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CMS Innovation Center Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model Summary

In early December, 2025, the Center for Medicare and Medicaid Innovation (CMMI, aka, Innovation Center) at the Centers for Medicare & Medicaid Services (CMS) announced a new model – Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) – which is a national, voluntary, 10-year alternative payment model (APM) designed to test whether outcome-based payments for technology-enabled chronic care reduces expenditures while preserving or enhancing quality of care for Medicare fee-for-service (FFS) beneficiaries.[1] In connection with the ACCESS model, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) announced its Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot to promote access to certain digital health devices while safeguarding patient safety.[2] The Request for Application[3] for the ACCESS model was subsequently published on December 19, 2025 on the Innovation Center website and the application window opened on January 12, 2026.

Introduction to the CMS Innovation Center

CMMI is one of several centers within CMS in the Department of Health and Human Services (HHS). CMMI was established under the Affordable Care Act[4] in order to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to beneficiaries of those programs.

The Innovation Center has broad discretion for model design. CMMI models are alternative payment models (APMs) which reward health care providers for delivering high quality and cost-efficient care. The models can focus on a specific health condition (such as end stage renal disease), a care episode (such as joint replacement), provider type (such as primary care physicians), community (such as rural areas), or innovation within a Medicare, Medicaid, or CHIP program (such as Medicare Advantage or Part D plans).[5]

CMMI models are time-limited and the Innovation Center solicits and selects model participants through open competition.[6] CMMI is also required to monitor and evaluate the results of each model, specifically, the quality of care and changes in spending in each model. As a result, requirements are built into each model that facilitate the collection of information that is necessary for both monitoring and evaluation of the model. The duration and scope of a model may be considered for expansion through rulemaking if the expansion is expected to reduce

[1] Modernizing America's Care for Better Health, HHS-CMS event, December 4, 2025. The event may be viewed at: https://www.youtube.com/watch?v=vM1guSugkQU
[2] Federal Register :: Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot
[3] The Innovation Center Request for Application can be found at: Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model
[4] The Affordable Care Act established CMMI under section 1115A of the Social Security Act.
[5] About the CMS Innovation Center | CMS
[6] *Ibid*

spending without reducing quality of care or improve the quality of patient care without increasing spending.

As of late 2025, the Innovation Center was testing or evaluating 24 models and had announced another twelve, including the ACCESS model, many of which align with the current Administration's Make America Health Again (MAHA) priorities. An additional 66 models are inactive or withdrawn and only one (the Home Health Value-Base Purchasing Model) authorized for expansion.[7]

ACCESS Model Overview and Authority

According to the ACCESS model Request for Applications (RFA), the ACCESS model will test whether an alternative payment methodology—Outcome-Aligned Payments (OAPs)—for technology-enabled chronic care reduces expenditures while preserving or enhancing quality of care for Medicare FFS beneficiaries. It is designed to expand choice for patients and clinicians by offering a new payment option that removes payment barriers to technology-enabled care, while maintaining accountability for clinical and patient reported outcomes. CMS expects the model to reduce Medicare expenditures by enabling efficient care that achieves improved clinical outcomes and prevents avoidable utilization.[8]

The model will be offered in all 50 States, territories and the District of Columbia. It is scheduled to run for 10 years, with applications accepted on a rolling basis until April 2033. Under the model, eligible ACCESS Participants will be responsible for enrolling Medicare FFS beneficiaries who have certain qualifying healthcare conditions and billing Medicare for actively managing the beneficiaries' chronic conditions across a wide range of technology-enabled modalities, and will receive fixed, per-patient quarterly payments for doing so. ACCESS Participants will routinely collect and report CMS-specified track-specific outcomes measures data over the course of a 12-month care period. CMS will evaluate ACCESS model data semi-annually and determine whether an ACCESS Participant has qualified for full payment for the beneficiaries that have completed their 12-month care period.

Referring clinicians and clinicians who co-manage beneficiaries with an ACCESS Participant may qualify for a co-management service payment for care coordination activities and documentation and review of clinical updates that ACCESS Participants are required to provide them.

To implement this model, the Innovation Center will leverage its section 1115A waiver authority to:

- Waive requirements of section 1848(q) of the Social Security Act (SSA) (e.g., MIPS eligibility, reporting, and payment adjustments) and section 1833(a)(1) of the SSA (e.g., the amounts paid under Medicare Part B for services payable under that part).[9]
- Provide alternative payments outside the Medicare FFS structure.

[7] Innovation Models | CMS

[8] Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model

[9] The RFA is not entirely clear or consistent on CMMI intends to leverage its waiver authority with respect to MIPS.

- Allow CMS to pay 100 percent of the reasonable charge of certain services for Co-Management Payments.
- Withhold payment based on outcome performance.
- Apply payment adjustments without complex reconciliation.
- Support access and integration through specific waivers and safe harbors, including benefit enhancements, and program waivers as needed to provide for alternate payment mechanisms, allow for services to be provided via telehealth, asynchronously, and/or directly through the applicable technology.

CMS also intends to offer the CMS-sponsored model patient incentive safe harbor (42 CFR 1001.952(ii)(2)) to ACCESS Participants who wish to forego collection of beneficiary cost-sharing for OAPs as a beneficiary engagement incentive.

Duration, Timing, and Application

The ACCESS model is scheduled to run 10 years from July 2026 through June 2036. The application period is now open (as of January 12, 2026), and CMMI is accepting applications for the first cohort of participants until April 1 for the July 2026 start date. The next application period will close October 1, 2026 for the January 1, 2027 start date. CMMI expects to continue accepting applications on a rolling basis with quarterly start dates. The last application deadline will be April 1, 2033 for a July 2033 start date. The model is scheduled to end June 30, 2036.

Applications must be submitted through an online portal[10] on the ACCESS model website. A sample application can be found in the online RFA. If CMS staff have questions about the application information, they may contact applicant for clarification. If selected for participation, the organization would execute a Participation Agreement with CMS.
An ACCESS Participant may terminate its participation with advance written notice to CMS, at least 180 days prior to the effective date of termination. Until the effective date of termination, the ACCESS Participant must continue to provide model services to aligned beneficiaries and may not accept the voluntary alignment of new beneficiaries. The ACCESS Participant must also notify its aligned beneficiaries of its withdrawal and refer beneficiaries to suitable health care providers as appropriate to ensure continuity of care for the remainder of the care period.

Participant and Beneficiary Eligibility and Enrollment[11]

To be eligible to be an ACCESS Participant, an organization must have a Medicare enrolled Tax ID (TIN) that is eligible to bill under the Medicare physician fee schedule (PFS).[12] Certain provider and supplier types (even if Medicare enrolled) are excluded from the model, such as DMEPOS and laboratory suppliers. ACCESS Participant organizations must be covered entities

[10] A sample application can be found in Appendix A of the RFA. Applicants must register in order to login and submit an application via the online portal: CMS IDM Login
[11] CMS uses the terms 'alignment' and 'enrollment' interchangeably in the ACCESS model RFA.
[12] Enrollment can be completed online through the CMS Provider Enrollment, Chain, and Ownership System (PECOS). Organizations not already enrolled should first obtain a National Provider Identifier (NPI) through the National Plan and Provider Enumeration System (NPPES) before submitting a Medicare enrollment application.

as defined by the Health Insurance Portability and Accountability Act (HIPAA) and must comply with applicable Federal requirements for protecting beneficiaries' protected health information (PHI).

Participation is defined at the taxpayer identification number (TIN) level, not the individual practitioner level. However, all clinicians furnishing or supervising the care of aligned beneficiaries must be individually Medicare enrolled. As part of its application, the prospective ACCESS Participant must submit and maintain an up-to-date roster of these practitioners. CMS will complete a CMS program integrity screening of each participant, including the list of clinicians, prior to offering the applicant a participation agreement.

CMS envisions that ACCESS Participant organizations will be technology-enabled clinical programs and practices that are Medicare enrolled. The RFA provides several examples of this vision, including:

- A virtual musculoskeletal program that uses AI-guided exercise therapy and wearable monitoring overseen by a licensed physical therapist;
- A cardiometabolic clinic delivering app-based lifestyle and dietary coaching along with remote medication management; or
- A virtual health care provider group overseeing use of an FDA-cleared cognitive behavioral therapy application.

To be eligible for alignment to the model, beneficiaries must be enrolled in Medicare FFS Part A and B, and Medicare must be the primary payer. Certain exclusions apply, for example, the beneficiary cannot be enrolled in PACE or MA or hospice; aligned to another ACCESS Participant for the same track; or assigned to the control group. The beneficiary must also have a track-specific qualifying condition (described below).

Alignment is voluntary and prospective. Beneficiaries enroll directly with the ACCESS Participant, and alignment may be initiated by either the beneficiary or the ACCESS Participant. CMS will support patient and referring clinician awareness of the model, including by maintaining a CMS-hosted public directory. ACCESS Participants may also engage in marketing and outreach to potentially eligible beneficiaries.[13] Once a beneficiary has been identified for alignment, the ACCESS Participants must:

- Confirm the beneficiary's coverage eligibility via CMS' Eligibility API.
- Obtain and document the beneficiary's informed consent to participate, including informing them of the possibility of being randomly assigned to a control group and, if applicable, that the device used is participating in an FDA pilot and that certain data will be shared with the FDA.[14]
- Validate and document the beneficiary's clinical eligibility.
- Provisionally align the beneficiary via CMS' Alignment API.
- Submit the beneficiary's baseline clinical and Patient Reported Outcomes (PRO) measures via CMS' Reporting API.

[13] ACCESS Participants must adhere to CMS marketing guidelines: https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/medicare-guidelines

[14] https://www.cms.gov/priorities/innovation/access-technical-frequently-asked-questions

Beneficiaries remain aligned for a minimum alignment period of 90 days or until ineligible. Beneficiaries may choose to disenroll or switch tracks after 90 days for any reason. By contrast, disenrollment initiated by ACCESS Participants is allowed only under limited circumstances, for example, if the beneficiary relocates outside the ACCESS Participant's services area, there is loss of contact with the beneficiary despite good-faith efforts on the part of the ACCESS Participant, or the beneficiary becomes ineligible.

To support an organized wind-down of model operations and ensure that all aligned beneficiaries receive meaningful support from the ACCESS model, new beneficiaries may not be aligned during the final year of the ACCESS model (July 2035 through June 2036).

Clinical Tracks, Qualifying Conditions, and Outcome Measures

Four qualifying conditions and tracks are currently available for beneficiary alignment, which are shown in the table below. CMS has indicated that it may consider additional clinical tracks in future years.

Track	Qualifying Condition	OAP Measure
Early cardio-kidney-metabolic (eCKM)	Hypertension and two or more of the following: dyslipidemia, obesity or overweight, prediabetes	• Control or minimum improvement in blood pressure, lipids, weight, and hemoglobin A1c
Cardio-kidney metabolic (CKM)	One or more of the following: diabetes mellitus, chronic kidney disease, atherosclerotic cardiovascular disease	• Control or minimum improvement in blood pressure, lipids, weight, and hemoglobin A1c • Submission of kidney disease markers (eGRF and uACR)
Musculoskeletal (MSK)	Chronic musculoskeletal pain	• Minimum improvement in pain intensity, interference, and overall function (PROM and PGIC assessment)
Behavioral health (BH)	One or more of the following: anxiety, depression	• Control or minimum improvement in symptoms (PHQ-9 or GAD-7 assessment, and submission of WHODAS 2.0 12-item, PGIC)

ACCESS Participants will be required to validate and document each beneficiary's qualifying condition before initiating services and must provide care for all qualifying conditions that a

beneficiary has within their enrollment track. ACCESS Participants can validate the qualifying conditions in different ways:

- If the beneficiary is already a patient of the ACCESS Participant, then the ACCESS Participant can establish the qualifying conditions directly as a result of their own clinical assessment.
- A beneficiary could be referred to the ACCESS Participant from another clinician for the specific conditions that were established as a result of the referring clinician's clinical assessment.
- The ACCESS Participant can identify potential enrollees by gathering evidence of a qualifying diagnosis from the beneficiary's clinical record or claims history.

The agency intends to publish additional guidance on qualifying conditions, including ICD-10 codes which may be used to validate qualifying conditions.

Appendix D in the RFA lists the clinical exclusions that apply for each track. As part of the application process, an ACCESS Participant applicant can request additional clinical exclusions for CMS' consideration. There's no guarantee that the request will be approved, but the availability of the request process signals a willingness for CMS to work with applicants to ensure the patient population being tested is the appropriate one.

As a general rule, beneficiaries can align with only one ACCESS Participant in a given track at a time. However, beneficiaries are permitted to simultaneously align with the same or different participants if they are in different tracks. For example, a beneficiary may be aligned to ACCESS Participant A in the CKM track while being simultaneously aligned to ACCESS Participant B in the Behavioral Health track. One exception to this rule is that beneficiaries may not be enrolled in both the eCKM and CKM tracks at the same time, as switching seamlessly between these tracks is permitted.

Care Delivery and Performance Measurement

The ACCESS model is designed to value outcomes over specific activities, for example, instead of focusing on whether and how a blood pressure was taken or obtained, the blood pressure measurement itself is tracked and performance is based on blood pressure control or improvement. As a result of the model's focus on outcomes, a wide range of care delivery services is permitted which may be delivered in-person, virtually, asynchronously, or through other technology-enabled modalities. ACCESS Participants must ensure these services provide safe, high-quality care that is consistent with clinical guidelines.

ACCESS Participants must also facilitate care transition when clinical needs of the beneficiary exceed the scope of services available and designate a Medical Director who is a Medicare-enrolled physician to, among other things, oversee the organization's care delivery protocols and activities.

ACCESS Participants must track and submit clinical information which will form the basis for quality performance. The ACCESS Participant is responsible for obtaining baseline, follow-up, and final clinical measurement data which must be submitted within defined timeframes within

and after the 12-month care period via CMS' FHIR-based reporting API. Performance targets are set relative to each beneficiary's baseline and focus on control or 'minimum improvement'. The ACCESS Participant's performance is assessed by CMS based on the share of completed periods where all targets are met and in comparison to CMS-specified benchmarks for each measure. More detail on outcome measures and clinical data collections requirements can be found in Appendices B and C in the RFA, although precise measurement targets and denominator exclusions will be specified by CMS in future guidance.

Payment Design and Billing Mechanics

Overview

The ACCESS model Outcome-Aligned Payments (OAPs) are designed to provide revenue stability and support investment in innovative care with up to 50% of the total annual OAP amount paid to the ACCESS Participants in quarterly installments for management of an aligned beneficiary's qualifying condition(s). The remainder of the payment will be withheld and paid following conclusion of the 12-month care period, contingent on achieving track-specific CMS-selected clinical outcome targets. The OAP rates will be subject to various adjustments (such as annual Medicare FFS rate changes and efficiency adjustments) and calibrated to reflect expected resource needs of the patients in each track.[15] Rates will be higher for initial care periods and lower for continued management during follow-on periods.

Claims Billing and FFS Exclusions

During participation in the model, ACCESS Participants will submit claims through a process similar to submitting standard FFS claims for Medicare Part B services to the Medicare Administrative Contractors (MACs) using new track-specific ACCESS model G-codes.[16] ACCESS Participants must submit all OAP claims within 90 days of the date of service. These claims will be processed as 'zero-paid' by MACs. The Innovation Payment Contractor (IPC) will issue quarterly payments, net of applicable adjustments, based on validated claims submitted for aligned beneficiaries during the prior quarter.

OAPs will not include payment for certain services such as medications, laboratory services, imaging, or durable medical equipment. Such services may be coordinated by ACCESS Participants but must be billed separately through a "financially unaffiliated entity". Additionally, to preserve model integrity and prevent duplicative Medicare payments, ACCESS Participants and their "affiliated entities" may not submit Medicare FFS claims for aligned beneficiaries during active care periods. Medicare claims processing systems will include automatic controls to suppress FFS billing from ACCESS Participants for aligned beneficiaries. In general,[17] for purposes of the FFS Exclusion, an "affiliation" with another organization means: (i) a 5 percent or greater direct or indirect ownership interest, (ii) direct or indirect

[15] CMS intends to issue additional payment rate information prior to the first application due date.
[16] CMS intends to issue implementation guidance prior to model launch.
[17] Please see the RFA for the precise FFS Exclusion definition.

operational or managerial control, or (iii) any claims billing reassignment relationship under 42 CFR § 424.80.

Semi-annual reconciliation

CMS will conduct payment reconciliations on a semi-annual basis, assessing performance across each participant's aligned patient panel, including all aligned patients whose 12-month care period ended during the prior six-month assessment window. At the time of the semi-annual reconciliation, CMS will apply one of two potential downward adjustments to the ACCESS Participant's withheld payments: the Clinical Outcome Adjustment or the Substitute Spend Adjustment.

The purpose of the Clinical Outcome Adjustment is to balance outcome accountability with model accessibility. The Clinical Outcome Adjustment is applied based on the percentage of beneficiaries who completed their 12-month period during the past 6 months and met their OAP measure target (the Outcome Attainment Rate, OAR) compared to a CMS-defined Outcome Attainment Threshold (OAT) which is set at 50% for the model's first performance year.[18] The following formula applies: Clinical Outcome Adjustment = 1 – (OAR ÷ OAT). This means that if the ACCESS Participant's OAR is equal to or above 50%, the Clinical Outcome Adjustment would be zero and the ACCESS Participant will earn the full OAP amount. The Clinical Outcome Adjustment is capped at 50%, regardless of participant performance, however, ACCESS Participants that fall short of this threshold may be subject to termination.

The Substitute Spend Adjustment follows the same general approach as the Clinical Outcome Adjustment, but in this case, the adjustment is designed to minimize avoidable duplicative services reasonably within the ACCESS Participant's control. The Substitute Spend Adjustment is applied based on the percentage of aligned beneficiaries who did not receive any track-specific Substitute Spend List services[19] from other providers for the same condition during the 12-month care period (the Substitute Spend Rate – SSR) compared to a CMS-defined Substitute Spend Threshold (SST) which is set at 90% for the model's first performance year. The following formula applies: Substitute Spend Adjustment = 1 – (SSR ÷ SST). This means that if the ACCESS Participant's SSR is equal to or above 90%, the Substitute Spend Adjustment would be zero and the participant will earn the full OAP amount. The Substitute Spend Adjustment is capped at 25%.

CMS will apply only the larger of either the Clinical Outcome Adjustment or the Substitute Spend Adjustment.[20] CMS will net the reduction against the Participant's withheld payments, and CMS will issue any remaining amounts owed to the participant through a subsequent quarterly payment. If additional recovery is needed beyond available withheld payments, CMS may offset against future payments or initiate formal overpayment recovery processes.

[18] CMS anticipates that the OAT percentage will increase in subsequent participation years and will publish them in advance of the initial application period for the later model years.
[19] See Appendix E in the RFA for detailed track-specific service lists. CMS may add or remove services over time to reflect changes in PFS billing codes as well as CMS' analyses of utilization patterns and billing trends.
[20] CMS provides several examples in the RFA of how the Adjustments are calculated and their interactions.

Co-Management Payment and Beneficiary Cost-Sharing

Clinicians who co-manage ACCESS beneficiaries with an ACCESS Participant may bill a new ACCESS model Co-Management service for documented review of ACCESS updates and care coordination activities. The service will be paid at approximately $30 per service.[21] To bill the Co-Management code, the consulting clinician must review the ACCESS Care Update and place a brief written note in the EHR documenting the assessment and any care-coordination action. Clinicians who assist a beneficiary with onboarding and initial setup activities may also bill the Co-Management code with a CMS-specified modifier the first time they bill for that beneficiary to receive an additional payment of approximately $10.[22,23]

The payment will be limited to once every four months per beneficiary per track, up to approximately $100 per year. There will not be Part B beneficiary cost-sharing for this service and advance consent from beneficiaries will not be required. Documentation requirements ensure that co-management payments reflect genuine care coordination activities. CMS may adjust the payment amount in later years based on operational experience related to utilization, care-coordination patterns, and overall model goals.

Additionally, ACCESS Participants have the option of waiving beneficiary cost-sharing for OAPs as a beneficiary engagement incentive. The ACCESS Participant's policy must be applied uniformly to all beneficiaries and consistent with beneficiary incentive safe harbor requirements.[24] If an ACCESS Participant elects to collect OAP beneficiary cost-sharing, they must clearly disclose the expected beneficiary payment amount before beneficiary enrollment.

Data Reporting and Data Sharing

ACCESS Participants will be required to collect and report to CMS clinical outcome data, utilization information, and other model-specific metrics. All clinical data must be submitted via FHIR®-based APIs with standardized data elements. In addition, ACCESS Participants will have certain data sharing access and opportunities, including access to certain Medicare claims data via the Beneficiary Claims Data API to support care coordination for aligned beneficiaries, and CMS-generated reports on alignment, payment, and performance. Finally, CMS intends to launch an informational resource – an ACCESS Tools Directory – that will help organizations identify optional software and hardware tools that may support model participation and compliance.[25]

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[21] Subject to a geographic adjustment and all Medicare payment adjustments and penalties that may apply.
[22] *Ibid.*
[23] CMS intends to share the ACCESS Co-Management Payment G-code and its modifier in 2026.
[24] CMS intends to offer the CMS-sponsored model patient incentive safe harbor (42 CFR §1001.952(ii)(2)) to facilitate waivers of beneficiary cost-sharing.
[25] Vendors would submit their own listings in the ACCESS Tools Directory and self-certify that their products meet all applicable State and Federal requirement, including applicable FDA requirements. Vendors listed in the directory may also choose to include optional promotional offers for ACCESS Participants.

To promote transparency, beneficiary choice, and quality-based competition, CMS intends to maintain a public-facing directory of all ACCESS Participants that includes information about each organization's tracks, conditions treated, and risk-adjusted outcomes. CMS believes that this directory will strengthen referral relationships and create new opportunities for high-performing ACCESS Participants.

ACCESS Participants are required to support care coordination by making reasonable efforts to identify beneficiaries' existing care team members—specifically any primary care practitioner (PCP) and referring clinician, if applicable—and to share standardized clinical updates at key points in care. This requirements include:

- Making and documenting a good-faith effort to determine whether a beneficiary has an existing primary care provider or referring clinician.[26]
- Making and documenting reasonable, good-faith efforts to proactively share care updates with each beneficiary's identified care team using secure data exchange methods.[27]

To ensure consistency in data sharing and minimize burden for beneficiary care teams, CMS will provide a concise, standardized care plan and update template[28] that ACCESS Participants must use. At minimum, ACCESS Participants must send the care plan and updates to the care team within 10 days of care initiation, within 30 days after the end of the 12-month care period, and within 10 days of any transition of the beneficiary to another clinician or care setting. The ACCESS Participant must also make the care plans and updates reasonably accessible to the beneficiary.

All data sharing must use health information technology (HIT) that meets standards and specifications under 45 CFR Part 170, Subpart B, and certain certification criteria adopted under 45 CFR Part 170, Subpart C, consistent with the ONC Health IT Certification Program. ACCESS Participants must also meet certain minimum HIT requirements, including: (1) ensuring patients and authorized health care providers can access and exchange electronic health information using FHIR-based standards, (2) establishing and maintaining connectivity to a health information exchange (HIE), (3) ensuring the ability to transmit required clinical and patient-reported outcomes through CMMI's FHIR®-based reporting FHIR® server.

Monitoring

CMS will monitor ACCESS Participants on a regular, ongoing basis to ensure program integrity and support patient safety. ACCESS Participants must maintain copies of all documentation related to implementation of the model in the event of an audit which may occur randomly or based on anomalous claims, utilization, quality measures, or other model related data. ACCESS

[26] Specific activities to support this requirement are outlined in more detail in the RFA.
[27] Specific activities and requirements related to these good-faith efforts are outlined in more detail in the RFA.
[28] The template will include fields for information related to beneficiary identifiers, ACCESS Participant contact information (including monitoring and Medical Director contact information), baseline metrics and treatment goals, active medications and laboratory results, narrative summary of progress and outcomes, and the treatment plan.

Participants may also be subject to 30-day notice periods for overpayment recovery, with standard Medicare interest rates applying to amounts exceeding the notice period, in alignment with standard Medicare overpayment recovery procedures under 45 CFR 30.11(b)(1)(ii). Finally, annual financial audits are required for participants exceeding specified payment thresholds, ensuring appropriate use of Medicare funds and compliance with model requirements. Real-time monitoring systems have been integrated within existing CMS fraud detection capabilities to identify unusual billing patterns or potential program integrity concerns.

CMS reserves the right to terminate an ACCESS Participant's Participation Agreement at any time during the term of the Participation Agreement for reasons associated with poor performance, program integrity issues, non-compliance with the terms and conditions of the Participation Agreement, or as otherwise specified in the Participation Agreement.

CMS Evaluation of the Model and Beneficiary Control Group

All ACCESS Participants are required to cooperate with CMS model evaluation efforts, which may include completion of surveys and participation in interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive evaluation.

CMS will conduct the randomization of beneficiaries and communicate assignment results to Participants through the CMS Eligibility API. As a result, before querying the API to verify a beneficiary's eligibility, Participants must inform the beneficiary that the service is offered as part of a new CMS payment model test and that, as part of model evaluation, their data may be shared with CMS subject to federal privacy and security protections; that they may be randomly assigned to a comparison group and therefore ineligible to participate in the clinical track while continuing to have access to all usual Medicare benefits and services; and that such assignment will not affect their Medicare benefits, rights, or coverage. If a beneficiary is assigned to the control group, they will not be eligible to participate in the model for the following 12-month period. The randomization rate will start with a 90:10 intervention-to-control ratio in the first year and may be adjusted or eliminated in future years depending on the number of beneficiaries enrolled in the model and the evaluation's ability to detect impact of the model on improved quality and reduced Medicare spending. The evaluation will assess cost, utilization patterns, quality measures, and beneficiary outcomes using Medicare claims data, surveys, and other data sources.

Program Interactions and Avoidance of Overlaps

The ACCESS model will not qualify as an Advanced Alternative Payment Model and CMS does not anticipate that ACCESS furnished services would contribute to Merit-Based Incentive Payment System (MIPS) eligibility and reporting, nor will they be subject to MIPS payment adjustments.

Aligned beneficiaries may be concurrently attributed to other CMS models such as the Medicare Shared Savings Program (MSSP) and ACO REACH. Organizations (identified at the TIN-level) and individual practitioners (identified at the NPI level) may participate in both the ACCESS model and other Innovation Center models. Organizations and individual practitioners may also

participate in both the ACCESS model and the MSSP. However, despite these flexibilities, ACCESS Participants are not expected to align the same beneficiary to ACCESS and another model in which they are participating (see the FFS Exclusion). Costs associated with the ACCESS G-codes would be treated like other FFS claims for purposes of MSSP Accountable Care Organization (ACO) reconciliation.[29]

Certain beneficiary exclusions apply to avoid overlapping participation in programs addressing the same clinical conditions. Specifically, beneficiaries that are receiving dialysis for ESRD may not also be aligned to the eCKM and CKM track. Additionally, beneficiaries in the BH track may not be enrolled in a Certified Community Behavioral Health Clinic (CCBHC) program.

CMS has made an effort to design the ACCESS model to support potential adoption by other payers, including Medicare Advantage, Medicaid, and commercial plans. For example, ACCESS Participants will use CMS-defined, track-specific codes that could also be used by other payers. CMS may also publish optional payer implementation resources in the future.

FDA's TEMPO Pilot

To promote access to certain digital health devices while safeguarding patient safety, FDA announced the TEMPO pilot in connection with the ACCESS model. Under the TEMPO pilot, manufacturers of certain digital health devices that are intended to improve patient outcomes and are not already authorized by FDA may request that FDA exercise enforcement discretion when their device is used by an ACCESS Participant.[30] Devices that qualify must not present a potential for serious risk to the health, safety, or welfare of patients.

Under the TEMPO pilot, the FDA expects participating manufactures to collect real-world data (RWD) related to the intended uses of their devices, share these data with FDA, and, using the data collected during participation, seek appropriate marketing authorization from the FDA.[31,32]

The FDA plans to limit participation to up to about ten manufacturers based in the United States in each of four "clinical use areas" that align with the four ACCESS model tracks. Beginning January 2, 2026, manufacturers that are interested in participating in the TEMPO pilot should email the FDA at FDA-TEMPOPilot@fda.hhs.gov using the subject heading "Statement of

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[29] The RFA includes the following caveat: *"…although CMS is currently evaluating a temporary exclusion of ACCESS spending from ACO financial benchmarks and reconciliation during the first year of the model."* However, a FAQ on the CMMI website states: *"For 2026 and 2027, CMS will be making system changes to support model operations, and CMS anticipates that there will be no impact from ACCESS OAPs on ACO benchmark and performance year calculations for the Medicare Shared Savings Program and ACO REACH. Beginning in 2028, expenditures associated with ACCESS OAPs will be included in ACO benchmark and performance year calculations."*

[30] https://www.federalregister.gov/documents/2025/12/08/2025-22190/technology-enabled-meaningful-patient-outcomes-tempo-for-digital-health-devices-pilot

[31] *Federal Register* :: Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

[32] The patient consent implications for such data collection and sharing is not clarified in either the RFA or the FDA's *Federal Register* notice, however, HPA notes that the FDA recently revised its guidance related to real-world data such that it will accept information extracted from large data pools without private, individual information. Federal Register :: Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

Interest for Participation in the TEMPO Pilot" and include (i) identification of the manufacturer and device (including any current authorizations or prior FDA interactions related to the device); (ii) proposed indications for use consistent with the ACCESS model; and (iii) a request that FDA exercise enforcement discretion. On or about March 2, 2026, FDA will begin sending follow-up requests for additional information, including the following:[33]

- A device description and proposed indications for use;
- Data demonstrating the device is adequately safe;
- Information about the manufacturer's quality management system;
- A risk mitigation plan that provides for data collection, monitoring, and reporting;
- Proposed performance goals;
- Proposed timeline for premarket notification submission;
- Proposed interim reporting plan;

If selected for participation, pilot participants will be encouraged to engage in "sprint" discussions that may relate to the planned marketing submission.[34]

Opportunities and Gaps

The CMS Innovation Center's ACCESS model seeks to fast-track innovative digital technologies that address common chronic conditions and for manufacturers to generate real-world data in parallel with FDA approval and CMS payment, thus streamlining the pathway from approval to payment. The model includes design features that are rare among CMMI models such as the cross-collaboration with FDA and the new TEMPO pilot, a randomized control FFS population and direct enrollment of beneficiaries, and the model's billing and payment structure through the IPC. Once operationalized, CMS could build on these processes and design features in future models.

There is clear participation interest in the med tech community, with over 250 of the leading technology-enabled care organizations expressing their intent to apply,[35] however, it remains to be seen whether the model's structure and benefits will be enough to spur a similar response across the provider community, although model design features such as the co-management payment and co-payment waiver may help to incentivize referrals and beneficiary access to ACCESS Participants. CMS also anticipates that the public-facing ACCESS directory may also serve to drive clinician and self-referrals to high performing organizations.

Despite recent release of the RFA, many policy and implementation gaps remain. Throughout the RFA, CMS indicates that the agency anticipates publishing additional details and guidance on a number of critical issues, including OAP rates; OAP adjustment thresholds; billing instructions; qualifying conditions and ICD-10 codes; quality outcome targets that define

[33] For a complete list, please see the *Federal Register* notice here: Federal Register :: Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

[34] For more information about FDA "sprint discussions", see: Breakthrough Devices Program FDA Guidance for Industry and Food and Drug Administration Staff (issued September 15, 2023)

[35] As of early December, as CMS noted in: Introducing ACCESS | Modernizing America's Care for Better Health | HHS-CMS Event

'improvement' and 'maintenance'; and the public ACCESS directory. In particular, knowing the OAP rates will help organizations better plan for participation. The FDA's TEMPO pilot announcement raises additional implementation questions, for example, how TEMPO might interact with 'regular' FDA approval pathways and how a manufacturer might interact with the ACCESS Participant to ensure beneficiary consent and other necessary FDA requirements are met.

While the goal of directly incentivizing technology-enabled solutions for improving FFS patient outcomes is laudable, potential participating organizations will have to carefully consider whether participation in the model is a good business fit. For example, potential participants may struggle to assume the responsibilities and compliance requirements that are inherent in Medicare enrollment. By contrast, existing Medicare enrolled providers and suppliers that might otherwise be interested in applying may be wary of the FFS Exclusions which, among other things, will limit their ability to bill any Medicare FFS claims for aligned beneficiaries during active care periods. Some existing digital health care and chronic care management organizations that have partnerships with commercial or MA plan may be well-positioned to participate in ACCESS, but the requirements and exclusions of the ACCESS model will materially shape partnership decisions with FFS Medicare providers and suppliers. Additionally, organizations interested in becoming ACCESS Model participants that are not already participating in Medicare should be performing readiness assessments and planning for the time needed to apply and be approved as a Medicare-enrolled provider or supplier.