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The CMS ACCESS Model and FDA TEMPO Pilot: Outcome-Based Payments and Digital Health Innovation

April 7, 2026
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The Centers for Medicare & Medicaid Services' ("CMS") Advancing Chronic Care with Effective, Scalable Solutions ("ACCESS") Model is a Center for Medicare and Medicaid Innovation ("CMMI") initiative testing outcome-aligned payments ("OAP") tied to measurable improvements in clinical and patient-reported outcomes for Medicare Part B providers. The Food & Drug Administration's ("FDA") Technology-Enabled Meaningful Patient Outcomes ("TEMPO") pilot program is aligned with and runs concurrently with ACCESS, creating a digital-health technology for Medicare and supporting the introduction of new digital-health technologies so they can be used to support the measurable outcomes for ACCESS. It is important to note that although technology is a crucial component of these models, care delivery remains the core of the model, with digital tools positioned as enablers rather than substitutes.

All ACCESS participants must be Medicare Part B enrolled and in good standing, with no flexibility on this requirement. Participants must also designate a Medicare-enrolled medical director responsible for clinical oversight and patient safety. For many digital-health companies, enrolling as a Medicare provider or supplier could represent a significant shift in compliance requirements, including a commitment to ongoing compliance with state and federal laws, as well as heightened fraud, waste, and abuse risks associated with federal healthcare programs. It is likely that CMS may favor ACCESS applicants with prior patient volume, including Medicare-eligible populations, and geographic reach, particularly those that demonstrate operational readiness and the ability to scale.

Participation in ACCESS requires full accountability across clinical tracks and comorbidities. Those organizations which participate must be able to manage all conditions within each selected track and report required clinical data, emphasizing "whole person care" and guideline-based management to account for the fact that many chronic conditions are comorbid and occur in the same beneficiary. Participants must also be able to escalate care when necessary, which CMS frames as a patient-safety feature of the model.

ACCESS's payment structure introduces substantive downside risk and favors financially stable organizations by providing quarterly, per-beneficiary payments during a 12-month care delivery period, but only 50% of the OAP is paid upfront. The remaining 50% is withheld and subject to reconciliation. During the reconciliation period, CMS will apply a downward adjustment to the withheld amount based on the larger of:

- Clinical-outcomes performance (up to a 50% reduction of the full OAP), or
- Substitute-spend impacts (up to a 25% reduction of the full OAP).

This structure allows CMS to support care delivery with predictable payments while maintaining accountability for outcomes

and spending. Due to the payment structure, CMS is likely to favor applicants that can absorb the associated financial risk.

Under TEMPO, manufacturers may request temporary FDA enforcement discretion for certain regulatory requirements when devices are used in ACCESS, which could allow some digital-health devices to be used within the model prior to full FDA authorization. The FDA is contemplating discretion related to premarket authorization and certain investigational device exemption, informed consent, or institutional review board requirements, but has not indicated that such discretion would extend to core device controls such as quality-system or adverse-event reporting obligations. Manufacturers may email the FDA to express interest, identify their device's current regulatory status, and specify which requirements from which they are seeking relief.

Participation is limited to 10 United States-based manufacturers per clinical track and is only available to manufacturers with devices in the four clinical access areas. Manufacturers must collect and share real-world data with the FDA during the pilot.