

The Connected Health Initiative (CHI) is the leading cross-sectoral group of innovators and healthcare organizations that harness the power of mobile connectivity to improve patient engagement and health outcomes. CHI members include a diverse array of healthcare stakeholders, including physician groups, patient groups, device manufacturers, pharmaceutical companies, software companies, venture capital firms, and research universities. CHI is the only effort that has pulled these disparate interests together to find agreement on needed policy and law changes that will enable the responsible uptake of digital health tools. CHI is the policymaker go-to for connected health questions and proposals



in areas including reimbursement and payment, privacy and security, the Food & Drug Administration's (FDA) role in addressing emerging medical technologies, health data interoperability, and the role of Al/machine learning in care delivery.

Digital medicine must play a more substantial role in healthcare as the current physician shortage of 30,000 increases to an estimated 90,000 by 2025. And by 2030, an estimated 70 million Americans will be over the age of 65, about 80 percent of whom will have at least one chronic condition. To meet Americans' evolving healthcare needs, it is critical to extend each physician's reach to a larger population using connected health technologies. The COVID-19 emergency further exacerbated problems within America's healthcare system, highlighting the need for rapid modernization that will bring continuous care to patients outside of the four walls of the doctor's office.



A well-established and growing evidence base demonstrates that digital health tools improve patient engagement and outcomes, while also enhancing accountability and reducing costs throughout the healthcare value chain. As more connected health innovations enter the marketplace, patient outcomes and consumer wellness will continue to improve, but only if federal policies allow them to do so. CHI has led in advancing policy changes that have brought new connected health innovations into the continuum of care and which enjoy bipartisan support, such as through Medicare and Medicaid payment changes, new rules to promote health data interoperability, and attaining key guidance from the FDA addressing software as a medical device and clinical decision support software tools, among others. These policy changes must be sustained and built upon by Congress, federal agencies, and others.

Even more recently, the COVID-19 pandemic has prompted federal agencies and Congress to enable the use of digital health innovations including telehealth and remote patient monitoring (RPM) by removing further legacy barriers to their use with no connection to the needs of a modern healthcare system or patient expectations. Temporary allowances enacted by Congress do permit Medicare coverage for patients in a much wider set of circumstances than are possible under permanent statute, but once the Public Health Emergency (PHE) declared by the Secretary of Health and Human Services expires, these temporary flexibilities go away. A reversion to the pre-pandemic status quo is unacceptable, and Congress needs to act to ensure broader utilization of digital health tools permanently. With these additional flexibilities enabling patients to access care from home (or elsewhere), usage during the COVID-19 PHE has spiked by 4,300 percent nationwide. If the law is not permanently changed, the bureaucracy will once again be failing patients—reverting to a pre-internet approach to healthcare and preventing patients from getting care when, how, and where they need it.



To Support Interoperability, Reimbursement, Security, and Privacy in the Digital Health Space, CHI Urges Congress to:

- Pass measures like the Telehealth Modernization Act (H.R. 1332/S. 386, 117th), which would permanently sideline outdated statutory restrictions on CMS' ability to cover telehealth services furnished to Medicare patients. Especially important to CHI is the addition of "any site" at which the patient is located at the time the service is furnished and the removal of geographic restrictions. Telehealth should not be arbitrarily limited to Medicare patients fitting a very narrow set of criteria as it is in current law.
- Pass legislation like the Wearable Equipment Adoption and Reinforcement and Investment in Technology (WEAR IT) Act to ensure that taxpayers can use their flexible or health savings accounts (FSAs/HSAs) to purchase wearables and connected health software apps and platforms. Currently, HSAs and FSAs cover individual devices such as blood glucose monitors, but they do not cover a wearable device that collects blood glucose data via a sensor and an app and is also capable of capturing an EKG reading. Multi-function devices and their associated software components are better suited for consumers who want to track more than one health-related variable, and these items should benefit from the same tax advantages as single-function devices.
- Peel away the overly burdensome restrictions on telehealth under 1834(m) of the Social Security Act and consider requiring the Congressional Budget Office (CBO) to look beyond the 10-year budget window, including by passing the **Preventive Health** Savings Act (H.R. 2584/S. 1361, 116th).
- Work with CHI to understand the impact and potential of cutting-edge technologies and innovations on the healthcare industry (e.g., machine learning/artificial intelligence).
- Speed the evolution of the Medicare system to value-based care that leverages telehealth and other digital health tools by passing measures like the Value in Health Care Act of 2020 (H.R. 7791, 116th) as well as legislation like the PREVENT DIABETES Act (S. 4709/H.R. 8861, 116th). This legislation would include diabetes prevention programs with virtual components in the Medicare Diabetes Prevention Program (MDPP), empowering patients to make use of their mobile devices and internet connectivity to access key prevention services.



- Support access to broadband, especially in rural areas—including using unlicensed spectrum—to enable connected health technologies to reach rural populations that suffer from high rates of chronic disease.
- Make appropriate updates to regulatory vestiges—like features of the Anti-Kickback Statute and the Stark Law—intended to reduce fraud, waste, and abuse that can occur under fee-for-service practices.

