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June 16, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0938-AV68

Dear Secretary Kennedy:

Thank you for the opportunity to respond to the Request for Information on the Health Technology Ecosystem. The Consumer Technology Association (CTA®) and our member companies value our longstanding partnership with HHS, and we look forward to future work together to leverage technology to make Americans healthier.

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands helping support more than 18 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world. CTA is the trade association representing more than 1200 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA's Health Division advances consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, health systems, and biopharmaceutical innovators. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

General Comments

CTA applauds CMS and ASTP/ONC for the focus and prioritization of health data interoperability. Aligning program incentives with technical requirements for developers is critical to fully leveraging technology to address some of our health care system's biggest challenges, including access to care and affordability.

As an American National Standards Institute (ANSI) accredited standards development organization, CTA is helping advance the use of technology in healthcare by driving industry consensus. With 34 published digital health standards, CTA is advancing cutting-edge technology in health AI, stress

monitoring, physical activity monitoring, and sleep tracking. CTA also has the advantage of advancing technology used in other sectors to also advance health and wellbeing. For example, Ripple™ is advancing open-radar API standards to enable hardware and software interoperability while accelerating the growth of applications for general purpose consumer radar. The Ripple API can have many healthcare use cases, including touchless gesture control, occupancy detection and non-invasive wellness monitoring, keeping patients safe at home and out of high-risk and expensive hospital settings.

CTA is helping advance the use of AI and ML in health care by driving industry consensus. To date, CTA's Artificial Intelligence Committee has already developed a number of health AI standards, including:

- Definitions/Characteristics of Artificial Intelligence in Health Care (ANSI/CTA-2089.1)
- The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)
- The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)

CTA continues to focus on developing additional industry standards to advance the adoption of health AI, to include current work underway on verification and validation for pre-market/pre-release and operations and monitoring for post-market/post-release application for predictive health AI.

CTA also serves an important role as a convener of associations focused on health AI with the formation of the 'Health AI Collaborative' to consider use cases for health AI and policy recommendations. The Health AI Collaborative believes health AI holds promise to:

1. Improve Decision-Making
2. Enhance Communication and Patient Access
3. Streamline Processes
4. Integrate Data Sets[1]

When considering any AI regulation, the Administration should consider the unique use cases of AI in health care. CTA believes a risk-based approach to regulating AI in health care balances the huge benefits of innovation with appropriate patient safety protections. HHS should continue to engage in industry consensus-based standards to drive transparency and accountability in AI. Standards can be nimbler and more reactive to changes in the market and are often adopted in federal health IT regulation, as highlighted in the RFI. We support incorporation and reference to standards in health AI regulation.

Specific Responses

PC-3. Are you aware of health management, care navigation, or personal health record apps that would be useful to Medicare beneficiaries and their caregivers?

CTA members are developing cutting-edge digital health tools to detect, prevent, manage, and combat chronic disease. Early detection and management are key to bending the health care cost curve, and technology is leading the way. Some examples include:

- *AI/ML Products*
    - **Curai Health** deploys machine learning into clinical workflows to extend clinicians' abilities to care for their patients, with a focus on chronic disease management, including hypertension, diabetes, and anxiety/depression. As a primary care provider, Curai also

[1] *Support the Thoughtful Application of Trustworthy AI in Healthcare*. Consumer Technology Association.

leverages AI to drive behavior change at scale, using advanced models to identify personal barriers to health goals and support consumers in overcoming obstacles with clinically informed protocols.

- **Hippocratic AI** leverages advanced machine learning to support chronic disease management, including hypertension and chronic kidney disease. Through AI-driven outreach, patients receive timely assessments, monitoring, and escalations to clinical teams as needed. This proactive approach helps improve patient outcomes by addressing both medical and social determinants of health.

- AI and ML are also being integrated into traditional medical devices like continuous glucose monitors (CGMs) to help Americans better manage their health, like the CGM systems developed by **Dexcom**. These systems, including the first over-the-counter CGM, utilize generative AI to deliver personalized, consumer-centered care. By incorporating advanced AI technologies, Dexcom's CGMs empower millions of Americans—both with and without diabetes—to make more informed health choices, track their glucose levels in real time, and create lasting lifestyle changes that improve their overall well-being.

- **Verily Lightpath** is designed to be a proactive, personalized, dynamic and responsive chronic care platform, which is fueled by continuous data integration and AI. Lightpath pairs health coaches and an advanced licensed clinical team including endocrinologists, pharmacists, primary care physicians, nurses and registered dietitians, through an affiliated medical group. This allows Lightpath to serve a variety of acuity levels within a single solution based on member need. Lightpath's care modules and pathways are dynamic and personalized, and use AI as a self-learning system. The intent is to help members achieve their goals by driving behavior change through rapid feedback loops. This means Lightpath can help members overcome barriers, either in partnership with their current providers, or by working with our advanced clinical care teams.
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- *Telehealth and Remote Monitoring*
  - **Abbott** is at the forefront with its CardioMEMS Heart Failure Monitoring System, a small pressure sensor implanted in the pulmonary artery that allows physicians to remotely monitor changes in a person's pulmonary artery pressure. This early detection of worsening heart failure enables doctors to adjust medications or make other interventions before symptoms even appear, reducing hospital admissions and improving patient quality of life. Abbott also offers NeuroSphere Virtual Clinic, an FDA-approved platform that allows doctors to remotely adjust deep brain stimulation devices for patients with Parkinson's disease, significantly reducing the need for travel. These technologies, part of Abbott's broader Connected Care offerings, help patients manage complex, chronic health conditions from the comfort of their homes.

  - **Philips** offers a remote patient monitoring program for individuals with chronic conditions such as diabetes, hypertension, and heart failure. Through this program, patients can communicate with specialists, submit test results, and respond to clinical messages on cellular-enabled devices. Program participants have experienced significant improvements, including a 3.06% reduction in average HbA1c levels and a 38% reduction in emergency department visits. These examples demonstrate how remote monitoring technologies can enhance care accessibility and improve health outcomes for individuals

with chronic conditions.

- Obstructive sleep apnea (OSA) is a chronic condition impacting tens of millions of Americans and approximately one billion people worldwide, most of whom remain undiagnosed, according to **Resmed**. Telehealth and remote patient monitoring are revolutionizing OSA management by making critical therapies like CPAP more accessible and effective. Resmed pioneered the first connected CPAP and accompanying patient engagement applications, demonstrating how the immediacy of data tracking and personalized support can significantly improve therapy adherence. These innovations not only enhance patient outcomes and reduce the increased risk of comorbidities associated with untreated OSA, including stroke, hypertension, cardiovascular disease and dementia, but also help strengthen our nation's healthcare infrastructure by leveraging digital tools to deliver cost-effective care.

- **Teladoc's** Online Diabetes Prevention Program provides comprehensive care via virtual support and coaching to members to reduce their risk of developing type 2 diabetes. Though Medicare currently reimburses for diabetes prevention, current regulations mandate that programs like these must be delivered in person, limiting the availability for those who need it most.

- *Consumer Wearables*
  - **Samsung** has been a key innovator in this space, releasing the first FDA-cleared obstructive sleep apnea risk detection feature for consumer wearables. By leveraging photoplethysmography (PPG) technology, Samsung's Galaxy Watch can identify breathing interruptions during sleep. With nearly 80% of sleep apnea cases going undetected, such widespread consumer-grade devices with advanced technology have the potential to improve millions of lives and reduce the clinical burdens associated with chronic conditions.
  - **Google** is a leading innovator in the consumer wearables space through its Pixel Watch and Fitbit devices, which are designed to provide comprehensive health and wellness insights. Leveraging advanced sensor technology, Fitbit devices offer continuous heart rate tracking, detailed sleep stage analysis, and stress management tools. For example, the Fitbit Sense 2 includes an Electrodermal Activity (EDA) sensor to detect electrodermal activity responses, which may indicate stress. The Google Pixel Watch, building on Fitbit's expertise, integrates seamlessly with Android, offering enhanced connectivity and the precision of Google's health algorithms. A key differentiating feature is the deep integration of Google's AI and machine learning capabilities, which power personalized insights and health recommendations, going beyond basic tracking to provide actionable guidance for improving overall well-being. This comprehensive ecosystem helps users understand their health holistically, promoting proactive lifestyle management and early detection of potential issues. These offerings integrate with Google's Health Connect, which is a platform designed to help Android users securely store non-clinical health and fitness data on their phones and easily share it with their preferred apps. Health Connect now supports Personal Health Records (PHR), including new clinical categories like problems & conditions, medications, allergies, immunizations, and lab results, accessible through new Android Health APIs.

- *Prescription Digital Therapeutics*
  - **Big Health's** FDA-approved SleepioRx is a prescription digital therapeutic to treat insomnia. A first-line non-pharmaceutical treatment, Sleepio delivers digital cognitive behavioral therapy that is clinically beneficial and cost effective. Instead of going through

time-consuming and resource-heavy treatments with a health care provider in-office or virtually, a provider can prescribe or order a prescription digital therapeutic treatment that a patient can do on their own. This provides first-line care that helps prevent reliance on second-line medications that are higher risk for patients, especially Medicare beneficiaries.

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

a. *What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?*

CTA research has found that one of the most important factors in consumer adoption of health technology is insurance coverage.[2] To support the innovations discussed above, HHS must:

- Continue to support Medicare reimbursement of telehealth and remote monitoring without artificial restrictions;
- Accept new CPT codes that allow for reimbursement of remote monitoring if a device is used for less than 16 days in a calendar month;
- Permanently allow for virtual suppliers in the Medicare Diabetes Prevention Program; and
- Support reimbursement for all FDA-cleared or approved prescription digital therapeutics, not just those cleared or approved by the FDA under 21 CFR 882.5801.

Moving forward, HHS must consider how to ensure appropriate adoption of AI and ML tools, as well as other software as a service (SaaS)/software as a medical device (SaMD) products. Currently, time-based reimbursement codes incentivize inefficient clinician workflows so providers can receive payment. This hurts the adoption of AI innovations, which seek to make health care less expensive and more efficient for clinicians and patients. CMS must consider the impact of AI and ML tools on current valuations and a path forward to ensuring adequate provider reimbursement for tools that will improve patient outcomes and reduce provider burden while still delivering cost savings.

In approving specific digital health product categories for reimbursement, CTA supports the Administration's statement in the Making America Healthy Again Executive Order that "agencies shall ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits that support beneficial lifestyle changes and disease prevention."[3].

b. *What changes would enable timely access to high quality CMS and provider generated data on patients?*

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[2] *Driving Consumer Adoption of Digital Health Solutions* (February 2023). Consumer Technology Association.

[3] *Establishing the President's Make America Healthy Again Commission* (February 13, 2025). The White House.

CMS must also consider the growing number of consumer wearables that have FDA cleared or approved software functions and can provide high-quality clinical patient data, many of which do not qualify for reimbursement under existing benefit categories.

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in PC-5) digital health products for their patients?

a. *What are the current obstacles?*

According to CTA research, healthcare providers are often frustrated when data from digital health tools are not integrated into the electronic health record (EHR) as it creates more work and confusion.[4] Data should be integrated directly into a provider's workflow. Additionally, research found that in many cases the cost of the technology can be prohibitive for patients, making coverage essential for adoption. Fifty-seven percent of surveyed providers said an increase in patient reimbursement and forty-seven percent said no out-of-pocket costs for patients will help digital health solutions to reach their full potential.[5] Additionally, sixty-three percent called for clinical evidence that digital health devices and tools are successful in managing patients.

Additionally, there are a growing number of third-party health tools that are not covered by HIPAA yet manage sensitive health data. Thirty percent of providers surveyed said evidence of increased security of patient data would help drive better adoption. To this end, CTA published "Guiding Principles for the Privacy of Personal Health Data" to help developers understand privacy best practices in developing digital health tools.[6] However, to best ensure data privacy, CTA supports a national privacy law that addresses the current patchwork of state laws and regulations.

TD-5. How could a nationwide directory of FHIR endpoints improve health data access?

CTA supports establishing a nationwide directory of FHIR endpoints as it would enhance efficiency, reduce burden, and support interoperability.

Conclusion

CTA appreciates the opportunity to help shape HHS' approach to health technology. We look forward to working with you and the team at CMS and ASTP/ONC to create a modern, technology-enabled healthcare system focused on prevention, increasing access, and decreasing costs.

Sincerely,

René Quashie
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Catherine Pugh
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[4] Ibid
[5] Ibid
[6] *Guiding Principles for the Privacy of Personal Health Data* (2021). Consumer Technology Association.