ConnectedHealthInitiative

July 26, 2024

The Honorable Jason Smith
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, District of Columbia 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
Washington, District of Columbia 20515

RE: Statement for the Record of Brian Scarpelli, executive director of the Connected Health Initiative, on the hearing *Access to Health Care in America: Unleashing Medical Innovation and Economic Prosperity*

Dear Chairman Smith and Ranking Member Neal:

Thank you for holding this hearing on modernizing healthcare in America through medical innovation. Digital medicine is foundational to enhancing access to care through innovative methods. Digital tools can connect health practitioners to more patients, empower those patients to better understand their health, and help physicians more effectively diagnose and treat conditions. Digital health and telemedicine modalities are now well-demonstrated to enable efficacious and cost-effective healthcare delivery. I urge you to expand flexibilities and otherwise enable digital health innovations to give patients the care they need.

The Connected Health Initiative (CHI) is a coalition of healthcare stakeholders from across the value chain, including patients, physicians and other types of providers, research universities, and software and device companies. We advocate for policies that enable all patients, and their providers, to harness the power of technology to spur patient engagement, improve health outcomes, and control costs.

Flexibilities for Digital Healthcare Tools and Services

During the COVID-19 public health emergency (PHE), the Department of Health and Human Services (HHS), under its emergency authority, provided much-needed flexibilities for providers and patients in several key areas to facilitate efficient and efficacious care. Patients could take telehealth appointments from their homes, reach their doctors more easily online, and take up innovative remote monitoring tools and services with far fewer hurdles (including no copay). From the perspective of physicians and other providers, numerous outdated restrictions on digital health capabilities were set aside, such as the Centers for Medicare & Medicaid Services (CMS) suspending geographic and originating site restrictions for telehealth visits. For physicians, other providers, and patients, the experience of the PHE illustrated the untapped potential of

digital health tools to improve outcomes and save costs across a range of use cases, and highlighted how legacy restrictions in statute and regulation are diminishing that potential without benefit to the public. Despite increased utilization in response to demand, a recent study has shown that there was not any correlated trends of fraud or overuse. Based on the experience during the PHE, we call on Congress and HHS to take the steps needed to fully enable these digital health tools to advance the Quadruple Aim in health care of enhancing patient experience, improving population health, reducing costs, and improving professional satisfaction for physicians and other providers.

Congress has already taken important steps in response to the country's COVID-19 PHE experience that can and should be built on. Thanks to this Committee's work and both chambers prioritizing the issue, restrictions over a quarter of a century old in Section 1834(m) of the Social Security Act, which blocked Medicare coverage of live audio and video visits except in rather narrow circumstances and disallowed access to those services from a patient's home (and which were suspended during the PHE), have been temporarily lifted through the end of 2024. We have long supported the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act (H.R. 4189) as well as the Telehealth Modernization Act (H.R. 7623). CHI also supported H.R. 8261, the Preserving Telehealth, Hospital, and Ambulance Access Act, bipartisan legislation focused on telehealth that passed out of the Ways and Means Committee unanimously in May 2024. Each bill would unlock Medicare coverage for live audio / video visits, including visits conducted at the home of patients, with the most recent version of H.R. 4189 making those changes permanent and the most recent versions of H.R. 7623 and H.R. 8621 extending those changes to the end of 2026.

Virtual care is now mainstream. People in rural and underserved areas benefit most from being able to visit with their caregivers virtually, and they are a major reason why Section 1834(m)'s restrictions must be permanently eliminated. Similarly, the PHE flexibilities allowed for coverage of audio-only telehealth services, recognizing that a video component requirement unnecessarily impedes access to care for individuals without reliable internet access and disproportionately harms rural and underserved populations. Flexibility for audio-only telehealth services was extended to the end of this calendar year, but we encourage its permanent extension.

Remote Physiologic and Therapeutic Monitoring

Asynchronous remote monitoring tools and services allow great flexibility for patients to access their care. One member of CHI, Avenue Health, demonstrates the potential of remote monitoring every day. Nurses employed by Avenue Health remotely monitor patients with conditions like hypertension, and patients can call these nurses when they are feeling poorly. Access to remote monitoring and instruction from these nurses

reduces emergency visits by patients, saving the health system money. This care at home—or wherever a patient experiences an issue—is a key means of care for rural communities in particular. Many more patients could benefit from this type of monitoring for a variety of chronic and acute conditions.

We applaud the positive steps taken by CMS to support the use of remote monitoring tools and services, such as allowing remote monitoring at Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs) in last year's Medicare Physician Fee Schedule (PFS), which has provided overdue support for the use of remote monitoring tools by frontline providers serving America's most vulnerable populations. However, several barriers impede the wider adoption of remote monitoring innovations already shown to improve outcomes, reduce costs, and augment providers' experience. For example, remote monitoring services are subject to the 20 percent copay required for Medicare coverage. Too many Medicare beneficiaries are unable to afford a monthly bill for remote monitoring, even if it may greatly benefit their health. Notably, during the PHE, HHS waived this requirement and others; responsibly expanding patient access in this way leads to better management of chronic conditions, ultimately saving money in Medicare expenditures. Over three years of digital health usage during the PHE showed that, without legacy restrictions that have little or no public benefit, it is being used responsibly and appropriately.

The copay requirement is one of many outdated restrictions still in place that no longer has a connection to the public benefit. Eliminating arbitrary barriers like this would help more providers see the benefit of remote monitoring and increase innovation. CHI members already work to innovate in the healthcare sector, but bureaucratic barriers stop them from reaching their full potential.

Appropriately Categorizing Software-as-a-Medical Device (SaMD)

CMS must advance Medicare coverage and payment policy changes that appropriately categorize artificial intelligence (AI) through steps like recognizing that AI software as a medical device is appropriately categorized and paid for as a direct practice expense and
responsibly expanding support for AI's use in the prevention and treatment of beneficiaries' acute and chronic conditions. From CHI's perspective, many new innovations are supporting safe and efficacious treatments for patients suffering from a wide range of health conditions, and should be accessible to all Medicare beneficiaries. In light of this, we have urged CMS to clearly acknowledge that it is incorrect to categorize all software, particularly SaMD, as general "Computer Software" with an indirect PE that is non-allocable. We have also called on CMS to propose steps for collaboration with our community to find ways to leverage opportunities and overcome challenges related to Medicare coverage and payment policies for innovative technologies.

Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute. For instance, CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories and if so, which category. Congress, and the Ways and Means Committee, should encourage CMS to use their existing authority to properly evaluate these innovations.

The WEAR IT Act

To further the adoption of digital medicine and improve rural healthcare, CHI supports H.R. 6279, the Wearable Equipment Adoption, Reinforcement, and Investment in Technology (WEAR IT) Act, led by Congresswoman Michelle Steel (R-CA). The WEAR IT Act would allow individuals to access certain wearable health technology through their tax-advantaged flexible spending accounts (FSAs) and health savings accounts (HSAs). Currently the Internal Revenue Service (IRS) allows HSA and FSA funds to be spent primarily on single-purpose devices. In a recent development, the IRS now considers the Oura Ring and the Aura Pulse Comprehensive Health Tracker eligible for FSA and HSA expenditures, two exceptions to the IRS's general rule against such devices. Many cutting-edge wearable health devices have multiple functions such as catastrophic fall detection, heart rate monitoring, and/or blood oxygen measuring. Although these devices outperform covered legacy technology in many cases, they are generally not covered (with the exceptions described above) because of the IRS's historical interpretation of the law, which is outdated. The IRS has recently begun to modernize its approach to HSA and FSA eligibility, but only in unpredictably narrow cases. If Congress enacts the WEAR IT Act, patients, consumers, physicians and other providers will benefit from greater certainty that such devices will be covered by FSAs and HSAs. In turn, healthcare stakeholders will have more choice and additional ways to improve outcomes and control costs. Moreover, the use of wearable health technology in rural and underserved settings will help patients and providers by collecting more detailed information that can improve treatment, especially for chronic conditions. This could be life-changing for patients who live far from their doctors.

Preventing Overuse and Fraud Using Digital Health Tools

Digital medicine and telehealth services are a clear value add to the provision of healthcare services, especially in rural areas. Studies have consistently demonstrated that telehealth services are not more susceptible to fraud than in-person healthcare, and that including telehealth services does not lead to over-utilization. According to the

Alliance for Connected Care, telehealth usage in Medicare currently accounts for about 5 percent of services, a number which has remained steady since the start of the PHE. Even with the addition of telehealth usage, the overall usage of Medicare services has not increased significantly. Generally digitizing the healthcare system makes utilization and other fraud-related trends easier to track and respond to since automated tools are being used. And ultimately, restricting telehealth services due to fears of over-utilization will just mean that rural areas continue to lack access to key healthcare supports.

CHI understands that addressing waste, fraud, and abuse is a key goal for the Committee as you look at Medicare spending. We agree that tackling these issues will help bring down the overall costs of healthcare spending, but we stress that telehealth has proven no more prone to fraud than other healthcare modalities. It is important to distinguish between telehealth fraud, the perpetration of healthcare fraud using telehealth modalities, and "telefraud," the use of telemarketing to defraud consumers, including healthcare consumers. This second type of fraud is better addressed through existing authorities at the Federal Trade Commission (FTC). This February, the HHS Office of the Inspector General (OIG) released a report examining the incidence of telehealth fraud in Medicare and found that the telehealth services provided to Medicare beneficiaries did not show signs of fraud. We urge the Committee to recognize that digital health tools are an asset to preventing fraud and overuse.

Conclusion

Addressing issues in medical innovation is vital to ensuring a system that benefits all patients. Digital health technology, including wearable and remote monitoring technology, can make a huge difference for individuals and patient groups as a whole. CHI urges the adoption of policies that allow for flexibility to innovate and provide the care that patients need.

Sincerely,

Brian Scarpelli
Executive Director
Connected Health Initiative