

Alert | Digital Health



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CMS and FDA Unveil a Digital Health Pilot for Chronic Conditions

Medicare program's existing statutory framework and reimbursement policies long-predicate digital health technologies, including digital therapeutics, remote patient monitoring (RPM), and wearables, and in many cases have presented a lack of payment options for Medicare beneficiaries to access novel technology-enabled care.

The Centers for Medicare and Medicaid Services (CMS) recently announced the **Advancing Chronic Care with Effective, Scalable Solutions (ACCESS)** model, which is an outcome-aligned payment approach designed to expand access to technology-supported care for people with certain chronic conditions. The ACCESS program also reflects the movement from the current fee-for-service payment model to value-based payment models, which reimburse providers and services based on outcomes.

In connection with the ACCESS model, the U.S. Food and Drug Administration (FDA) announced the Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot, aimed at permitting use of certain digital health devices under the ACCESS model prior to the FDA's premarket authorization through agency enforcement discretion.

Additionally, HHS is currently **seeking public comment** for actions it can take to accelerate the adoption and use of AI as part of clinical care.

CMS ACCESS Model

The ACCESS model focuses on clinical improvement or control of specific chronic conditions based on each patient's starting point and will allow for patient care to be provided through in-person, virtual, asynchronous, or other technology-enabled methods that are deemed clinically appropriate. The participating organizations will receive Outcome Aligned Payments (OAPs) for managing patients' qualifying conditions, with full payment tied to achieving measurable health outcomes (OAP Measures). CMS will base payment on the overall share of an organization's patients who meet their targets; therefore, organizations may earn full payment through strong overall performance, even if some patients do not meet their targets.

CMS intends to issue new track-specific G-Codes for monthly claim submission but has indicated that ACCESS participants and their affiliated entities may not submit Medicare fee-for-service claims (directly, or indirectly through another organization for which they provide contracted services) for those patients enrolled under the ACCESS model during the performance period. To what extent this restriction may deter or limit the type of ACCESS participants remains uncertain at this stage.

ACCESS will focus on four chronic condition tracks:

1. Early cardio-kidney-metabolic conditions (eCKM): high blood pressure, dyslipidemia, obesity, and prediabetes;
2. Cardio-kidney-metabolic conditions (CKM): diabetes, chronic kidney disease, and atherosclerotic cardiovascular disease (including heart disease);
3. Musculoskeletal conditions (MSK): chronic musculoskeletal pain; and
4. Behavioral health conditions (BH): depression and anxiety.

To participate, **organizations must be enrolled in** Medicare Part B and designate a clinical director responsible for care quality and compliance. However, durable medical equipment (DME) suppliers and clinical laboratories are excluded from participation. To be considered for the model's first performance period, which begins July 1, 2026, organizations must submit applications by April 1, 2026. Applications received after this date **will be considered** for a Jan. 1, 2027, start. Relevant stakeholders may submit an **ACCESS Model Interest Form** to be notified when the application becomes available.

FDA TEMPO Pilot

The TEMPO pilot will permit manufacturers to offer digital health devices to be used by participating organizations under the ACCESS model pursuant to the agency's enforcement discretion of certain applicable requirements (e.g., premarket authorization requirements, investigational device exemption requirements, and requirements under 21 CFR Parts 50 and 56). This pilot is **intended to help the FDA and CMS better understand** how digital health technologies perform in real-life settings and how they may improve care for people living with chronic diseases.

The FDA plans to limit participation in the TEMPO pilot and currently expects to select up to 10 manufacturers based in the United States in each of the four clinical use areas identified in the ACCESS model (eCKM, CKM, MSK, and BH).

The FDA will collect statements of interest for participation in the TEMPO pilot beginning around Jan. 2, 2026, and will follow up with certain potential pilot participants to request additional information beginning around March 2, 2026. To request participation in the TEMPO pilot, a manufacturer should

consider **emailing the FDA** and identifying the manufacturer and the manufacturer's device, including any current authorizations or prior FDA interactions related to the device. The correspondence may also need to include both a proposed indications for use statement identifying the intended use to improve patient outcomes in a clinical use area consistent with participation in the ACCESS model and a request that the FDA give the manufacturer a statement that the FDA does not intend to enforce certain legal requirements.

HHS Public Comments

The HHS is seeking public comments on the actions it can take to establish an approach to accelerate the adoption and use of AI as part of clinical care. Specifically, HHS is looking for comments to develop three areas:

1. **Regulations:** Seeking feedback on how current HHS regulations impact AI adoption and use for clinical care.
2. **Reimbursement Policies:** Seeking feedback on payment policy changes that ensure payers have the incentive and ability to promote access to high-value AI clinical interventions, foster competition among clinical care AI tool builders, and accelerate access to and affordability of AI tools for clinical care.
3. **Research and Development:** Seeking feedback on ways in which HHS can invest in research and development to integrate AI in care delivery and create new, long-term market opportunities.

In addition to the general requests for information on research, reimbursement policies, and research and development, HHS seeks input on 10 specific **questions** related to digital healthcare systems.

Organizations and individuals may submit their comments until Feb. 23, 2026, through the Federal eRulemaking portal, regular, express, or overnight mail, or hand delivery.

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