

April 9, 2020

The Honorable Nancy Pelosi  
Speaker of the House  
U. S. House of Representatives  
1236 Longworth House Office Building

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
317 Russell Senate Office Building

The Honorable Kevin McCarthy  
Minority Leader  
U.S. House of Representatives  
2421 Rayburn House Office Building

The Honorable Charles Schumer  
Minority Leader  
U.S. Senate  
322 Hart Senate Office Building

Dear Speaker Pelosi, Leader McCarthy, Leader McConnell, and Leader Schumer,

Thank you for ensuring that patients can receive care via telehealth as part of the first three COVID-19 response packages. Through this legislation, you provided an important waiver authority for the Department of Health and Human Services (HHS) to bypass statutory restrictions on Medicare coverage of live voice and video (telehealth) interactions between providers and patients. Now, we encourage you to build on this important progress to enable digital healthcare innovations to enable the defeat of COVID-19 at every step in the continuum of care. We urge you to include a few additional measures in the fourth COVID-19 response package (COVID 4.0):

**Tax Relief for Consumers and Patients for Digital Health.** Unfortunately, “medical care” for the purposes of FSAs and HSAs currently does not include important digital health tools, including software apps and platforms that collect and transfer physiologic data to monitor a variety of acute or chronic healthcare conditions. Similarly, FSA funds generally may not be spent on devices that can monitor various kinds of physiologic data (some of which are even FDA listed for this purpose), but also have non-medical purposes. As software and hardware improve in their ability to accurately track and analyze physiologic data for wellness and medical purposes, the law is falling further behind modern digital health capabilities, which we can access through smart devices and software. Minority populations, in particular, rely heavily on connectivity through smart devices,<sup>1</sup> so clinicians are increasingly looking for ways to provide care through those connections. With this heavy reliance on digital health—coupled with the wide availability of FSAs—in mind, we should continue to reduce barriers that stand in the way of patients and consumers managing and preventing health conditions using software and devices.

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<sup>1</sup> See, e.g., Andrew Perrin and Erica Turner, “Smartphones help blacks, Hispanics bridge some – but not all – digital gaps with whites,” PEW RESEARCH CENTER (Aug. 20, 2019), [available at https://www.pewresearch.org/fact-tank/2019/08/20/smartphones-help-blacks-hispanics-bridge-some-but-not-all-digital-gaps-with-whites/](https://www.pewresearch.org/fact-tank/2019/08/20/smartphones-help-blacks-hispanics-bridge-some-but-not-all-digital-gaps-with-whites/).

During the crisis, we are also seeing how digital health and smart devices are helping caregivers and health officials better understand the spread and characteristics of the pandemic. For example, the Kinsa connected thermometer provides public health officials in Florida with key data that helps inform the health system's resource needs in the coming weeks.<sup>2</sup> Although the Kinsa thermometer can be purchased through FSAs and HSAs, the Internal Revenue Service (IRS) could decide to remove it from coverage during its annual determination.<sup>3</sup> In order to ensure that these devices remain eligible for FSA and HSA coverage, an update to the underlying statute is necessary. We therefore urge you to update the definition of "medical care" in Section 213 of the Social Security Act to include devices and software capable of collecting and transmitting clinically valuable physiologic data to a care team. These tools are vital not just in clinicians' efforts to combat the COVID-19 pandemic, but they are also essential to modern efforts by consumers, patients, and caregivers to manage or prevent an increasingly broad set of chronic and acute conditions. Leaving them out of tax-advantaged savings accounts is an outdated approach we must correct.

**Anti-Kickback Statute.** As clinicians remotely monitor patients at home who may have COVID-19, there is a lingering concern that any equipment or access to software platforms provided without charge may inadvertently trigger liability under the Anti-Kickback Statute (AKS). The operative definition for "remuneration" in this statutory provision, at 42 U.S.C. 1320a-7a(i)(6), is broad, and we recommend directing the HHS Office of Inspector General (OIG) to enable the provisioning of remote physiologic monitoring (RPM), telehealth, and other tech-driven healthcare tools without triggering AKS liability. Alternatively, we urge you to include Section 11 of the CONNECT for Health Act of 2019 (S. 2741) in the COVID 4.0 package, which would carve the provision of certain RPM and telehealth technologies out of the definition of "remuneration" for the purposes of AKS.

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<sup>2</sup> Mary Ellen Klas, "Thermometer company: Florida compares only to NYC in spike in fever data," MIAMI HERALD (Mar. 20, 2020), *available at* <https://www.miamiherald.com/news/coronavirus/article241372271.html>.

<sup>3</sup> Internal Rev. Svc., About Pub. 502, Med. and Dental Expenses, *available at* <https://www.irs.gov/forms-pubs/about-publication-502>.

**Co-pays.** Another hurdle to the use of RPM, telehealth, and other digital modalities of care for Medicare patients is the mandatory 20 percent co-pays. Providers should not be in a situation during this crisis and beyond where regulations require them to charge the patient for remote monitoring that becomes necessary to keep the patient at home. In fact, HHS OIG recently issued guidance clarifying that it will not issue sanctions against practitioners for reducing or waiving co-pays for telehealth *and* RPM.<sup>4</sup> Although patients will benefit from the use of RPM—unencumbered by mandatory copays—during the national emergency, re-imposing a mandate for providers to bill them for RPM would be met with frustration and unfortunately, some patients would decline the services. Therefore, we urge you to direct HHS OIG to *permanently* provide flexibility to providers so that they can choose to waive or reduce co-pay charges for telehealth and RPM services. Alternatively, we recommend including a provision directing Medicare to pay for 100 percent of the cost of RPM services (instead of 80 percent), similar to the bipartisan Chronic Care Management Improvement Act (H.R. 3436), except applied to RPM codes instead of Chronic Care Management (CCM) codes.

**Privacy rules.** 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. The CARES Act should direct OCR to continue this enforcement discretion until the national emergency and the national public health emergency have lapsed. However, we also urge you to direct OCR to issue guidance clarifying that certain telehealth tools that are fully end-to-end encrypted are mere “conduits” and thus not required to enter business associate agreements (BAAs). The guidance should clarify that the providers of such telehealth services should only store ePHI on a temporary basis incident to the transmission service.

**Bring the Promise of Artificial and Augmented Intelligence-Enabled Technology to American Patients.** Artificial/augmented intelligence (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>5</sup> And 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, while providers are using AI-driven decision support and triaging tools to manage their services and patients. Yet,

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<sup>4</sup> U.S. DEPT. OF HEALTH AND HUMAN SVCS., OFFC. OF INSPECTOR GEN., OIG POLICY STATEMENT REGARDING PHYSICIANS AND OTHER PRACTITIONERS THAT REDUCE OR WAIVE AMOUNTS OWED BY FEDERAL HEALTH CARE PROGRAM BENEFICIARIES FOR TELEHEALTH SERVICES DURING THE 2019 NOVEL CORONAVIRUS (COVID-19) OUTBREAK (Mar. 17, 2020), *available at* <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>; *see also* FAQs—OIG POLICY STATEMENT REGARDING PHYSICIANS AND OTHER PRACTITIONERS THAT REDUCE OR WAIVE AMOUNTS OWED BY FEDERAL HEALTH CARE PROGRAM BENEFICIARIES FOR TELEHEALTH SERVICES DURING THE 2019 NOVEL CORONAVIRUS (COVID-19) OUTBREAK, OFFC. OF INSPECTOR GEN. (As of Mar. 24, 2020), *available at* <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/telehealth-waiver-faq-2020.pdf>.

<sup>5</sup> *See* <https://thehill.com/opinion/technology/490005-enlisting-ai-in-our-war-on-coronavirus-potential-and-pitfalls>.

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, 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 AI systems in healthcare must be informed by real-world workflow, human-centered design and usability principles, and end-user needs, facilitating the “Quadruple Aim.”<sup>6</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>7</sup> Notably, given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as steward of significant amounts of patient data, CHI calls for the development of a federal government-wide healthcare AI strategy, which will be vital to achieving the promise that AI offers to patients and the healthcare sector. We call on Congress 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 Congress to provide funding to HHS for streamlined 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, tax credits, etc.) to encourage private and non-profit sector research and development aimed to combat the COVID-19 public health emergency.

**Require Medicare to Support Preventive Care and Virtual Management.** Medicare generally declines to support effective care plans for at-risk patients to prevent the development of costly and life-threatening chronic conditions for at-risk Americans, and in the rare circumstances where allowances have been made, they are insufficient. For example, the Medicare Diabetes Prevention Program (MDPP), a pilot program designed to serve 110,000 Medicare beneficiaries annually, does not permit counseling via a virtual modality and has signed up far fewer patients than need this service based on their high risk for developing Type 2 diabetes. While CMS is temporarily allowing the use of virtual methods of communications in MDPP programs during the public health emergency, this change is temporary. Providers of pre-diabetes counseling services point to compliance costs associated with participating in MDPP—but the other glaring reason for a lack of participation is the failure of the program to support counseling services with virtual components. In other words, MDPP programs must conduct all of their counseling and patient evaluations in-person and using paper pamphlets. Meanwhile, 79 percent of COVID-19 patients who have been admitted to the intensive care unit had at least one underlying condition, while *94 percent American patients who died from COVID-19 related complications had at least one underlying*

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<sup>6</sup> See <https://www.ama-assn.org/system/files/2018-11/playbook-resources-step-3-quadruple-aim-value.pdf>.

<sup>7</sup> <https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf>.

conditions.<sup>8</sup> This is evidence of the unacceptable risks people with unmanaged chronic conditions are exposed to and illustrates emphatically how access to prevention programs can save lives. We strongly commend CMS for making temporary changes to MDPP to allow virtual components in MDPP programs for the duration of the public health emergency. However, we call on Congress to enable CMS to enable a virtual MDPP permanently, as patients need to be able to access these services to better position them for survival in a pandemic like COVID-19. We also request that Medicare cover the provision of validated devices, including self-measured blood pressure devices, particularly as hypertension is an underlying risk factor for exacerbated COVID-19 adverse outcomes.

In addition to MDPP, Medicare Part B also covers outpatient diabetes self-management training (DSMT) programs. Similar to MDPP, many of the DSMT sites would be able to reach patients more efficiently and effectively if they were able to offer parts of the training virtually in addition to or instead of in-person classes. For a variety of reasons, it is difficult to have patients show up in-person for every class so that they receive the full 10 hours of training Medicare covers in a year. Especially during the COVID-19 pandemic, Medicare beneficiaries should have the option of participating in diabetes training programs virtually from their homes. Diabetes has proven to be an underlying condition that puts COVID-19 patients at higher risk of becoming very sick. Avoiding in-person visits is therefore an important policy goal during the crisis, but in general the program would be much more effective if classes and components of the programs could be provided virtually. We urge you to clarify that Medicare-covered DSMT programs that are approved by the American Diabetes Association or the American Association of Diabetes Educators may provide virtual components, including virtual classes for beneficiaries.

**Durable Medical Equipment (DME).** CHI supports Congress's goal of unleashing innovation to address the COVID-19 public health emergency, particularly with respect to DME. 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 patient-generated health data (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 in the future of the DME program.

CHI also calls upon Congress to support DMEPOS providers as they work to expand their capacity to care for patients at home by pausing the implementation of the competitive bidding program (CBP) through the later of 12 months after the end of the PHE or December 31, 2021, and extending the blended rate in rural areas and newly created non-CBA, nonrural rates during the same time period. Many DME suppliers may not win contracts, and as of January 1, 2021, will not be allowed to service beneficiaries in half of the United States. Therefore, it may not make practical financial sense for them to increase investments in capital equipment to serve COVID-19 patients, if those same suppliers won't be able to use that increased inventory starting in January 2021. We call on Congress to mandate that CMS clarify that it will cover dual-use devices or devices with the capability to provide secure and reliable transmission of valuable PGHD.

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<sup>8</sup> [https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm?s\\_cid=mm6913e2\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm?s_cid=mm6913e2_w).

Thank you for considering our requests. We look forward to working with you on the extremely important and bipartisan task of responding to the COVID-19 pandemic.

Sincerely,

A handwritten signature in black ink that reads "Morgan Reed". The signature is fluid and cursive, with the first name "Morgan" and last name "Reed" clearly distinguishable.

Morgan Reed  
Executive Director  
Connected Health Initiative

*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, 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, see [www.connectedhi.com](http://www.connectedhi.com).