September 5, 2025

The Honorable Brett Guthrie
Chairman
Committee on Energy and Commerce
Washington, District of Columbia 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
Washington, District of Columbia 20515

The Honorable Morgan Griffith
Chairman
Committee on Energy and Commerce
Subcommittee on Health
Washington, District of Columbia 20515

The Honorable Diana DeGette
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
Washington, District of Columbia 20515

Dear Chairman Guthrie, Ranking Member Pallone, Chairman Griffith, and Ranking Member DeGette:

Thank you for the opportunity to provide testimony for the record on today's hearing, titled "Examining Opportunities to Advance American Health Care through the Use of Artificial Intelligence Technologies." The Connected Health Initiative (CHI) is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. I urge you to support the inclusion of artificial intelligence (AI) tools in healthcare in a risk-based, ethical way.

A well-established and growing evidence base continues to demonstrate that the responsible use of safe and effective digital health solutions produces better patient outcomes, reduces costs, augments population health management, and improves the healthcare workforce experience (the Quadruple Aim[1]). Digital health tools, increasingly powered by AI, leverage patient-generated health data (PGHD) and include cloud-enabled solutions to reduce administrative burden, support medical and clinical decision-making, and manage chronic and acute care. The use of these tools is also vital in supporting unserved and underserved Americans' access to prevention, diagnosis, and treatment for both acute and chronic conditions.

Your attention to healthcare's use of AI comes at a critical time. Tapping into the tremendous potential of AI is critical to empowering Americans with personalized solutions; equipping healthcare providers with better and timely data about the patients they serve and improving health outcomes; and shifting the paradigm for healthcare to a system that fosters prevention, wellness, and chronic disease management. Many AI use cases, ranging from solving administrative/backend efficiencies to supportive clinical decisions, have already demonstrated their capacity to advance the Quadruple Aim.

As Congress works toward a stronger and more effective health system, it is imperative that you keep safety and security for patient and healthcare practitioners top of mind. To that aim we encourage you to set policy aligned with the following principles:
- **Quality Assurance and Oversight:** Congress should continue to encourage the Department of Health and Human Services (HHS) to adopt a risk-based approach to healthcare AI that tailors

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[1] Bodenheimer, T., & Sinsky, C. (2014). "From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider." *Annals of Family Medicine*, 12(6), 573-576.

risk mitigation to the potential harms of intended and expected uses. Responsibility for managing risks should be shared among developers, vendors, and providers based on their knowledge of, and ability to address, those risks in alignment with leading standards such as ISO/IEC 42001.[2] HHS should clarify liability considerations for clinicians using AI and providers offering digital health tools, with the goal of encouraging innovation and adoption.

- **Transparency and Explainability:** Require HHS to provide clear, risk-based communications that inform downstream healthcare stakeholders about relevant data requirements, intended uses, limitations, target populations, bias mitigation, and applications of AI tools. These communications should disclose sufficient detail to help providers assess when a tool is appropriate for individual patients, clarify whether the tool augments or automates clinical workflows, and specify compliance with all applicable legal and regulatory requirements.

- **Access and Affordability:** Prioritize measures that will ensure digital health technologies and AI systems in healthcare are accessible and affordable across research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building health AI infrastructure; preparing personnel and training; and appropriately incenting the responsible uptake and consistent use of AI tools demonstrated to advance the Quadruple Aim. Notably, the Centers for Medicare & Medicaid Services (CMS) should modernize the way AI software is categorized and supported, and provide unbundled support in Medicare for AI tools to improve Medicare beneficiaries' experience and care (as well as working with states to achieve a harmonized expansion of similar support for AI in Medicaid). Further, CMS should make overdue modernizations to key disease prevention programs (e.g., diabetes prevention) and support preventative healthcare by fully leveraging digital health technology tools, such as patient-facing wearables and AI-enabled services. AI must also have a central role in the transition to value-based care by providing essential population health tools and providing enhanced scalability and patient support.

- **Interoperability:** Ease data access and improve interoperability, while protecting data security, to foster cooperation, trust, and openness among patients, providers, health AI technology developers, and researchers. A truly interoperable healthcare system is one that enables and engages patients across multiple privacy-preserving platforms using open application programming interfaces (APIs), enabling the secure integration of PGDH into electronic health records. Interoperability rules under the 21st Century Cures Act should enable clinicians' access to medical records and patients to get their data and provide it to other organizations, including for research. The success of AI tools for precision medicine, population health, and clinical decision support, all of which are key tools in addressing chronic diseases, depends on accessible and interoperable data.

- **Ethics:** Given the longstanding, deeply rooted, and well-developed body of medical and biomedical ethics, it will be critical to preserve existing and emerging ethical norms developed by providers and healthcare professional organizations for broader adherence by technologists, innovators, computer scientists, and those who use such systems. From design to development to use, healthcare AI solutions should align with all relevant ethical obligations.

- **Workforce:** The United States faces a stark, and growing, healthcare workforce shortage. Successful creation and deployment of AI-enabled technologies which help care providers streamline tasks and meet the needs of their patients will be an essential part of addressing this shortage. Policies should support user education and workforce development through AI

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[2] https://www.iso.org/standard/42001.

upskilling, strengthen the clinician-patient relationship, and appropriately balance between human care and decision-making and augmented capabilities from AI-enabled technologies and tools.

- **Education:** Support education on AI in healthcare, highlight successful AI applications, and promote stakeholder engagement to keep policies responsive to new opportunities and challenges. Education should be developed by healthcare professional organizations in partnership with AI developers. Educating the public about how AI is used in their care increases transparency, fosters trust, and enables patients to make informed decisions about their health.

- **Collaboration:** We strongly encourage you to leverage the public-private partnership framework to collaborate with providers, patients, industry, research institutions, and government agencies to advance the above and to more broadly drive safe and effective innovation in healthcare AI.

I also urge you to consider the following resources that the CHI community has developed to assist policymakers in their efforts to responsibly bring AI innovations into the healthcare continuum:

- CHI's *Health AI Policy Principles*, a comprehensive set of recommendations across key areas that should be addressed by any policymaker considering AI's use in healthcare (available at https://bit.ly/3m9ZBLv);

- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, comprehensive recommendations on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5); and

- CHI's *Health AI Roles and Interdependencies Framework*, which describes the health AI value chain, defining actors and describing roles for ensuring safety and efficacy as well as the interdependencies between these actors, mapping these roles to functions in the National Institute of Standards and Technology's AI Risk Management Framework (https://connectedhi.com/wpcontent/uploads/2024/02/CHI-Health-AI-Roles.pdf).

I appreciate your consideration of our input at this critical time for the American healthcare system and the countless Americans who depend on it. CHI and our partner organizations stand ready to assist you further in any way that we can.

Sincerely,

Brian Scarpelli
Executive Director
Connected Health Initiative