

MODERNIZING MEDICARE COVERAGE OF DIGITAL HEALTH TECHNOLOGIES

Digital health technologies, such as telehealth, remote patient monitoring, artificial intelligence and other software, can advance health care decision-making and care management — not only for patients, but also for physicians, hospitals, health plans, and providers of community-based services. However, the lack of a systematic approach to coverage and payment has limited beneficiary access to these advancements in care.

A new white paper from the Advanced Medical Technology Association (AdvaMed) and CapView Strategies outlines opportunities for the Centers for Medicare and Medicaid Services (CMS) to use its existing regulatory authority to modernize Medicare regulations on coverage and payment for digital health technologies.

Medicare can modernize its approach to coverage and payment for digital health technologies — and improve and transform care for beneficiaries. The report recommends numerous actions CMS — the largest payer of health care services in the U.S. — can take to reaffirm its leadership role in fostering collaborative efforts across government agencies and health care stakeholders to deploy digital health solutions to improve care and reduce costs. Recommendations are based on primary policy and regulatory research, interviews with digital health manufacturers, and other stakeholders. The report focuses on digital health technologies that facilitate the electronic or mobile collection and analysis of data used to inform health care decision-making or behaviors and to support the provision of care on a remote basis.

The COVID-19 pandemic has highlighted the role of digital health in transforming care delivery and making the health system nimbler and more responsive to changing needs. In response to the pandemic, CMS acted quickly in enacting unprecedented Medicare waivers of statutory and regulatory obstacles to care. In particular, the increased flexibility in the use of telehealth and remote monitoring technologies have facilitated patient access to critically needed care. The speed with which digital communications platforms were used to deliver care via telehealth underscores how these technologies can build a more nimble, resilient health care system. Their role in maintaining and enhancing beneficiary access to care highlights the importance of CMS further evaluating digital health technologies to deliver patient-focused, community-based care.

Coverage and payment for digital health technologies can be modernized through existing pathways. The white paper identifies key issues and opportunities for digital health technology coverage and payment within major pathways in the Medicare program, including Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); the Physician Fee Schedule; the Inpatient and Outpatient Prospective Payment Systems; Home Health Agency and Skilled Nursing Facility payment systems, as well as payments to end-stage renal disease facilities (ESRD) and Medicare Advantage plans. Importantly, the report makes recommendations to accommodate these technologies across settings and users.

Recommendations focus on recognizing the value of innovative software and applications, expanding the use of remote patient monitoring and other digital communications between patients and providers, and better linking approval and clearance of innovative and breakthrough technologies by FDA with Medicare coverage processes.

- In areas where technologies could be covered directly, such as in **home and community settings**, recommendations are made to cover digital health technologies under the durable medical equipment (DME) benefit category as well as prosthetics, orthotics and their corresponding supplies. These recommendations address improving coverage of software under these categories as well as speeding coverage of devices that have achieved FDA's breakthrough designation.
- For technologies that may be indirectly covered as allowable costs within **physician, hospital inpatient and outpatient, end-stage renal disease facilities, and in post-acute care settings**, recommendations are made to update assessments of costs, review coding processes, and to better address alignment between FDA clearance and CMS coverage and payment determination processes.
- In **alternative payment models**, recommendations are made to better align incentives for the use of cost-saving technologies and for CMS to test new payment and delivery models integrating digital health technologies into model design.
- In **Medicare Advantage**, recommendations focus on encouraging the use of flexibilities health plans have in expanding access to digital health technologies.

CMS can move forward with these recommendations under current law — without changes to Medicare's statute — to realize the game-changing potential of digital health technologies across health care. In addition, the white paper recommends that:

- CMS should review all Medicare regulations, policy guidance, and program manual instructions to determine which changes should be made to accommodate digital health technologies.
- CMS should apply and expand the lessons learned from the increased coverage and use of digital health technologies under the COVID-19 public health emergency waivers.
- HHS should establish an Inter-agency Task Force to explore policies to improve access to and coverage of digital health technologies, including coordination across federal and state agencies.
- HHS should create a Public-Private Consortium to support the use and diffusion of digital health technologies.