HEALTH INNOVATION ALLIANCE

October 15, 2023

Chairman Jodey Arrington
House Budget Committee
204 House Office Building
Washington, DC 20515

Congressman Michael Burgess
2161 Rayburn House Office Building
Washington, DC 20515

Congressman Drew Ferguson
2239 Rayburn House Office Building
Washington, DC 20515

Congressman Buddy Carter
2432 Rayburn House Office Building
Washington, DC 20515

Congressman Lloyd Smucker
302 Cannon House Office Building
Washington, DC 20515

Congressman Blake Moore
1131 Longworth House Office Building
Washington, DC 20515

Congressman Rudy Yakym
349 Cannon House Office Building
Washington, DC 20515

Dear Chairman Arrington and Representatives Burgess, Ferguson, Carter, Smucker, Moore, and Yakym:

Thank you for the opportunity to respond to the Health Care Task Force's request for information (RFI) studying the drivers of health care spending and exploring solutions resulting in better health outcomes. 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 are focused on bettering outcomes through modernizing the United States' health care system and welcome the opportunity to work further with the Task Force on the priorities it has established including supporting innovation, modernizing the health care system, and increasing patient access.

HIA believes that several policy areas must be addressed to accomplish these priorities including:

- Harnessing the power of AI in health care;
- Making telehealth a permanent option for Medicare beneficiaries;
- Supporting the appropriate use of wearable technology and remote patient monitoring; and
- Ensuring an interoperable, private, and secure system of health care information for providers,

payers, researchers, and patients.

As the Task Force 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 laws and authorities. The 21st Century Cures Act (Cures) passed by Congress in 2016 included provisions to improve the functionality and interoperability of electronic health records, but much of that law has yet to be implemented completely. Cures is a perfect example of a law that must be closely monitored by Congress to ensure the implementation matches the intent of the law. A provision in Cures clarifies the Food and Drug Administration's (FDA) role concerning clinical decision support (CDS) tools, for example, and FDA released a final guidance last year that contradicts Congress's law. We urge you to review FDA's authority and actions over CDS.

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. 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 across the private sector and should be used further in Medicare. AI and ML will allow the Department of Health and Human Services (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 the use of advanced analytics, we can expand access to innovative care and modernize our anti-fraud efforts in the process.

Fortunately, the HHS Office of the Inspector General 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.

Telehealth

The quick onset of COVID-19 in early 2020 highlighted problems in 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 the use and provision of telehealth. This resulted in patients having more access to providers in a more convenient way, and at a lower cost.

Congress needs to permanently extend all temporary telehealth flexibilities to ensure Medicare beneficiaries can continue to receive care remotely. Medicare should not have archaic policies that require patients to travel to an office to have a virtual visit with a doctor in a different location, when they could have the same visit from their own home.

Specifically, Congress should permanently:

- Remove originating site restrictions in Medicare allowing beneficiaries to receive remote care regardless of their location;

- 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.

There is evidence telehealth created an environment that fostered greater patient adherence to exams and prescribed care. Patients sought and received care via telehealth during a period when they were not coming to the office as much as in a pre-pandemic year and no-show rates were lower due to the use of telemedicine than in pre-pandemic years. A study from November 2021 found that 55 percent of patients were more satisfied with virtual visits than in-person visits for their care.[1]

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. This additional data – used correctly – can lead to slowing or stopping disease progression, alerting to a health issue before the need for hospitalization or advanced intervention, and signaling that therapy may need to be amended or changed, all leading to better outcomes and lower costs. 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 Task Force 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, 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 clinic settings. Devices surrounding the patient bed in acute settings as well as

[1] https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/covid-19-consumer-healthcare-insights-what-2021-may-hold

devices used by patients at home for health tracking and measurements should all be secure, reliable, connected, and easily usable. We encourage the Task Force to consider the potential of interoperable consumer and medical devices to improve care quality, outcomes, and efficiency.

Remote Patient Monitoring

One of the effects of the COVID-19 pandemic over the last three years has been an increase in the use of technology and virtual visits where in-person visits were previously the norm. This has been true in all facets of Americans' lives from grocery shopping to virtual meetings and celebrations, working from home, and utilizing telehealth for doctor visits. The health care delivery system has evolved out of necessity and a concern for both providers' and patients' safety. One method to promote better patient care and lower burdens on our health system is the use of digital technology known as remote patient or remote physiologic monitoring (RPM).

The FDA defines digital health as including "categories such as mobile health, health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine."[2] RPM, a subset of digital health, is a category that needs to be recognized in public policy moving forward. RPM includes items like mobile health apps and wearable monitoring devices to help track a patient's vitals, provide alerts about needed care, help patients access their providers, and lower health care costs by preventing disease progression and costly hospital visits.

According to a survey published by Ernst & Young in January 2021, only 18 percent of health and human services organizations have "managed to embed digital tools in the way they work[ed]" prior to the COVID-19 pandemic.[3] In an effort to continue to care for patients while the world moved to virtual care, the survey also found that, globally, 62 percent of health organizations increased their use of digital technologies throughout the pandemic including those utilizing mobile sensors or wearable devices almost doubling.[4]

Patients deserve to take advantage of the latest technologies that can help them improve their health and access to care. In a time when the health care system and our health care providers are overburdened, we need to allow for the use of technology to lighten that load while also providing valuable insight into the patient's wellbeing, care, and treatment.

The shortage of health care providers in the U.S. has progressively worsened over the last several years and without some course correction and intervention, the trend will continue. The Association of American Medical Colleges projects that by 2034 primary care in the U.S. could see a shortage of up to 48,000 providers and up to just over 77,000 for non-primary specialties.[5] Those living in Health Professional Shortage Areas could very well have a difficult time gaining access to needed health visits due to the lack of providers in the area.

---

[2] https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health
[3] https://www.ey.com/en_us/government-public-sector/embracing-digital-is-covid-19-the-catalyst-for-lasting-change
[4] https://www.ey.com/en_us/government-public-sector/embracing-digital-is-covid-19-the-catalyst-for-lasting-change
[5] https://www.aamc.org/news-insights/press-releases/aamc-report-reinforces-mounting-physician-shortage

With a lack of health professionals comes a lack of available in-person visits. RPM is a safe and secure way for patients and providers to help manage chronic diseases and conditions, gather data needed for treatment plans, and communicate about treatment adjustments between in-person visits. These tools are enhancements to our care delivery system and should be treated as such through supportive policies and reimbursements.

In early December 2020, CMS finalized the Calendar Year 2021 Medicare Physician Fee Schedule Rule and included several RPM-related items and updates in the regulation relating to utilization and reimbursement. This included clarifying who can bill for RPM services, requirements for RPM services after the COVID-19 Public Health Emergency ended, the need for RPM for acute and chronic conditions, and certain reimbursement requirements for specific Current Procedural Terminology, or CPT, codes. [6]

HIA encourages action to ensure Medicare regulations continue to take into account current verified technologies and expanded utilization as a means to increase patient access and quality of care while reducing the burden on providers. We also recommend that any legislation on these issues allow space for technologies to evolve and be recognized, especially in the realm of remote therapeutic monitoring for medication adherence.

Interoperability and Privacy

HIA is focused on the implementation of the interoperability provisions in Cures and recommendations of what additional actions are needed from the public and private sectors to make our health system more interoperable. HIA convened an interoperability working group and issued a report with several proposed solutions, benefitting patients and providers. Our solutions include:

- Requiring consistent imaging standards and developing a national plan to make images and imaging devices interoperable, including sharing images through cloud-based storage options;

- Creating an accelerated approval pathway for interoperable medical devices to increase access and competition;

- Developing historical patient records that can be easily accessed, exchanged, and used in care delivery, including digital tools that can make the information useful and digestible at the point of care;

- Ensuring clinicians have access to common-sense CDS tools for care delivery and clarifying software that is not subject to medical device regulation; and

- Solidifying in statute that covered entities will not be liable for HIPAA penalties for sharing patient information pursuant to a patient request to share that information.

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

[6] https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1

could lead to many entities being subject to duplicative requirements. The HIPAA Privacy Rule while important, 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 Task Force to consider legislation that would add much-needed recommendations specific to the future of health information privacy and use 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 policymakers to achieve the necessary balance of data liquidity and confidentiality necessary for a highly functional and trusted health system.

The National Conference of Insurance Legislators (NCOIL) just adopted a resolution HIA drafted to ensure that state consumer privacy legislation include exemptions for health privacy laws that cover medical research, patient care delivery, and other aspects of health care that are already well regulated. We reference this model resolution for you to examine to ensure policies you consider do not impede the active use of health information to produce new treatments and cures, protect patients from harm, and ensure caregivers have accurate information to treat their patients. We urge Congress to balance the advances made in health care interoperability, medical research, and care delivery with any proposals you consider to modernize privacy protections.

Thank you for the opportunity to engage with the Task Force. We look forward to working with you going forward.

Sincerely,

Brett Meeks
Executive Director