Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

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- Announced by the FDA's Center for Devices and Radiological Health on December 8, 2025
  - www.regulations.gov/document/FDA-2025-N-6461-0001
- FDA began collecting statements of interest for participation in the TEMPO pilot as of January 2, 2026.

Learning Objectives

- Explain the goals of the TEMPO pilot
- Describe features of the TEMPO pilot
- Summarize information to include in the statement of interest for participation in the TEMPO pilot
- Discuss the selection process for participation in the TEMPO pilot

Goals of the TEMPO Pilot

- Launched in connection with the Center for Medicare and Medicaid Innovation (CMMI) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model
- The TEMPO pilot aims to:
  - Promote access to certain digital health devices while safeguarding patient safety
  - Evaluate a risk-based enforcement approach that supports digital health devices intended to improve patient outcomes in certain conditions
  - Responsibly encourage innovation while collecting real-world evidence to better understand how these devices perform in real-life settings

TEMPO Pilot Features

CMMI ACCESS Model

- Through the CMMI ACCESS model, the Centers for Medicare and Medicaid Services (CMS) will test a new payment option that emphasizes patient outcomes, enabling clinicians to offer innovative technology-supported care to improve patients' health and prevent and manage chronic disease.
- The CMMI ACCESS model introduces Outcome-Aligned Payments, which are recurring payments for managing a patient's qualifying condition, with payment tied to achieving measurable health outcomes.
- CMS has designed the CMMI ACCESS model to include several safeguards to support clinical quality and accountability; under the CMMI ACCESS model, CMS will monitor performance and may terminate organizations who fail to meet quality, safety, or outcome standards, and will publish risk-adjusted outcomes in a public directory.

CMS, "ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model," available at www.cms.gov/priorities/innovation/innovation-models/access (last accessed on December 1, 2025).

What is the TEMPO Pilot?

- In general, if a manufacturer wishes to offer its device for an intended use to improve patient outcomes, the device must, among other things, be authorized by FDA for that use.
- Through the TEMPO pilot, a manufacturer may request that FDA exercise enforcement discretion for certain requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.
- FDA will work with participants to identify the circumstances when enforcement discretion may be appropriate for that manufacturer's device.

FDA Expects TEMPO Pilot Participants will:

- collect real-world data related to the intended uses of their devices to improve patient outcomes while offering the devices for use in providing care covered by the CMMI ACCESS model
- share the data with FDA during participation in the TEMPO pilot
- seek appropriate marketing authorization from FDA using the data collected during their participation in the TEMPO pilot, along with other information

TEMPO Pilot Participation

- FDA will offer and encourage pilot participants to engage in “sprint” discussions with the goal of reaching mutual agreement on a specific topic within a set time period (such as 45 days) that may relate to the planned marketing submission.
  - The number, format, and duration of interactions within a sprint discussion may vary based on project needs.
- Although data collected during participation in the TEMPO pilot are intended to be supportive of a marketing submission to FDA, additional data may also be needed to support a marketing submission.
- Participation in the TEMPO pilot is not an indication of whether FDA will issue a positive decision for a future marketing submission.

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Statement of Interest

What to Include in a Statement of Interest

To request to participate in the TEMPO pilot

- Contact FDA at FDA-TEMPOPilot@fda.hhs.gov
- Title the communication “Statement of Interest for Participation in the TEMPO Pilot”
- Identify the manufacturer and their device, including any current authorizations or prior FDA interactions (e.g., relevant submission numbers) related to the device
- Include a proposed indications for use statement identifying the intended use to improve patient outcomes in a clinical use area consistent with participation in CMMI ACCESS program
- Include a request that FDA give the manufacturer a statement that FDA does not intend to enforce certain legal requirements (e.g., a statement that FDA does not intend to enforce premarket authorization requirements, IDE requirements, and requirements under 21 CFR parts 50 and 56)

TEMPO Pilot Selection Process

TEMPO Pilot Participants

FDA plans to initially limit participation since this is a pilot.

- Intend to select up to about 10 U.S.-based manufacturers in each of the 4 clinical use areas described in the ACCESS model
- A broad representation of manufacturers of all sizes, types, and maturities is desired

TEMPO Pilot is Intended for Digital Health Devices

In selecting participants, FDA intends to evaluate whether

- Devices would **not** present potential serious risk to health, safety, or welfare of patients
- Products meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act, and are intended to be used in conjunction with clinician-supervised outpatient treatment for certain conditions in one of the four CMMI ACCESS clinical use areas:
  - early cardio-kidney-metabolic
  - cardio-kidney-metabolic
  - musculoskeletal
  - behavioral health
- Digital health devices may rely on off-the-shelf platforms such as general-purpose computing platforms or wearable products (that may or may not be regulated wearable devices).

Key Dates

- **January 2, 2026:** FDA began collecting statements of interest for participation in the TEMPO pilot.
- **Around March 2, 2026:** FDA will begin sending follow up requests to certain potential pilot participants who reflect a broad spectrum of manufacturers to request additional information to help enable FDA to make a decision concerning participation.

Additional Information Requests

The types of information that would be helpful to submit may vary depending on the specific device, but we believe the following general types of information may be helpful:

1. A device description, including proposed indications for use and proposed claims clearly describing the intended use to improve patient outcomes for which the manufacturer wishes to offer the device in connection with the CMMI ACCESS model
2. Data to demonstrate the device is adequately safe and can function as designed, and to support a reasonable expectation that the device could provide patient benefit (e.g., a bibliography and copies of publications and a summary of unpublished information relevant to an evaluation of the safety of the device, and to justifying a reasonable expectation that the device could provide patient benefit)
3. Information about the manufacturer's quality management system
4. A plan that sufficiently mitigates risks to patients and provides for the collection, monitoring, analysis, and reporting of real-world performance data
5. Proposed performance goals and a statistical analysis plan for patient outcomes
6. A proposed timeline for data collection and submission to FDA of a premarket notification (510(k)) or other type of marketing submission (as applicable) for the device for the intended use for which the manufacturer offers the device in connection with the CMMI ACCESS model
7. A proposed interim reporting plan, including frequency (such as every 6 months), to report (for example) adverse events, new risks, and progress with respect to timelines

Resources

Slide Number	Cited Resource	URL
3	Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot	www.regulations.gov/document/FDA-2025-N-6461-0001
7	CMS ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model	www.cms.gov/priorities/innovation/innovation-models/access
16	Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321(h))	USCODE-2024-title21-chap9-subchapII-sec321.pdf

Summary

- The TEMPO pilot aims to promote access to certain digital health devices while safeguarding patient safety.
- The TEMPO pilot supports the CMMI ACCESS Model, which aims to increase beneficiary access to technology-enabled, integrated care.
- Through the pilot, manufacturers may request that FDA exercise enforcement discretion for certain requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.
- TEMPO pilot participants are expected to collect real-world data demonstrating the digital health device's performance and share the data with FDA.
- FDA expects to select up to about 10 U.S.-based manufacturers in each of the four clinical use areas and to have broad representation of manufacturers of all sizes, types, and maturities.


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Frequently Asked Questions

Is there a submission deadline for statements of interest?

- There is no specified deadline for when FDA will stop accepting statements of interest for participation in the TEMPO pilot. FDA encourages manufacturers to submit their statements of interest before March 2, 2026.
- However, as the TEMPO pilot is a pilot, FDA plans to limit participation, and currently expects to select up to about ten manufacturers based in the United States in each of the four clinical use areas identified for the TEMPO pilot. FDA began accepting statements of interest on January 2, 2026, and expects to begin sending follow-up requests around March 2, 2026, to certain potential pilot participants who reflect a broad spectrum of manufacturers.

What are the eligibility requirements for manufacturers?

- Manufacturers must be based in the United States.
- FDA will select manufacturers of digital health devices that
  - meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))
  - are intended to be used in conjunction with clinician-supervised outpatient treatment to patients with conditions in one of the four CMMI ACCESS clinical use areas
  - do not present potential for serious risk to patient health, safety, or welfare
  - have an intended use to improve patient outcomes consistent with the CMMI ACCESS program

Are devices that are already FDA-cleared eligible for the TEMPO Pilot?

- Manufacturers of certain digital health devices that are **not already authorized by FDA for an intended use to improve patient outcomes in one of the four CMMI ACCESS clinical use areas** (early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health) may request to participate in the TEMPO pilot.

Is CMMI ACCESS participation required for TEMPO?

- Through the TEMPO pilot, a manufacturer may request that FDA exercise enforcement discretion and not enforce certain applicable requirements when their device is offered to or by CMMI ACCESS participants for an intended use to improve patient outcomes, to be used in providing care expected to be covered by the CMMI ACCESS model.
- This may include, for example, when the manufacturer is itself a participating organization under the CMMI ACCESS model, or when the manufacturer offers the device to other entities that are participants under the CMMI ACCESS model for an intended use to improve patient outcomes.

Will devices in the TEMPO Pilot be expected to receive FDA authorization?

- Although FDA may exercise enforcement discretion and not enforce premarket authorization requirements for a device while participating in the pilot, FDA expects manufacturers participating in the pilot to ultimately seek appropriate marketing authorization from FDA, using the data collected during their participation in the pilot (along with additional information to support a marketing submission). FDA expects to discuss proposed timelines for submission of a 510(k) or other type of marketing submission with participants.

Final Thoughts

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- Manufacturers should endeavor to submit their statements of interest for participation in the TEMPO pilot before March 2, 2026.
- Manufacturers should send their questions about the TEMPO pilot to FDA-TEMPOPilot@fda.hhs.gov
- We are currently developing a TEMPO FAQ webpage and will provide more information once it's available.

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1-800-638-2041 or (301) 796-7100 (9 am – 12:30 pm; 1 – 4:30 pm ET)


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