



March 25, 2022

Via Electronic Mail Only: connectedhealth@ostp.eop.gov

Dr. Alondra Nelson, Director

White House Office of Science and Technology Policy (OSTP)

Attn: Connected Health RFI

Dear Dr. Nelson:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to the Request for Information from the White House Office of Science and Technology Policy, and actions related to strengthening community health through digital health technologies. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments, including a wide array of digital technologies, and others with digital components, that are transforming the delivery of health care services and enabling improvements in patient health care outcomes.

Successful Models Within the U.S. of Digital Technologies Delivering Health Care/Improving Health Care Outcomes. AdvaMed member companies produce many digital technologies as well as those with digital components that are serving patients in the community as they improve outcomes, including:

- ***Continuous glucose monitors (CGM)*** are wearable devices that use a sensor inserted under the skin, usually on the abdomen or arm, that allow persons with diabetes to measure their interstitial glucose levels, or the glucose found in the fluid between the cells. The sensor tests glucose levels every few minutes and a transmitter wirelessly sends the information to a monitor or receiver, which can also be a smartphone. has been demonstrated to have significant benefits for patients with diabetes, including: reduced A1C,ⁱ increased Time in Range (TIR),ⁱⁱ reduced hospitalizations,ⁱⁱⁱ reduced absenteeism,^{iv} and improved quality of life.^v CGM has also enabled diabetes care with telemedicine during the COVID pandemic. Clinicians have been able to evaluate remotely the glucose data generated by CGMs with their patients and make treatment changes to enable appropriate care.^{vi} CGM and telemedicine together allow patients to follow up with clinicians with higher frequency and with less disruption to their daily lives. A meta-analysis by Tchero et al. showed that telemedicine was at least as effective as face-to-face visits for managing care for people with diabetes.^{vii} Unfortunately, once the public health emergency (PHE) ends, Medicare National and Local Coverage Decisions will once again require in-person visits and prohibit use of telehealth as a substitute for in-person visits.
- ***Long-term continuous electrocardiographic (LT-ECG) monitoring devices*** are used to detect cardiac rhythm disorders associated with approximately one-third of the deaths from heart disease, approximately one-fourth of strokes, and the dominant cause of loss of consciousness associated with heart disease resulting in fractures and accidents in the elderly. LT-ECG monitors, because of their engineering, software, and practical wearability allow long-term recordings of up to 14 days, an important factor in detecting cardiac rhythm disorders. LTC-ECG has been evaluated in over 35 peer-reviewed published articles^{viii} to have significant diagnostic sensitivity and direct impact on care management for patients with known or suspected arrhythmias.^{ix} Critically, during the pandemic, LT-ECG has enabled care with telemedicine. Clinicians have been able to receive,



prescribe, and review LT-ECG data generated by patients remotely. This has enabled continuous, appropriate diagnosis and care for those at risk. LT-ECG technology faces significant Medicare reimbursement challenges because CMS has left to Medicare Administrative Contractors (MACs) the responsibility of setting payment rates. These rates have failed to recognize the total costs of providing LT-ECG services to Medicare beneficiaries, as determined by a KPMG cost analysis commissioned by AdvaMed.

- **Chronic respiratory disease and cloud-connected medical devices** have transformed care for people with sleep apnea, chronic obstructive pulmonary disease (COPD), and other chronic diseases. Respiratory devices that incorporate fully integrated cloud-based technologies capture real-time physiological data, aiding physicians in providing targeted patient care and enable coordination between the patient's home and providers. The cloud-connected devices have also been shown to increase patient adherence to use of the devices.^x However, low payment rates for chronic respiratory devices under Medicare's Competitive Bidding Program create disincentives for developers of these technologies to continue to innovate with new patient-facing digital features that will improve patient outcomes. Medicare has also failed through its coding process for new technologies to recognize the extra value cloud-based features bring to patients and providers alike.
- **Prescription digital therapeutics (PDTs)** are a new therapeutic class that uses software to directly treat a wide-range of serious diseases and conditions, such as substance use and opioid use disorders, attention-deficit hyperactivity disorders, insomnia, major depression, diabetes, cancer, and stroke under a care model where patients receive treatment in their homes. PDTs are cleared, approved, or de novo authorized by FDA after demonstrating safety and efficacy in randomized clinical trials and a clinician prescribes the PDT for patient use. Unlike a physician's office, patients have 24/7 access to care during critical moments when they are in their homes. By way of example, patients interact with treatment modules that deliver cognitive behavior therapy, contingency management, and fluency training to reinforce proficiency during use of a PDT for substance use disorder. Studies have shown that PDT use results in better patient outcomes, which have been associated reduced emergency room visits and hospitalization, and lower costs.^{xi} Medicare, however, has yet to find a coverage and payment pathway for PDTs under any of its benefit categories.

Barriers to Use of Digital Health Technologies in Community-Based Settings. Digital technologies are opening new frontiers in diagnosis, health care delivery, and health management of patient conditions they are designed to treat, but Medicare regulatory barriers like those mentioned above for specific digital technologies limit the scope and breadth of patient and provider use of the technologies. Medicare statute does not directly address coverage of digital health technologies; nor does the statute specifically limit or prohibit coverage of digital health technologies within the program's benefit categories. The Medicare statute was written, and Medicare regulations and other coverage and payment policies, were implemented long before digital health technologies played the major role they are assuming today. Without clear and explicit pathways to coverage and reimbursement defined in regulatory policies, Medicare regulations create barriers to deployment and use of digital technologies by patients and providers. As AdvaMed's report, *Modernizing Medicare's Coverage of Digital Health Technologies*, argues, updating program regulations and other policies is necessary to accommodate digital advances in medical technologies that improve the standard of care and patient engagement. AdvaMed acknowledges CMS's recognition of this need by establishing new codes that allow Medicare to pay for remote physiologic and remote therapeutic monitoring and approving a New Technology Add-On Payment (NTAP) application that use AI with a CT scan technology to assist physicians in diagnosing a stroke in patients hours earlier than a CT scan alone.




It is, however, the pace at which CMS is accommodating and recognizing the need for changes in coding, coverage, and payment policies for digital technologies that needs to be accelerated. Furthermore, given the importance of Medicare in the health care marketplace, CMS and policymakers in Congress must take a leadership role in coordinating and collaborating with a wide range of stakeholders to ensure that the health benefits of digital technologies are available to all the patients who might benefit from them regardless of insurance status—including Medicaid patients and those with private insurance. AdvaMed’s report with its specific recommendations for updating Medicare’s regulatory framework can be found [here](#).

Trends from the Pandemic in Use of Digital Health Technologies. The waivers authorized by Congress and implemented by the Centers for Medicare & Medicaid Services at the onset of the pandemic have dramatically changed our understanding and assumptions about the nature of health care services delivery and expanded our perspectives on the appropriateness of serving patients in the community and their homes. The waivers were applied across provisions of Medicare and Medicaid statutes, regulations, and other national and local coverage and payment policies. They have provided expanded access to telehealth and other communication technology-based services, such as remote patient monitoring and diagnostic testing. We are concerned that an end to the public health emergency (PHE) will result in a return to the constraints of the statute and underlying CMS regulatory policies without a systematic evaluation of the impact, both positive and negative, that the flexibilities have had on expanding access to care in the community—including impact on disparities in care for minority groups and vulnerable populations. These evaluations should be undertaken immediately.

Health Equity in Community-Based Care. Digital technologies have the potential to assist in the management of chronic and other health conditions and could be instrumental in resolving disparate health outcomes—including those linked to lack of access to care facilities, lack of specialist access, transportation concerns, etc. Digital technologies have the potential, as we have seen during the PHE, to allow patients to continue to engage in regular monitoring and care for various conditions. This access should be continued post-PHE but should also be broadened beyond telehealth statutory restrictions and include more extensive monitoring and management of various chronic and other health conditions. Digital technologies, particularly if used in underserved communities with shortages of clinicians and other providers, could make a meaningful difference in the ability of patients to remain healthy and to seek routine care from the clinical professionals and in the facilities in their immediate communities. This can only happen if federal, state, and private insurance plans cover and ensure appropriate reimbursement for these services. We also emphasize the need to ensure infrastructure capabilities including broadband access, high speed internet, and sufficient data plans to facilitate use of these technologies by patients and recognize that the Infrastructure Investment and Jobs Act, will begin to assist with these needs.

We appreciate this opportunity to bring to your attention issues of great importance to our members. If you have any questions, please contact Richard Price in AdvaMed’s Payment and Health Care Delivery Department at rprice@AdvaMed.org.

Sincerely yours,



Richard Price, SVP, Payment & Health Care Delivery Policy and Head of Research
Advanced Medical Technology Association (AdvaMed)



References

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