

December 16, 2019

The Honorable Diana DeGette 2111 Rayburn House Office Building Washington, DC 20515-0601 The Honorable Fred Upton 2183 Rayburn House Office Building Washington, DC 20515-2206

Re: CURES 2.0 Call to Action

Dear Representatives DeGette and Upton:

The American Telemedicine Association (ATA) appreciates the opportunity to provide comments as you and your colleagues work to expand and build on the 21st Century Cures Act of 2016. As the only organization completely focused on advancing telehealth, the ATA is committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA represents a broad and inclusive member network of technology solution providers and payers, as well as partner organizations and alliances, working to advance industry adoption of telehealth, promote responsible policy, advocate for government and market normalization, and provide education and resources to help integrate virtual care into emerging value-based delivery models.

With appreciation for the legislative successes that were achieved last Congress, and the efforts made by the Centers for Medicare and Medicaid Services (CMS) to implement those policies, the ATA encourages Congress to consider additional steps to expand the coverage and reimbursement of telehealth and digital health technologies and offer the following areas of opportunity for consideration in advancing potential Cures 2.0 legislation:

Enhance patient choice and outcomes while supporting caregivers through the elimination of artificial barriers to telehealth, including coverage, reimbursement, geographic discrimination, and restrictions on the use of telehealth in Medicare.

For many Americans living with chronic conditions, traveling to a provider, clinic, or hospital is often not feasible or difficult at best. Caregivers and family are often placed under enormous



stress and must take time off work to assist with transporting patients to frequent in-person visits with one or more specialists, which are often concentrated in major cities and far from patients' homes. The nature of managing chronic conditions makes reduced time and convenience critical and barriers to access often lead patients to simply forego care or fail to adhere to their care plan because it is too overwhelming or costly. Telehealth and virtual care technologies not only improve access and convenience for these patients, but also significantly reduce costs. Allowing providers and patients to manage care at home can prevent expensive emergency or inpatient admissions, which are often the consequence of no or inadequate care.

Studies have consistently shown that the quality of healthcare services delivered via telehealth are as good as those given in traditional in-person consultations. In some specialties, particularly in mental health and ICU care, telehealth delivers a superior experience, with greater outcomes, faster response times, and higher patient satisfaction. In delivering quality care, telehealth increases efficiency and reduces the cost of healthcare with better management of chronic diseases, reduced wait times, and improved triaging using patient-focused technology and software. These technologies support better team-based care that utilizes providers' greatest scope of practice while extending the geographic reach and expertise of physicians and health facilities which help reduce readmissions and overall costs.

ATA believes all Medicare beneficiaries should have access to high-quality care, regardless of their geographic location. While we work toward more value-based and patient-centered care, we need to recognize the ability of technology, when used properly, to provide for a more connected care team and system. Importantly, expanding the use of digital health products and providing patients with access to new technologies will require greater support for clinicians and health care providers that are seeking to incorporate these emerging technologies into care delivery. Many health care providers are hesitant to invest in new digital health technologies because of the lack of clarity with respect to coverage and reimbursement.

Given the uncertainty in the Medicare program and specific restrictions placed on providers delivering care via telemedicine under traditional Medicare, the incentives for the broader adoption and use of digital health tools remain limited.

¹ Shigekawa, Erin, Margaret Fix, Garen Corbett, Dylan H. Roby, and Janet Coffman. "The Current State Of Telehealth Evidence: A Rapid Review." Health Affairs 37, no. 12 (December 1, 2018): 1975–82. https://doi.org/10.1377/hlthaff.2018.05132.



As you know, Section 1834(m) of the Social Security Act has prevented expanded access to telehealth due to rigid originating site and geographic location restrictions. Current law permits Medicare to pay for telehealth services only if the beneficiary receives services at an originating site located in certain types of geographic areas, specifically a rural Health Professional Shortage Area (HPSA) or a county outside of a Metropolitan Statistical Area (MSA).

Progress was made in the 115th Congress with the passage of the Bipartisan Budget Act of 2018 and the SUPPORT for Patients and Communities Act, both of which included important telehealth provisions that expanded originating site locations for tele-stroke services, telehealth services for ESRD patient receiving home dialysis and substance use disorder treatments, and importantly, provided telehealth as a base benefit under Medicare Advantage plans. However, even with these incremental steps, the fragmented and patchwork approach to coverage and reimbursement of remote care has led to limited uptake of these important services.

The Centers for Medicare and Medicaid Services data show that only one quarter of one percent of the more than 35 million FFS Medicare beneficiaries took advantage of telehealth services in 2016.² Low rates of utilization of telehealth in Medicare are cause for disappointment as evidence continues to demonstrate that these services not only provide expanded access to care at reduced costs but address growing disparities in underserved rural communities where health care can be difficult to access and afford. While expanding access in rural communities has historically been a focus for Congress, it is important to note that underserved urban communities experience the same disparities and need Congress' support in accessing expanded digital health services.³

Recommendation:

ATA recommends incorporating the CONNECT for Health Act of 2019 (S.2741/H.R.4932) into any potential CURES 2.0 legislation.

While the ATA has concerns about the broader incremental approach Congress has historically taken to expanding telehealth, we believe that the best path forward for this Congress is further consideration of the CONNECT for Health Act of 2019 (S.2741/H.R.4932), which would provide

² Centers for Medicare & Medicaid Services. (2018, November 15). Information on Medicare Telehealth. Retrieved from https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf

³ "Giving Urban Health Care Access Issues The Attention They Deserve In Telemedicine Reimbursement Policies, " Health Affairs Blog, October 12, 2017.DOI: 10.1377/hblog20171022.713615



the HHS Secretary authority to waive telehealth restrictions when certain criteria are met, remove geographic restrictions and add the home as an originating site for mental health services, and remove geographic restrictions on certain originating sites for emergency medical care services.

Streamline Medicare coverage determination and reimbursement of breakthrough digital health products

The 21st Century Cures Act of 2016 provided the US FDA expanded authority to implement the agency's Breakthrough Device Program, an expedited regulatory pathway for devices and combination products that demonstrate effective treatment or diagnosis of life-threatening or debilitating diseases. While these reforms have addressed some of the regulatory and market access challenges in bringing digital health products to market, there remains no equivalent process at CMS to facilitate coding, coverage and payment of these emerging technologies.

This disconnect means that while cutting edge technologies can be marketed in the US, Medicare patients are unable to benefit and must often wait years for these innovations due to frequent coverage and reimbursement delays.

Recommendation:

ATA recommends creating a new temporary CMS coverage and reimbursement pathway for breakthrough technologies approved or cleared by FDA.

The ATA supports streamlining Medicare coverage determinations for products cleared or approved under the FDA Breakthrough Device Program by requiring transitional coverage for three years during which CMS could work to identify what additional data would be needed to make a permanent coverage determination. We also support providing flexibility to HHS to make transitional coverage and payment decisions on digital therapies that have no current benefit category under Medicare.

Finally, the ATA supports measures that would foster the broader growth, expansion, and integration of digital health technologies needed to support and advance a connected US health care system, including:

- Increasing access to affordable broadband;
- Supporting and advancing patient data and ERH interoperability; and
- Encouraging consumer access to data and patient empowerment while maintaining privacy and security.



The vision of a health care system where all patients receive timely care when and where they need it should be something that we all strive to achieve. The potential for virtual care and digital health technologies to transform our system should not be underestimated. While we work toward more value-based and patient-centered care, we need to recognize the capacity of technology and innovation-focused policy to drive better care coordination across the care continuum and improve health care quality at lower costs for all Americans.

Thank you again for the opportunity to provide feedback as you and your colleagues address these critical issues. If you have any questions or would like to further discuss these recommendations, please contact me at kharper@americantelemed.org.

Sincerely,

Kevin Harper

Director, Public Policy

ATA