from speeding research and development to enabling improved care decisions to individual patients to predictions of key trends. We strongly encourage HHS to:

- Provide for timely grants to support and facilitate research and development of AI tools to combat the COVID-19 crisis; and to provide necessary incentives (e.g., streamlined availability of appropriately protected data to developers) to encourage private and non-profit sector research and development aimed to combat the COVID-19 public health emergency;
- Activate emergency Healthcare Common Procedure Coding System (HCPCS) code(s) to support for key AI use cases, such as AI-enabled triaging chatbots to enable in screening of patients, and in assessment biometric data in the diagnosing of COVID-19.

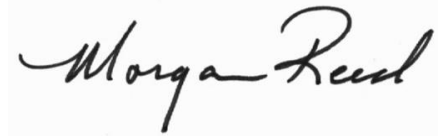
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<sup>2</sup> See <https://www.ama-assn.org/system/files/2018-11/playbook-resources-step-3-quadruple-aim-value.pdf>.

<sup>3</sup> <https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf>.

- **CHI supports Congress’s goal of unleashing innovation to address the COVID-19 PHE with respect to durable medical equipment (DME) through clarifying that it will cover dual-use devices or devices with the capability to provide secure and reliable transmission of valuable PGHD.** At a minimum, CMS’ approach to DME payment must encourage the utilization of connected health technology in a significantly expanded way. To date, CMS has not provided the public with its vision for the responsible use of connected health technologies in the DME context to address the COVID-19 public health emergency, including dual-use devices or devices with the capability to provide secure and reliable transmission of valuable PGHD. CHI maintains that this glaring oversight forces eligible clinicians, as well as other key stakeholders and organizations, to conclude that connected health technologies (already clearly demonstrated to improve outcomes while reducing costs) do not have a role with respect to the DME program and combatting the public health emergency, or in the future of the DME program. We call on CMS to clarify that it will cover dual-use devices or devices with the capability to provide secure and reliable transmission of valuable PGHD.

Thank you for considering our request. We look forward to working with you on the extremely important and bipartisan task of responding to the coronavirus pandemic.



Morgan Reed  
Executive Director  
Connected Health Initiative

CC:

The Honorable Mitch McConnell, Majority Leader, United States Senate  
The Honorable Charles Schumer, Minority Leader, United States Senate  
The Honorable Nancy Pelosi, Speaker of the House, United States House of Representatives  
The Honorable Kevin McCarthy, Minority Leader, United States House of Representatives

*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, Bose Corporation, Boston Children's Hospital, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, Intel Corporation, Kaia Health, Microsoft, Novo Nordisk, The Omega Question, Otsuka Pharmaceutical, Podometrics, 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.*

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