



March 4, 2022

Congresswoman Mariannette J. Miller-Meeks  
1716 Longworth House Office Building  
Washington, DC 20515

Congressman Mike Kelly  
1707 Longworth House Office Building  
Washington, DC 20515

Congressman H. Morgan Griffith  
2202 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Miller-Meeks, Kelly, and Griffith:

Thank you for the opportunity to respond to the Healthy Futures Task Force Modernization Subcommittee's request for information (RFI) regarding the utilization of wearable technologies, the expansion of telemedicine, and digital modernization efforts in the United States health care system. We write to support your work and offer our suggestions for your consideration.

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs. We have been focused on modernizing health care for years and welcome the opportunity to work closely with the Subcommittee to refine and execute its agenda. HIA's primary priority areas this Congress are making telehealth a permanent fixture option for health care delivery and access; improving the collection, sharing, and use of public health data; and ensuring an interoperable, private, and secure system of health care information for use by providers, payers, researchers, and patients.

The Subcommittee is right to focus on the use of modern technologies such as wearables, telehealth platforms, and artificial intelligence (AI) as methods of improving health care. However, we caution you to ensure an appropriate balance of government encouragement and private sector innovation to allow the health care and technology industries to succeed at modernization. Too much government intervention could further complicate an already complex and hyperregulated field. For example, Congress's goal of digitizing medical records in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 was largely successful in that most clinical encounters now are recorded in electronic health record systems (EHRs), but HITECH has also been credited with increasing physician burnout due to new demands on clinical workload and the constant updating and maintaining of EHRs.

As the Subcommittee considers different types of actions, we urge you to balance Congress's ability to create new laws and requirements with Congress's duty to oversee the administration's implementation of current law and authorities. The 21st Century Cures Act (Cures) passed by Congress in 2016 included provisions to improve EHR functionality and interoperability, and much of the law has yet to be implemented completely. Cures is a perfect example of a law intended to improve many aspects of health care that must be closely monitored by Congress to ensure the implementation matches the

intent of the law. One provision in Cures, for example, clarifies the Food and Drug Administration's (FDA) role with respect to clinical decision support tools is still being implemented by the FDA. If this provision is implemented too stringently by the FDA, many tools that could foster more efficient and effective delivery of care may never become available due to an overly burdensome federal approval process.

### *Wearable Technologies and Connected Devices*

HIA supports the adoption and use of wearable technologies, as we believe they are effective tools for patients to track their health and wellness. By incentivizing the use of wearables through public and private insurance plans, we can begin to put patients' health care more directly into their own hands. However, we believe there is still work to be done to demonstrate the clinical utility of wearables and the data they generate. The Subcommittee should consider funding research to determine the usefulness of wearable data in different clinical contexts. Congress should also encourage the development of more remote health technologies like wearables and connected medical devices for home use. For example, glucose monitors and blood pressure cuffs could allow for a more thorough virtual visit between patients and clinicians. However, home devices like these are not connected in reliable or standardized ways for clinicians to access the data securely and reliably.

HIA believes that Congress, the Department of Health and Human Services (HHS), the Office of the National Coordinator for Health Information Technology (ONC), and the FDA should all work together to make connected medical devices a reality in both the home and in clinical settings. Devices surrounding the patient bed in acute settings as well as devices used by patients at home for health tracking and measurements should all be secure, reliable, connected, and easily usable. We encourage the Subcommittee to consider the potential of interoperable consumer and medical devices to improve care quality, outcomes, and efficiency.

### *Telehealth*

The quick onset of the COVID-19 pandemic in early 2020 brought about not only severe health challenges, but also problems delivering in-person care for patients who contracted COVID-19 and for patients who needed routine medical care for other diseases and conditions. Congress and the Centers for Medicare and Medicaid Services (CMS) waived government rules that held back use and provision of telehealth leading to an experiment where patients are getting more access to care, care is more convenient to the patient, and costs may be lower.

As we move beyond the COVID-19 pandemic, Congress needs to permanently extend all temporary telehealth flexibilities to ensure Medicare beneficiaries can continue to receive care remotely once the public health emergency (PHE) ends. Beyond the PHE, beneficiaries should be allowed to continue to access their providers through telehealth. Medicare should not have archaic policies that require patients to travel to a doctor's office to have a virtual visit with another doctor in another office, especially if that patient could easily conduct the same visit from the convenience and safety of their own home.

Specifically, Congress should permanently:

- Remove the originating site restrictions in Medicare to allow beneficiaries to receive remote care regardless of their location, including their own homes. Congress should eliminate the originating site requirement altogether and allow patients to access care anywhere;

- Eliminate geographic requirements to expand telehealth services into suburban and urban areas;
- Allow more sites of service and providers to use telehealth to treat beneficiaries. Federally qualified health centers and rural health clinics, for example, should be able to provide remote care to their patients. Additionally, more care professionals, like physical therapists, speech pathologists, and occupational therapists, should be allowed to use and bill for telehealth services;
- Allow first-dollar coverage for telehealth services through Health Savings Accounts;
- Allow audio-only telehealth visits for patients who do not have the option of using video technology; and
- Allow the remote authorization of dialysis care through telehealth technologies instead of requiring an in-person visit.

While there was an increase in telehealth services in 2020, the U.S. did not see a drastic increase in overall health spending. According to a study from Altarum based on data from the U.S. Bureau of Economic Analysis, total health spending in 2020 was two percent less than in 2019, a decline of about \$75.8 billion dollars.<sup>1</sup> Additionally, a study by Harvard, Phreesia, and the Commonwealth Fund showed that while telehealth expanded rapidly at the beginning of the pandemic as in-person visits fell off, telehealth services plateaued and in-person visits began to rise again during the summer of 2020. The number of overall visits, however remained at pre-pandemic levels, suggesting that there was not a surge in use due to expanded telehealth access.<sup>2</sup>

Further, there is evidence that the ease of telehealth created an environment that fostered greater patient adherence to exams and prescribed care. For example, based on data from one health system the overall condition of pre-diabetic patients did not worsen. Eye exams and other regularly recommended screenings were occurring and did not decrease in frequency based on payer scorecards. From this information, it is clear that patients sought and received care via telehealth during a period where they were not coming to the office as much as in a pre-pandemic year. No-show rates were also lower due to the use of telemedicine than in pre-pandemic years. This strongly indicates an ongoing demand for the types of telehealth services that were not available to communities in pre-pandemic years and a willingness to utilize these services when possible. A study from November 2021 found that 55 percent of patients were more satisfied with virtual visits than in-person visits for their care.<sup>3</sup>

More specifically to your questions about the substitution of traditional health care services through telehealth, HIA is conducting a study to determine whether telehealth has been additive or substitutive during the pandemic and additionally whether the preference for virtual care options during the COVID-19 PHE is a permanent behavior change. We look forward to sharing the results of this study with you once completed.

For licensure, HIA has worked on modernizing licensing to allow providers to deliver virtual care to Medicare beneficiaries when their patients are in other states without the need for duplicate state

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<sup>1</sup> <https://altarum.org/news/did-national-health-spending-2020-decline-first-year-recorded-history-preliminary-data-say-it>

<sup>2</sup> <https://www.commonwealthfund.org/publications/2021/feb/impact-covid-19-outpatient-visits-2020-visits-stable-despite-late-surge>

<sup>3</sup> <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/covid-19-consumer-healthcare-insights-what-2021-may-hold>

license. Federal programs, like the Department of Defense (DoD) and the Veterans Administration (VA), have effectively implemented a national telemedicine framework to facilitate the delivery of care to patients. Congress expanded the DoD state licensure exemption to allow credentialed health care professionals to work across state borders without having to obtain a new state license.

It also expanded the definition of an exempt health care professional to include qualified DoD civilians and contractors, while removing the service location requirement to allow for care regardless of where the health care professional or patient is located. This is not true in Medicare or the commercial market where doctors, nurses, and pharmacists are required to obtain multiple state licenses and adhere to multiple state rules to provide telemedicine services to patients across state lines. Patients are restricted from receiving remote medical services by physicians unlicensed in their own state, even if that same physician is licensed, credentialed, privileged, and providing quality health care in other states. Congress should build off the VA and DoD model and allow more telehealth across state lines.

Further, many large employer plans operate in multiple states and have vast contracted networks of doctors, nurses, and pharmacists to supply care to their employees. Because of archaic medical licensure requirements, care cannot be delivered via telehealth to employees of the same employer without licensing the provider in multiple states. Congress should encourage the use of virtual care through employer plans by allowing delivery of care to employees in other states.

#### *Artificial Intelligence (AI)*

One of the drivers of rising health care costs has been ever-present fraud, waste, and abuse in the Medicare fee-for-service program defrauding patients and costing taxpayers billions. While there will always be bad actors, Congress can take steps to ensure HHS and CMS have the resources necessary to identify and reduce fraud in real time.

Current efforts to combat fraud have hinged on expensive, frequent audits of providers and requiring patients to see doctors in person before using vital telehealth visits or other remote care. AI and machine learning (ML) have proven effective at reducing fraud, waste, and abuse across the private sector, and we should further use in Medicare. The use of AI and ML will allow HHS to identify and prevent fraud and inappropriate care before it occurs without costly audits and burdensome in-person requirements that may have a limited impact on program integrity and an outsized impact on patient access. By incentivizing use of advanced analytics, we can expand access to innovative care and modernize our anti-fraud efforts in the process.

Fortunately, HHS-OIG already has a strategic plan in place to leverage AI and ML to better predict the potential for fraud, waste, and abuse and support the oversight of future programs. We should support the current plans in place and expand upon them.

#### *Interoperability and Privacy*

HIA continues to work on both implementation of the interoperability provisions in Cures and recommendations on what additional actions are needed from the public and private sectors to make our health system more interoperable. HIA convened an interoperability working group last year, and we plan to issue a report and recommendations in the next few months that we will share with you once complete. Cures passed over five years ago, but many of the requirements have yet to be implemented and interoperability continues to be a major issue in health care. Key areas we are focused include:

- Increasing the availability of useable, streamlined data at the point of care, including images, eligibility information, a longitudinal health record, and clinical decision support tools to streamline information for the care team;
- Connecting and making interoperable consumer health devices and clinical medical devices so that reliable consistent data can be used and referenced in the delivery of care;
- Improving access to and availability of medical research by modernizing consent processes and supporting decentralized clinical trials;
- Ensuring HIPAA covered entities are comfortable sharing health information to improve care and respond to patient access requests by creating a statutory safe harbor in HIPAA;
- Supporting the development and implementation of consistent standards to track and use Social Determinants of Health information across caregivers and payors, including funding for the translation of the information received by community and social workers into usable clinical data; and
- Modernizing public health reporting by ensuring consistency in data use agreements across states and localities and fostering bidirectional exchange of public health data both to and from public health authorities and providers on the ground.

Additionally, as health care information becomes more liquid, we must ensure patients trust how the data is being used. Congress is considering comprehensive privacy reform – and we support these efforts – but most of these conversations are focused on consumer technology and data. Health data is either carved out of these proposals or included in a new category of “consumer health data” which could lead to many entities being subject to duplicative requirements. The HIPAA law that led to today’s HIPAA Privacy Rule was passed over 25 years ago, and while HIPAA is still functioning well, it does not address the growing concerns regarding third-party applications or other technologies accessing health data that fall outside of HIPAA’s reach. Providers, health plans, and other covered entities and their business associates covered by the Privacy Rule as well as the patients they serve need clarity and consistency in health data privacy and use rules.

As Congress considers privacy reform, we urge the Modernization Subcommittee to support the Health Data Use and Privacy Commission Act, S. 3620, that will add much needed recommendations specific to the future of health information privacy and use. Given the advancements Congress has made in improving the interoperability of health care information and systems, HIA has worked to ensure robust consideration of health care data and privacy through a Health Data Use and Privacy Commission. Secure and private health information should not be the enemy of medical innovation, clinical process improvement, or public health response. Careful consideration of these issues by the commission will inform policy makers to achieve the necessary balance of data liquidity and confidentiality necessary for a highly functional and trusted health system.

According to the International Association of Privacy Professionals (IAPP), “state-level momentum for comprehensive privacy bills is at an all-time high.”<sup>4</sup> The patchwork of proposals across all 50 states could lead to further complexity and compliance burdens. According to the Information Technology and Innovation Foundation, should all 50 states pass privacy legislation in the absence of a federal law, compliance costs “could exceed \$1 trillion over 10 years, with at least \$200 billion hitting small

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<sup>4</sup> <https://iapp.org/resources/article/us-state-privacy-legislation-tracker/>

businesses.”<sup>5</sup> All of this stresses the need for a federal law governing data privacy, and there are at least 24 proposals related to data privacy before the 117<sup>th</sup> Congress according to the IAPP.<sup>6</sup> This issue is far too important to the functioning of our health care system and the trust of patients to get wrong, and we appreciate your consideration of this legislation to help get these policies right.

Thank you for the opportunity to engage with the Modernization Subcommittee of the Healthy Futures Task Force. We look forward to working with you going forward.

Sincerely,

A handwritten signature in black ink, appearing to read "Joel White".

Joel White  
Executive Director  
Health Innovation Alliance

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<sup>5</sup> <https://itif.org/publications/2022/01/24/looming-cost-patchwork-state-privacy-laws>

<sup>6</sup> <https://iapp.org/resources/article/us-federal-privacy-legislation-tracker/>