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FDA's TEMPO Pilot Seeks to Expand Access to Chronic Disease Technologies in CMS Collaboration

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On December 5, 2025, FDA announced its Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot, a new voluntary pilot that seeks to accelerate innovation and expand access to digital health devices for people living with chronic conditions. Under TEMPO, FDA will evaluate a new, risk-based enforcement approach that supports digital health devices intended for use to improve patient outcomes in cardio-kidney-metabolic, musculoskeletal and behavioral health conditions. Under the pilot, participating manufacturers may request that the agency exercise enforcement discretion for certain requirements, such as premarket authorization and investigational device requirements, while manufacturers collect and share real-world data demonstrating the device's performance.

FDA's TEMPO pilot was announced in connection with CMS's new Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, which focuses on expanding access to new technology-enabled care for chronic diseases, and this collaboration is a key feature of TEMPO. With TEMPO, FDA is also seeking to build on its Home as a Health Care Hub Initiative, which has been a key focus of the Center for Devices and Radiological Health under Dr. Tarver.

U.S. manufacturers may begin submitting statements of interest for participation in the TEMPO pilot starting in January 2026. FDA intends to select up to ten manufacturers based in the United States for participation in each of the four ACCESS clinical focus areas: early cardio-kidney-metabolic (hypertension, dyslipidemia, obesity or overweight with marker of

central obesity, or prediabetes), cardio-kidney-metabolic (diabetes, chronic kidney disease, or atherosclerotic cardiovascular disease), musculoskeletal (chronic musculoskeletal pain), or behavioral health (depression or anxiety). In weighing participation, manufacturers will need to keep in mind the risks of going to market under enforcement discretion, without marketing authorization.

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