

ConnectedHealthInitiative

January 25, 2023

The Honorable Kevin McCarthy
Speaker
United States House of Representatives
Washington, District of Columbia 20515

The Honorable Hakeem Jeffries
Minority Leader
United States House of Representatives
Washington, District of Columbia 20515

The Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, District of Columbia 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, District of Columbia 20510

Re: Connected Health Initiative's Priorities for the 118th Congress

Dear Speaker McCarthy, Minority Leader Jeffries, Majority Leader Schumer, and Minority Leader McConnell,

We write today to thank you and to support your efforts to enhance patients' and caregivers' access to digital health tools that improve availability, quality, and affordability of care. ACT | The App Association's Connected Health Initiative (CHI) represents a broad consensus of healthcare and technology leaders seeking a policy environment that encourages the use of connected health innovations. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system.

Over the last two years, Congress undertook important steps to unlock the potential of virtual modalities, such as live audio and video telehealth and other digital health tools, to improve the affordability of care. Notably, through the pandemic response bills, the 117th Congress provided an important waiver authority for the Department of Health and Human Services (HHS) to bypass statutory restrictions on Medicare coverage of telehealth visits between providers and patients. Most recently, Congress enacted an extension of some of HHS' statutory flexibilities beyond the expiration of the national public health emergency (PHE) until the end of 2024. Such steps by Congress reinforce the reality that numerous restrictions exist, both in statute and in regulation, that prevent the use of digital health innovations without public benefit. While Congressional action during the 117th Congress has been essential, we urge the 118th Congress to focus on several key priorities to realize the promise of digital health for your constituents.

Background

With the right legal and policy backdrop, digital health tools will play an increasingly vital role in a growing set of contexts, and offer a profound opportunity to improve patient care, reduce hospitalizations, avoid complications, and improve patient engagement (particularly for the chronically ill), all while reducing costs. Digital health technologies are more important than ever for managing chronic health conditions, as well as acute health conditions as well as preventing the onset of serious illnesses and disease. Investing in digital health-enabling policies and infrastructure helps patients and consumers live healthier and longer lives, assists in managing costs at countless



points in the healthcare value chain, and improves the caregiver experience at a time when the United States is enduring a devastating physician shortage.¹ Technologies designed to help manage health issues also help stem the spread acute viral infections and are central to public health efforts to prevent serious illness and death in future public health crises. For example, people with chronic conditions—over 75 percent of people over the age of 65 have more than one²—required intensive care unit (ICU) admission at five times the rate and died at 12 times the rate of patients without underlying conditions as a result of contracting COVID-19.³ A patient population that is able to better manage and prevent these chronic conditions is much better positioned to survive and avoid serious illness. Studies show clearly that wearable devices and apps can help reduce A1C levels for diabetic patients,⁴ increase activity and improve body composition for at-risk consumers,⁵ and reduce healthcare costs for insurance beneficiaries from a variety of demographics.⁶ Lastly, wearable devices have helped consumers and caregivers detect the onset of COVID-19 early, enabling them to start treatment and adjust plans accordingly and mitigate the spread of the disease.⁷

The 118th Congress gets underway at a vital time for Americans and their healthcare and has numerous opportunities to make common-sense policy changes that will improve healthcare delivery while lowering costs. We urge you to take action to address the following priority recommendations and welcome the opportunity to work with you to drive needed changes in healthcare.

Tax Provisions

Modernizing Flexible Spending Account and Health Savings Account (FSA/HSA) Coverage. Federal tax policy currently favors legacy equipment over modern and emerging wearable technologies, which unnecessarily constrains the incentive to further develop them and consumer choice. Certain wearable devices and apps—even some that include Food and Drug Administration (FDA) listed medical device electrocardiogram (EKG), catastrophic fall detection, and pulse oximetry reading capabilities—have always been left out of the Internal Revenue Service’s (IRS’) annual Publication 502, which lists items that are eligible for reimbursement from HSAs and FSAs. The definition of

¹ Press release, “U.S. physician shortage growing,” ASSOC. OF AMER. MED. COLLEGES (Jun. 26, 2020), available at <https://www.aamc.org/news-insights/us-physician-shortage-growing>.

² CTRS. FOR DISEASE CONTROL, PREVALENCE OF MULTIPLE CHRONIC CONDITIONS AMONG US ADULTS, 2018, Research Brief Vol. 17 (Sept. 17, 2020), available at https://www.cdc.gov/pcd/issues/2020/20_0130.htm.

³ See, e.g., CTRS. FOR DISEASE CONTROL, MORBIDITY AND MORTALITY WEEKLY RPT. (Jul. 24, 2020), available at https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm?s_cid=mm6929a1_w.

⁴ See Testimony of Dr. Karen S. Rheuban, Hearing on “Telehealth: Lessons from the COVID-19 Pandemic,” before the U.S. Senate Committee on Health, Education, Labor, and Pensions, at 3 (116th Cong.), Jun. 17, 2020, available at <https://www.help.senate.gov/imo/media/doc/Rheuban.pdf>; CLINICAL OUTCOMES: UNIV. OF MISSISSIPPI MED. CTR. DIABETES TELEHEALTH NETWORK, CARE INNOVATIONS (2018), available at https://connectwithcare.org/wp-content/uploads/2017/06/2016_Outcomes_Clinical-1.pdf.

⁵ Joanne DiFrancisco-Donoghue, et al., “Utilizing wearable technology to increase physical activity in future physicians: A randomized trial,” PREVENTIVE MEDICINE REPTS., Vol. 12 (Dec. 2018), available at <https://www.sciencedirect.com/science/article/pii/S2211335518301876?via%3Dihub>.

⁶ Christina Farr, “A giant insurer is offering free Apple Watches to customers who meet walking goals,” CNBC (Nov. 14, 2018), available at <https://www.cnbc.com/2018/11/14/unitedhealthcare-gives-free-apple-watches-if-walking-goals-met.html>.

⁷ See Giorgio Quer et al., “Wearable sensor data and self-reported symptoms for COVID-19 detection,” NATURE (Oct. 29, 2020), available at <https://www.nature.com/articles/s41591-020-1123-x#Abs1>.

“medical care” in the Social Security Act is a broad one that encompasses amounts paid “for the . . . mitigation, treatment, or prevention of disease . . .”⁸ We appreciate the balancing act the IRS must perform as it seeks to draw the line on which items qualify for the tax-advantaged status of medical care for HSA and FSA expenditures. This balancing test has to date resulted in the IRS leaving off the list newer items on the market that have multiple (including non-medical) functions. Unfortunately, this policy has led to a disincentive for manufacturers and developers to invest in better, smarter technologies because it advantages legacy technology. For example, even though the IRS currently interprets “medical care” to include the LifeAlert system, which is a wearable device that detects catastrophic falls (and does not have any other functions),⁹ the IRS excludes expenses on wearable devices with the same or better catastrophic fall detection capabilities, but which also happen to have other functions.

The IRS and Congress have periodically made important adjustments to account for new realities and market developments. For example, the IRS recently determined in a private letter that about half of the cost of 23andMe’s DNA tests—specifically, those that include a report on the consumer’s health and ancestry—qualify as “medical care” expenditures for the purpose of FSAs and HSAs.¹⁰ That determination recognized that even though tech-driven tools like DNA tests have non-medical purposes, there is an important policy interest in ensuring that their critical healthcare features qualify as FSA and HSA expenditures. Similarly, in 2010, when Congress passed a law delisting cell phones from “listed property” subject to strict recordkeeping requirements, the IRS issued Notice 2011-72, 2011-38 IRB 407, which deemed certain recordkeeping substantiation rules satisfied, even when cell phones were used for both business and other purposes.¹¹ In other words, the policy interest in promoting business investment in cell phones and smart devices was strong enough that it overcame countervailing revenue collection interests in maintaining onerous record-keeping requirements to assess a tax on non-work-related cell phone charges. We think the same balance of interests applies in this case.

Fortunately, Congress appears to agree. The House Appropriations Committee included report language accompanying the fiscal year 2022 (FY22) Financial Services and General Government (FSGG)—with bipartisan support—calling on the IRS to reverse its long-standing exclusion of life-saving wearable devices and associated software from FSA and HSA coverage. Specifically, on pages 28 to 29 of the FSGG Subcommittee’s report for FY22, the House Appropriations Committee calls on the IRS to “explore the possibility of treating wearable devices and associated software applications purchased for the purpose of medical care” as reimbursed expense for medical care for FSAs and HSAs.¹² The 118th Congress should either clarify in statute that certain wearable devices and software platforms are eligible for FSA and HSA reimbursement or else urge the IRS to treat wearable devices with powerful healthcare applications more equitably.

⁸ 26 U.S.C. Sec. 213(d)(1).

⁹ LIFE ALERT EMERGENCY MEDICAL ALERT SYSTEM: FSA ELIGIBILITY, FSASTORE.COM, *available at* <https://fsastore.com/fsa-eligibility-list/life-alert-emergency-medical-alert-system>.

¹⁰ Letter from Bridget Trombul, Branch Chief, Branch 2 (Income Tax & Accounting), Office of Assoc. Chief Counsel, Internal Revenue Svc., to 23andMe, Inc., regarding request that certain genetic testing services and resultant reports constitute medical care for purposes of Sec. 213(d)(1)(A) of the Internal Revenue Code (May 16, 2019).

¹¹ See Marianna G. Dyson and S. Michael Chittenden, “Is it Time for Deductions of Smartwatch Expenses?” TAXNOTES FED., at 203 (Jul. 8, 2019).

¹² H.R. Rep No. 117-79, at 28-29 (2021), *available at* <https://www.congress.gov/117/crpt/hrpt79/CRPT-117hrpt79.pdf>.

High-Deductible Health Plan (HDHP) Coverage of Telehealth and Other Remote Care Services. American beneficiaries with HDHPs faced a telehealth deadline at the end of 2022, when the statutory allowance for first-dollar coverage by HDHP plans for telehealth and “other remote care services” was due to expire.¹³ Fortunately, in the fiscal year 2023 (FY23) omnibus spending package, Congress extended the allowance until the end of 2024. Therefore, the 118th Congress faces a new deadline for HDHP beneficiaries at the end of the second session. We urge you to extend the safe harbor for HDHPs to cover telehealth and other remote care services with first-dollar coverage indefinitely. Similarly, we urge that Congress provide clarity—in report language or otherwise—as to what “other remote care services” includes. Live interactions are important, but platforms that enable physicians and caregivers to provide asynchronous care have also proven essential during and outside of the pandemic and should be included in “other remote care services.”

Medicare Coverage of Live Audio and Video Visits

The underlying statute governing Medicare’s coverage of live audio and video visits between qualified caregivers and patients is out of date, but recent temporary waivers have sidelined it until the end of 2024. Specifically, Section 1834(m) of the Social Security Act limits Medicare’s coverage of live audio and video visits to a rather narrow list of scenarios, including (1) the patient residing in a rural Healthcare Professional Shortage Area (HPSA) and (2) the patient’s home being ineligible as a location where care can “originate.” At the time of the statute’s enactment, video calls were mainly theoretical and only possible if the patient were at in-clinic provider’s office or regional telehealth center with specialized video equipment. As a result, originating sites do not include a patient’s own home (except temporarily until the end of 2024) and are essentially limited to other physicians’ offices in a narrow set of geographic areas that exclude Medicare beneficiaries outside of HPSAs, effectively excluding all urban and suburban, and many rural, Medicare beneficiaries. As alluded to above, thanks to the excellent work of the 117th Congress, until the end of 2024, those qualified originating sites include the “home of an individual,” and onerous geographic restrictions have been waived. However, the 118th Congress should permanently enable Medicare to cover live audio and video visits regardless of the location of the patient.

Evidence collected during the pandemic shows that access to telehealth has been both equitable and cost effective. In Virginia, Medicaid expenditures on healthcare services slightly decreased overall while telehealth expenditures stabilized toward the end of 2020 at about 6 percent of overall healthcare expenses.¹⁴ Importantly, the effect was more substitutive than additive: the amounts Virginia spent on telehealth services were roughly equal to the drop in in-person visits.¹⁵ The evidence here appears to provide no support whatsoever for arguments that access to telehealth would cause patients and providers to bill for unnecessary services, and the Congressional Budget Office (CBO) should factor this evidence into its assumptions as it forecasts the costs of legislation to remove barriers to coverage. The evidence also shows that coverage of telehealth services, including audio-only, improved equitable access to care. Before the pandemic, Black Medicaid beneficiaries accounted for 22 percent of claims for telehealth visits, but in the most intense months of the pandemic, they accounted for 30 percent of all telehealth claims.¹⁶ This relative

¹³ Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. No. 116-136), Sec. 3701.

¹⁴ Presentation by Dr. Chethan Bachireddy, Chief Medical Officer, Virginia Department of Medical Assistance Services (DMAS) for congressional staff (May 2021), Slide 8.

¹⁵ *Id.*

¹⁶ *Id.* at Slide 8.

increase in utilization weighs against notions that covering these services will only benefit advantaged patients.

Several bipartisan and popular bills from the 117th Congress would accomplish permanent reform along these lines. Examples include the Telehealth Modernization Act of 2021 (H.R. 1332/S. 368, 117th), the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2021 (H.R. 2903/S. 1512, 117th), and Advancing Telehealth Beyond COVID-19 Act of 2021 (H.R. 4040, 117th, as introduced). We urge the 118th Congress to advance measures like these with an eye toward providing maximum statutory flexibility for CMS to cover telehealth visits where appropriate.

Remote Patient Monitoring

CMS has made significant progress in supporting asynchronous remote patient monitoring services, including its decisions to provide unbundled support for both remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) Current Procedural Terminology (CPT) code families. However, further significant barriers remain that prevent realizing the potential of remote monitoring tools and services that are demonstrated to markedly improve both prevention and treatment of acute and chronic conditions. We recommend that the 118th Congress include a provision removing the requirement for providers to charge patients a 20 percent copay for asynchronous remote patient monitoring services. Such a provision could be similar to H.R. 4755 from the 117th Congress, which would provide that Medicare pays for 100 percent of chronic care management (CCM) services.¹⁷ While remote patient monitoring use is growing, mandatory cost-sharing requirements imposed on Medicare patients discourage socioeconomically disadvantaged populations from benefiting from these services. CHI Steering Committee member University of Mississippi Medical Center (UMMC) notes that 45 percent of the patients enrolled in its hypertension RPM project report an income below \$30,000, and 25 percent reside in federally designated rural areas. Clinically, UMMC's program shows substantial improvements in blood pressure control, which leads to reduced risk for future cardiovascular events. Copays of \$10 to \$20 per month associated with RPM codes can result in patients making difficult choices between paying for medications, transportation, groceries, housing, or other essential expenditures. Moreover, receiving a copay bill each month tends to frustrate patients, who are unlikely to acknowledge monthly billing for a doctor's orders. Eliminating copays would help extend these crucial remote patient monitoring services to those who benefit most.

In addition, we recommend that the 118th Congress direct CMS to provide unbundled billing codes for RPM services at federally qualified health centers (FQHCs) and rural health centers (RHCs). CMS has historically refused to issue digital health billing codes for use at FQHCs and RHCs, arguing that the payments for such services are covered by existing prospective payment service processes (in the case of FQHCs) or flat fee structures (in the case of RHCs). Without additional funding to invest capital in remote patient monitoring systems, FQHCs and RHCs are, in practice, unable to offer such services to their patients. As you know, the requirements around creating FQHCs and RHCs mean that these patients are more likely to live in rural areas, to have low socioeconomic status, and to lack access to other vital health care services. We appreciate that the bill currently clarifies that FQHCs and RHCs are allowed to furnish telehealth services, but the proposed language could be improved by explicitly allowing these health centers to leverage

¹⁷ The Seniors Chronic Care Management Improvement Act of 2021 (H.R. 4755, 117th Cong.) Sec. 2.

asynchronous remote patient monitoring tools. Such a policy change encourages the use of digital medicine widely and would take significant steps in addressing disparities in telehealth utilization.

Value-Based Care Opportunities

Centers for Medicare and Medicaid Services (CMS) Data Collection and Analytics. When Congress enacted the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015, it sought to transition traditional Medicare’s fee-for-service payment system to one that facilitates innovation and care coordination while also improving patients’ health outcomes. Digital health innovations include telehealth, remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), clinical decision support (CDS) software tools, and care coordination portals. These technologies can improve patient and physician shared decisionmaking about treatment plans, save costs, augment population health management, and better caregivers’ experience, and they already play a critical role in the transition to value-based care. We believe CMS should gather information and report on how these technologies lead to better, more cost-effective care. Empirical analyses like this would better enable policymakers to ensure patients and caregivers can leverage digital health tools where they are most effective. The 118th Congress should require or encourage CMS to collect data and produce analyses on the use of digital health tools and services across its alternative payment models.

Better Transitions from Merit-Based Incentive Payment System (MIPS) to Alternative Payment Models (APMs) and Advanced APMs. Congress should establish a third payment pathway between MIPS and APMs that facilitates preparation to participate in APMs and ultimately take on financial risk, as well as reducing unnecessary reporting burden. At least until there are many more APMs in which physicians can choose to participate and a higher proportion of physicians participating in them, the statute should continue to provide incentive payments for APM participation. The 118th Congress should consider reworking the incentive payments to address the problems that arise from the budget neutrality requirement in MIPS and facilitate transitions from MIPS to APMs—and should consider up-front payments to support investment in services like RPM and chronic care management by APM participants.¹⁸

Interoperability and Food and Drug Administration (FDA) Flexibilities

Information Blocking. Congress and the Department of Health and Human Services (HHS) created a framework that promotes progress on the interoperability of electronic health records (EHRs) so that patients’ data can be shared and used across providers and payers. For example, HHS’ Office of the National Coordinator for Health IT (ONC) oversees a process that periodically updates the interoperability standard certified EHR technology should use. To better enable patients to access their own protected health information and use it outside the EHR system, Congress also enacted a requirement for ONC to prohibit EHR and health information network practices that constitute “information blocking.” Although the rules are final, the Office of Civil Rights (OCR) has not yet settled on civil monetary penalty guidance for their enforcement and as a result, many patients are still unable to access their own medical records through organizations exchanging data. The information blocking rules are important to CHI and directly affect several of our members whose patients depend on accessing their records. The 118th Congress should conduct rigorous

¹⁸ For further detail on these value-based care recommendations, see Letter from Morgan Reed, executive director, Connected Health Initiative, to Members of Congress re: Value-based care (Oct. 31, 2022), available at <https://actonline.org/wp-content/uploads/2022-11-01-CHI-Response-to-VBC-RFI-FINAL.pdf>.

oversight to ensure the information blocking rules are as clear as possible and that the agency has the requisite resources to enforce them expeditiously.

Medical Device Data Interoperability. The federal interoperability framework around medical devices is in earlier stages of development than efforts to advance EHR interoperability, leading to a number of unnecessary inefficiencies, costs, and even risks to patient health and safety. For example, caregivers report that while some of the devices in a hospital or other provider location automatically upload physiologic data to the EHR system, others do not interoperate and require manual input. Physicians already spend up to half of their time on paperwork and electronic record-keeping, draining away time, energy, and resources that should be spent on patients themselves. Legislation introduced last year, the Better Interoperability for Devices Act (H.R. 9067, 117th), would address this issue by requiring FDA to work with ONC on a report to Congress about the state of medical device interoperability. The report would also include recommendations for Congress to consider adjusting incentives and FDA authorities to ensure more expeditious and secure data interoperability standard development and adoption. We urge the 118th Congress to reintroduce and enact this legislation.

Privacy and Data Security

Federal Privacy Reform. Multiple factors are at play that intensify the need for Congress to enact general privacy reform. For one, more data than ever is transferred or created outside the scope of the Health Insurance Portability and Accountability Act's (HIPAA's) privacy protections. While the Federal Trade Commission (FTC or Commission) has pursued companies for mishandling health information, Congress should better equip the Commission to prevent and punish privacy harms arising from abuse of sensitive personal information like health data. Additionally, the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* has led to a range of uncertainties around the privacy status of health information, especially information outside the scope of HIPAA. We urge Congress to enact a federal privacy law of general applicability setting a strong set of rules to prevent and penalize privacy and data security harms concerning health data outside the HIPAA umbrella.

Prioritize Secure, End-to-End Encrypted Services. Congress should clarify the status of end-to-end encrypted voice and video platforms for the purposes of HIPAA. Under HHS' current guidance, covered healthcare providers may use bona fide end-to-end encrypted voice platforms without signing a Business Associate Agreement (BAA), as the guidance indicates that such services likely mere "conduits."¹⁹ This practice is optimal because those end-to-end services do not retain data associated with the voice call—a BAA would require them to collect and store data they currently are unable to access. In scenarios where a caregiver has opted to use an end-to-end encrypted platform and does not seek to retain a recording of the visit, such services should not be required to retain that information. Therefore, the 118th Congress should clarify (or seek clarification from HHS) as to the status of fully end-to-end encrypted services as "conduits." Doing so would help protect patient safety by limiting any cybersecurity vulnerabilities to which they would otherwise be exposed in the likely event that HHS' guidance is retracted after the conclusion of the PHE.

¹⁹ See U.S. Dept. of Health and Human Svcs., Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth (last reviewed Jun. 13, 2022), available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html#footnote32_srbw7eZ.

Broadband Oversight

The 117th Congress allocated an unprecedented \$48 billion toward broadband infrastructure deployment and access programs through the National Telecommunications and Information Administration (NTIA).²⁰ The work is not done, however, and we urge the 118th Congress to conduct rigorous oversight to ensure that NTIA, and its state and territory grantees, prioritize the healthcare use case and meet congressional intent by ensuring that broadband funding better supports caregivers and patients preventing and managing chronic and acute health conditions with digital health tools.²¹

Conclusion

We look forward to working with you on measures to modernize American healthcare so that it enables caregivers, patients, and consumers to leverage digital health tools to benefit the accessibility, affordability, and quality of healthcare. We look forward to working with the 118th Congress to achieve our shared goals in this regard.

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, Cambia Health Solutions, Dogtown Media, George Washington University Hospital, GoodRX, Intel Corporation, Kaia Health, Microsoft, Noom, Inc., 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.

²⁰ Infrastructure Investment and Jobs Act (Pub. L. No. 117-58), 117th Cong., 2d Sess., available at <https://www.congress.gov/bill/117th-congress/house-bill/3684/text>.

²¹ See Comments of the Connected Health Initiative, *Infrastructure Investment and Jobs Act Implementation*, 87 Fed. Reg. 1123 (Jan. 10, 2022), available at <https://www.regulations.gov/comment/NTIA-2021-0002-0410>.