ConnectedHealth

July 6, 2018

Immediate Office of the Secretary
Office of the Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, District of Columbia 20201

RE: *RFI Regarding Healthcare Sector Innovation and Investment Workgroup (HHS-OS-2018-0011-0001)*

Dear Sir/Madam:

In response to the Federal Register notice issued on June 7, 2018,[1] ACT | The App Association's Connected Health Initiative (CHI) hereby submits comments to the United States Department of Health and Human Services (HHS) on the agency's proposed initiative to facilitate public-private dialogue to increase innovation and investment in the healthcare sector.

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system, and we seek HHS' partnership in facilitating private investment and innovation across the healthcare ecosystem. CHI has long worked with Congress, HHS, and other policymakers to advance the adoption and use of digital health tools.

Data and evidence from a variety of use cases continue to demonstrate how the connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. These tools, which include wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based

[1] Department of Health and Human Services, *Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector,* 83 FR 26485 (June 7, 2018).

patient portals, are revolutionizing American healthcare by enabling the secure exchange of health information and incorporating patient-generated health data (PGHD) throughout the continuum of care. To demonstrate these benefits, we append to this letter a list of studies and data showing the benefits of connected health technologies across key chronic conditions.

The ability of HHS to advance innovation and investment in the healthcare industry requires fully leveraging a wide range of connected health technology innovations. Yet, despite the broad evidence base supporting the value of connected health technology, the American healthcare system, particularly the Medicare program, lacks appropriate incentives for the use of new innovations in the delivery of healthcare. For example:

- Medicare provided just $13.9 million for telehealth reimbursements in 2014, including $12,482,270 for provider fees at the distant site (location of the provider) and $1,452,160 for originating site fees (location of the patient).[2]
- Until January 1, 2018, CMS reimbursement for general physiological remote monitoring did not exist. However, in the 2018 Physician Fee Schedule (PFS), CMS distinguishes between remote monitoring services and telehealth. In its final rule, CMS permitted separate payment for remote physiological data monitoring by activating and unbundling Current Procedural Terminology® (CPT) Code 99091 ("physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver"). The code, which has several limitations, allows reimbursement to physicians and qualified healthcare professionals who rely upon PGHD to monitor patients from wherever they may be. Additional codes have been developed by the CPT Editorial Panel, and CHI continues to seek advancement of these codes generally and their use throughout the Medicare system.[3]
- Numerous U.S. government programs maintain outdated and/or overly-burdensome regulatory requirements that discourage investment and innovation in the public and private healthcare landscape. For example, regarding the electronic prescribing of controlled substances (EPCS), healthcare innovators are effectively prevented from participating in the EPCS market due to onerous certification requirements. This leaves key programs addressing America's growing health problems (*e.g.*, the opioid epidemic) unable to benefit from competitive effects in the connected health technology marketplace.

[2] http://ctel.org/2015/05/cms-medicare-reimburses-nearly-14-million-for-telemedicine-in-2014/

[3] http://actonline.org/wp-content/uploads/MS-Letter-to-CMS-Verma-re-Remote-Monitoring-in-Medicare-061118-FINAL-w-cosigners.pdf

CHI believes HHS, in collaboration with the private sector, can do a tremendous amount to embrace and accelerate healthcare innovation within existing statutory authority, and without the need for legislative action. For example, we have urged HHS to create a Secretary-level initiative to promote connected health innovations within Medicare and Medicaid programs,[4] similar to the Department of Veterans Affairs' efforts to prioritize telehealth.[5]

Based on the above, we support HHS' planned initiative to "to develop a workgroup to facilitate constructive, high-level dialogue between HHS leadership and those focused on innovating and investing in the healthcare industry," and offer the following specific input on areas raised by HHS in its request for comment:

- Regarding HHS' request for input on specific areas of inquiry or focus for the workgroup:
    - CHI urges the workgroup's output to be realistic and tangible actions that HHS can take to increase innovation and investment in the healthcare sector. CHI also encourages the workgroup's outcomes be clearly stated in advance of the commencement of the workgroup's efforts.
    - CHI believes the workgroup's focus should be on potential cuts in regulation or changes to regulations under existing authority, not policy changes requiring congressional action or action by governmental entities outside of HHS. Such an effort would be well informed by (1) reviewing recent developments in health innovation and investing; (2) examining perceived barriers to innovation and competition in the healthcare industry; (3) encouraging outside parties to provide HHS with information about how they are affected by HHS programs or regulatory requirements; (4) providing a forum for the sharing of perspectives as to how HHS may improve relevant regulations, guidance, or other documents; and (5) examining ways to encourage private sector investment to help combat health crises (*e.g.*, the opioid epidemic). As noted above, the removal of barriers to the adoption of digital health innovations across the continuum of care must be a cornerstone of advancing the American healthcare system and should be a key theme in the workgroup's efforts. CHI has recently evaluated these barriers in the context of what HHS can do without congressional action, and we believe these recommendations would be an ideal starting point.[6]

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[4] https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/59f2740024a694ad62602847/1509061632752/10262017_HHS-Letter-Draft-Strategic-Plan_%28Final%29.pdf

[5] *See*, *e.g.*, https://www.va.gov/geriatrics/guide/longtermcare/telehealth_care.asp.

[6] In May of 2018, the CHI formulated a range of recommendations for HHS on ways it can advance the uptake of digital health tools without new legislation or additional regulations. This letter is accessible at https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5af9fcde758d468cf8ccb6f4/1526332639008/05102018_Connected-Health-Initiative-Input-to-WH.pdf.

- Within its examinations of connected health technology, CHI believes the workgroup should dedicate significant energy toward the examination of remote monitoring technologies (also referred to as "store-and-forward" technology). Specifically, we would object to myopic focus on "telehealth" as defined in the Medicare program (which is, effectively, a live voice or video call only). The workgroup should consider the wide range of technology innovations available today and in development that hold the potential to revolutionize the American healthcare system.
- The workgroup's efforts should be tied to HHS' implementation of key laws, including the 21st Century Cures Act and the Medicare Access and CHIP Reauthorization Act of 2015, among others.

- Regarding how the workgroup should be convened and structured, CHI offers the following:
  - CHI supports HHS leveraging the time-tested public-private model for dialogue, and we urge HHS to ensure the workgroup's membership is as inclusive as possible. We note that HHS advisory committees, work groups, etc. have omitted the viewpoint of the healthcare technology innovator community. The workgroup HHS proposes is a key opportunity to finally include such viewpoints. For this reason, we specifically support HHS' proposed inclusion of "healthcare innovation-focused companies, healthcare startup incubators and accelerators, healthcare investment professionals, healthcare-focused private equity firms, healthcare-focused venture capital firms, and lenders to healthcare investors and innovators." We support the reservation of two appointed seats on the workgroup for each of the segments proposed by HHS in its request for comments, as well as for small business healthcare software application developers, university hospitals, patients, etc. and others as appropriate.
  - CHI's experience is that the physician's voice is a vital, yet often missing, component in the development, implementation, and use of effective health technology. Clinicians and physician organizations waste time and resources on the adoption of solutions that are not sustainable, not scalable, or do not provide positive return on investment. This contributes to fatigue, increased health care costs, and reduced motivation to engage in future implementations of promising solutions. CHI recommends that HHS engage physicians when fostering new, practical, and innovative approaches in digital health to tackle the complicated challenges facing the health care industry.
  - CHI believes that workgroup meetings should be held at a monthly recurrence and publicly.

In conclusion, CHI supports HHS' goals of accelerating innovation and investment in the healthcare industry. We believe that, if scoped and structured appropriately, the proposed workgroup could provide key public-private consensus recommendations on actions HHS can take immediately to advance investment and innovation. We urge HHS' consideration of our views above, and stand committed to assist HHS moving forward in any way we can.

Sincerely,

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