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Will TEMPO Accelerate Your Market ACCESS and Reimbursement? FDA's New Pilot Program Offers Enforcement Discretion for Certain Digital Health Technologies

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In a move aimed at tying reimbursement to patient outcomes, the Centers for Medicare & Medicaid Services (CMS) Innovation Center announced the "Advancing Chronic Care with Effective Scalable Solutions" (ACCESS) model, a 10-year demonstration project that will begin in April 2026. Unlike traditional fee-for-service structures that reward activities, ACCESS will offer participating organizations reimbursement based on whether patients achieve defined health goals – rather than on the volume of services provided. The potential to receive reimbursement for technology-enabled services via ACCESS could be a boon for telehealth and disease management companies, especially those aimed at chronic conditions, such as obesity, diabetes, chronic musculoskeletal pain and depression, that may use technology-enabled services to complement traditional care pathways.

On December 8, 2025, the Food and Drug Administration (FDA) unveiled its companion pilot program, "Technology-Enabled Meaningful Patient Outcomes" (TEMPO), which seeks to "encourage the use of digital technologies that meet people where they are." TEMPO is a voluntary program that would enable up to 40 companies (approximately 10 for each of four program areas, namely, early cardio-kidney-metabolic conditions, cardio-kidney-metabolic conditions, musculoskeletal pain and behavioral health) to opt in to FDA's risk-based program whereby FDA would exercise enforcement discretion with respect to certain requirements for sponsors in the program, such as premarket review requirements, before commercialization. In exchange, those enrolled in TEMPO will collect, monitor and report to FDA real-world data for how these technologies perform in practice.

Participation in TEMPO requires an initial simple step. Interested parties need to submit only a "Statement of Interest" as early as January 2, 2026, that:

1. Identifies the manufacturer and its device, including any current authorizations or prior FDA interactions related to the device or proposed indications for use.
2. Requests from FDA a statement that FDA does not intend to enforce certain legal requirements, such as premarket authorization requirements, Investigational Use Device (IDE) requirements, and requirements under 21 CFR Parts 50 and 56.

In addition, the digital health devices in the TEMPO pilot must pose no serious risk to patients and be intended for clinician-supervised outpatient use. If selected, participants are expected to submit a much more detailed package to the agency in March 2026 that includes information such as device descriptions, safety data, quality management systems, risk mitigation plans, performance goals, timelines for marketing submissions and interim reporting strategies. Selected participants can also engage in "sprint" discussions with FDA to resolve specific issues within defined time frames. Importantly, participation in TEMPO does not guarantee future marketing authorization, though data generated during the pilot may support subsequent submissions.

The process for applying to ACCESS is also simple. Similar to the FDA process, to participate in ACCESS, an organization must first complete a nonbinding ACCESS Model Interest Form, followed by a full application. Although the application form has not yet been released, for the performance period beginning July 1, 2026, applications will be due by April 1, 2026.

Participation in ACCESS also requires Medicare Part B enrollment and a designated medical director to oversee care quality and compliance with applicable federal and state regulations, including licensure, Health Insurance Portability and Accountability Act (HIPAA) and privacy security, and FDA requirements. This last regulatory requirement is where ACCESS and TEMPO are meant to work together. Through TEMPO, sponsors of technology-enabled healthcare products may be able to offer their technology under the TEMPO program's

enforcement discretion policies to participants in the ACCESS model, which may be eligible to receive reimbursement for those technology-enabled services through ACCESS.

Key considerations before applying to ACCESS and TEMPO

Potential applicants should keep in mind that applying to one program does not require application to the other, though FDA stated that it expects TEMPO participants' devices to be offered to or by ACCESS participants. Therefore, when considering whether to apply to TEMPO and/or ACCESS, companies should consider the benefits of each separately and together. For digital health entities, such considerations often begin with understanding the product roadmap and overall regulatory framework for various software or functions and digital health tools. ACCESS may also present benefits for provider groups not currently engaged in remote patient monitoring, but which can now consider whether use of digital health tools could qualify for reimbursement through ACCESS.

Particularly for new and emerging companies, the ability to commercialize digital health technologies without having to wait for FDA marketing authorization is a huge incentive for applying to TEMPO. That said, entities should not rush to participate in the program without first considering some key questions, such as:

1. Is your digital health technology a medical device under the Federal Food, Drug, and Cosmetic Act, 21 USC 321(h)(1), or is it not a medical device under the carve outs to that definition created by the 21st Century Cures Act?
2. What is your plan and market positioning for your digital health technology? How are your competitors marketed? Are they medical devices or medical devices that are already subject to FDA's current enforcement discretion policies concerning "wellness products"?
3. Have you already engaged with FDA through submission of a 513(g) request or pre-submission meetings? If so, have you aligned with the agency on a regulatory approach for your product?
4. Do you have FDA's marketing authorization for any of your products? Do you have plans to modify your product with artificial intelligence or other technological enhancements? Are you looking to expand your indications to include one of the areas covered by ACCESS and TEMPO?
5. Are you looking to achieve enhanced reimbursement for your digital health technology?

Similarly, when considering whether to apply to ACCESS, companies should first think through their commercialization strategy, which builds from the above questions. For example, potential ACCESS applicants should consider the following before applying:

- Are you positioned to enroll directly in the Medicare program, or will you need to work via healthcare provider partners to offer your technology through ACCESS?
- Is your product otherwise eligible for reimbursement outside of the ACCESS program? For instance, is your digital health technology reasonable and necessary to deliver services already recognized under care management or remote patient monitoring codes?
- Are there features of your product or new products you are developing in areas that Medicare has not traditionally reimbursed, such as general wellness?

Cooley's life sciences and healthcare regulatory team closely monitors these new programs and actively works with clients to think through these and related strategic regulatory questions. We are available to discuss the implications of these programs for your organization and advise on FDA requirements and healthcare compliance more generally. For assistance, please contact the authors listed below.

Cooley associate Regina DeSantis and law clerk Laura Wenzel also contributed to this alert.

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