# The longest ACCESS article you'll eve find: CMS builds a chronic care marke where half your money lives in escro and clinical outcomes to determine whether you ever see it

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# Abstract

The Centers for Medicare and Medicaid Services Innovation Center released the Request for Applications for the Advancing Chronic Care with Effective, Scalab Solutions (ACCESS) Model on January 12, 2026. This is a ten-year nationwide voluntary model running July 1, 2026 through June 30, 2036, with rolling applic through early 2033 and quarterly cohort starts beginning January 1, 2027. The fi cohort launches July 1, 2026 for applications received by March 20, 2026.

ACCESS introduces Outcome-Aligned Payments for technology-enabled chronic disease management across four initial clinical tracks: early Cardio-Kidney-Met syndrome (eCKM), Cardio-Kidney-Metabolic syndrome (CKM), Musculoskeletal (MSK), and Behavioral Health (BH). The payment structure is fixed per beneficia track for twelve-month care periods, but only up to fifty percent of the annual payment is distributed during the care period via quarterly installments. The remaining fifty percent is withheld and reconciled after the care period ends bas performance against two adjustment mechanisms.

The Clinical Outcome Adjustment compares each participant's Outcome Attain Rate (the percentage of completed care periods where all required outcome meas targets were met) against an Outcome Attainment Threshold set at fifty percent year one. The Substitute Spend Adjustment compares the Substitute Spend Rate percentage of aligned beneficiaries who did not receive defined substitute servic from other Medicare providers for the same condition) against a Substitute Spen Threshold set at ninety percent in year one. CMS applies only the larger of the t adjustments in each semi-annual reconciliation period, with the Clinical Outcor Adjustment capped at fifty percent payment reduction and the Substitute Spend Adjustment capped at twenty-five percent reduction.

Participation requires Medicare Part B enrollment at the organizational TIN lev provider or supplier excluding DMEPOS and laboratory suppliers, designation c Medicare-enrolled physician as Clinical Director (the FAQ clarifies this role, dif slightly from the Medical Director terminology in the RFA), individual Medicare enrollment of all clinicians furnishing or supervising care with reassigned billin rights, standardized electronic care coordination with primary care and referrin clinicians, FHIR-based clinical and patient-reported outcome data submission, compliance with health information technology requirements including HIE connectivity within twelve months, and compliance with applicable FDA requirements or FDA enforcement discretion. An FFS exclusion prevents partic and affiliated entities from billing Medicare fee-for-service for aligned beneficia during active care periods.

CMS clarifies via FAQ that for 2026 and 2027, ACCESS Outcome-Aligned Payme will have no impact on ACO benchmark and performance year calculations for t Medicare Shared Savings Program and ACO REACH, with ACCESS expenditure be included beginning in 2028. This creates a two-year window where ACOs can leverage ACCESS participants without benchmark impact.

CMS will launch an ACCESS Tools Directory within the application and particip portal to help organizations identify optional software and hardware tools suppo model participation including data exchange and interoperability solutions, iden verification systems, optional connected clinical devices like blood pressure cuff tools supporting HIPAA compliance. Vendors may include promotional offers fo ACCESS participants subject to all applicable federal and state laws.

FDA introduces the Technology-Enabled Meaningful Patient Outcomes (TEMPO Digital Health Devices Pilot specifically for ACCESS, allowing manufacturers of certain digital health devices to request FDA enforcement discretion for devices in ACCESS that would generally require FDA premarket authorization but have yet obtained such authorization. Under TEMPO, manufacturers can offer device ACCESS participants for intended uses expected to be covered by ACCESS whil collecting real-world performance data under FDA oversight. TEMPO participa

optional and requires enhanced beneficiary consent informing them the device i participating in an FDA pilot and certain data will be shared with FDA.

For investors, ACCESS creates a fundamentally different underwriting problem typical digital health models. The fifty percent withholding creates working cap intensity that scales with patient volume. The outcome-based payment adjustme introduce revenue uncertainty tied directly to clinical performance across the pa panel. The measurement provenance requirements for blood pressure (validated arm cuffs with timestamped, source-verifiable transmission, manual entry prohi and other biomarkers eliminate self-reported data. The substitute spend control penalize participants when beneficiaries receive duplicate services elsewhere, ma leakage management a core operational competency. The FDA compliance requirements add regulatory complexity for device-dependent business models, though TEMPO provides a path for devices not yet cleared. The combination rev well-capitalized organizations with proven clinical outcomes, mature measurem operations, FDA compliance infrastructure, and care coordination capabilities, v punishing undercapitalized or operationally immature entrants regardless of pro quality or commercial traction.

# What ACCESS Actually Is and Why CMS Built It This Way

ACCESS is not another value-based care arrangement where Medicare splits theoretical savings with provider groups. It is not an extension of fee-for-service digital add-ons like the remote patient monitoring codes that created a cottage industry of device distribution companies with questionable clinical impact. AC is CMS attempting to buy finished clinical results for specific chronic condition using fixed prospective payments that are only fully earned if predefined outcom thresholds are met and duplicate spending is minimized.

The CMS FAQ frames this explicitly: “Rather than paying for a specific set of se the model rewards results, giving care teams flexibility to use technology, clinica tools, and care approaches that best support each patient’s needs.” This is CMS

acknowledging that activity-based payment does not align with how technology-enabled care actually works and creates administrative burden that undermines efficiency.

The design reflects four explicit policy intentions visible throughout the RFA an FAQ. First, CMS wants to remove activity-based billing as the primary economic driver for technology-enabled chronic care because fee-for-service incentivizes volume over outcomes and creates administrative burden. Second, CMS wants tc the cost explosion risk of broadly available RPM codes where the business mode became collecting device readings without demonstrated clinical impact. Third, wants to create an outcome-comparable market across vendors by standardizing measure definitions, reporting mechanisms, and public transparency of risk-adju performance. The FAQ emphasizes that "CMS will maintain a public directory o ACCESS participants, including the conditions they treat and their risk-adjustec clinical outcomes, so patients and referring providers can make informed choice Fourth, CMS wants Medicare to become a viable payer channel for digital chron care without ceding price control or enabling cherry-picking.

Every structural choice follows from these goals. The fixed payment per benefici per track eliminates billing complexity and volume incentives. The outcome thresholds and public reporting create quality-based competition. The substitut spend controls prevent participants from capturing payments while beneficiarie receive parallel care elsewhere. The measurement provenance requirements and submission standards ensure outcome data is auditable and comparable. The ter duration and rolling cohort design signal this is intended as permanent infrastructure, not a temporary demonstration.

The RFA explicitly states that technology-enabled care organizations deeply inte technology into delivery to provide continuous high-value care for chronic disea prevention and management, noting that most currently serve commercially insu populations where more flexible payment arrangements make participation feasi CMS is acknowledging that Medicare patients have limited access to these mode because existing payment structures do not support them, and ACCESS is desig

fix that market failure by creating a payment pathway aligned with how technolo enabled care actually works.

The implied economic theory is that technology reduces marginal cost of contin care delivery, making outcome-based payment models more viable than they wou for traditional brick-and-mortar provider organizations. AI-assisted documentat remote monitoring, asynchronous engagement, and automated patient support c deliver sustained clinical management at scale with lower variable costs than vis based care. If that theory holds, the fixed OAP should cover costs and generate n for effective participants. If it does not hold, participants will discover that technology-enabled care still requires expensive human clinical labor and the un economics fail under the payment rates CMS eventually sets.

## The Four Clinical Tracks and Why Bundling Kills Point Solutions

ACCESS launches with four clinical tracks, each grouping clinically related, frequently comorbid conditions that share similar care activities and intensity. T bundling structure is central to the model's design and has immediate implicatio for which companies can participate.

The eCKM track targets early-stage cardio-kidney-metabolic syndrome before progression to established diabetes, chronic kidney disease, or atherosclerotic cardiovascular disease. The FAQ clarifies qualifying conditions as hypertension, two or more of dyslipidemia, obesity or overweight with marker of central obesit (BMI greater than or equal to thirty, or BMI 25 to 29.99 with waist circumferenc greater than 40 inches for men or 35 inches for women), and prediabetes. The outcome measures require control or minimum improvement in blood pressure, cholesterol, weight, and hemoglobin A1c. CMS defines specific targets relative t beneficiary's baseline, such as a ten mmHg reduction in systolic blood pressure o achieving systolic blood pressure below 130 mmHg for hypertension.

The CKM track addresses established cardio-kidney-metabolic disease requiring or more of diabetes mellitus, chronic kidney disease stage 3a or 3b, or atheroscle

cardiovascular disease (the FAQ clarifies this includes heart disease). The outcon measures are identical to eCKM for blood pressure, lipids, weight, and A1c, but mandatory submission of estimated glomerular filtration rate and urine albumin creatinine ratio data for beneficiaries with CKD or diabetes. This kidney health monitoring requirement reflects CMS emphasis on progression prevention. Beneficiaries cannot enroll in both eCKM and CKM simultaneously since CKM encompasses all eCKM clinical measures and care, but can immediately switch f eCKM to CKM if disease progresses without the standard three-month lock-in p

The MSK track focuses on chronic musculoskeletal pain defined as pain lasting than three months affecting bones, joints, muscles, and connective tissues. Unlik metabolic tracks using clinical biomarkers, MSK relies entirely on patient-repor outcome measures. The outcome requirements include minimum improvement i pain intensity, interference, and overall function assessed via validated instrume The FAQ clarifies that "chronic is defined as pain lasting more than three month and "musculoskeletal disorders are defined broadly to include conditions affecti bones, joints, muscles, and connective tissues." The CMS FAQ also notes that "tl MSK track is focused on resolving chronic pain during the initial care period an not include an optional follow-on period," which is a critical economic detail sin limits lifetime value per patient for MSK-focused participants.

The BH track covers depression and anxiety requiring one or more of these cond at baseline. Outcome measures include minimum improvement in symptoms ass via PHQ-9 for depression and GAD-7 for anxiety, with mandatory submission of WHODAS 2.0 twelve-item scores measuring overall function. Both PHQ-9 and G are required for all BH track patients regardless of which condition was the qualifying diagnosis, reflecting high comorbidity between depression and anxiet quarterly reporting requirement is more frequent than lipid or A1c monitoring metabolic tracks, reflecting need for closer psychiatric symptom severity monito

The bundling structure matters because payment is per track, not per diagnosis. participant managing a beneficiary with hypertension, dyslipidemia, obesity, and prediabetes in the eCKM track receives one OAP and must address all four cond to meet outcome targets. A participant managing only hypertension education b

comprehensive metabolic risk modification is not what CMS is buying. This desi punishes narrow single-condition point solutions and rewards integrated care m that can manage the full clinical complexity within a track.

Each track includes extensive clinical exclusions beyond the qualifying conditio Required exclusions apply uniformly across all participants and include severe h failure (NYHA Class III-IV), active unstable angina or acute coronary syndrome, unstable or complex secondary hypertension requiring specialist management, C Stage 4 or 5/End Stage Renal Disease for eCKM and CKM, active eating disorde moderate to severe dementia or severe cognitive impairment, acute psychiatric conditions with suicidal or homicidal ideation, patients 81 and older with frailty indicators, patients receiving hospice or palliative care, and patients 66 and olde entering long-term nursing home care during the intervention window. Particip may propose additional exclusions during application review but cannot exclude entire conditions from a track, ensuring comprehensive care responsibility while allowing flexibility for different care delivery models.

## Payment Mechanics: OAPs, Withholdin and Two Independent Ways to Lose Revenue

The payment structure is where ACCESS becomes operationally complex and financially risky. Understanding the mechanics requires walking through benefi alignment, claims submission, quarterly payment distribution, and semi-annual reconciliation.

Beneficiaries align prospectively and voluntarily to an ACCESS participant for a specific track after the participant validates clinical eligibility and obtains infor consent. The participant queries the CMS Eligibility API to confirm Medicare coverage and exclusion criteria, then provisionally aligns the beneficiary through Alignment API once clinical eligibility is validated. Within a defined timeframe enrollment, participants must submit baseline clinical and patient-reported out measures through the CMS FHIR-based Reporting API to maintain enrollment.

The participant submits monthly claims using new track-specific G-codes throu standard Medicare Administrative Contractor channels. These claims process as paid claims meaning the MAC does not actually pay them. Instead, the claims se attestations that the participant is actively delivering care, meeting compliance requirements, and has submitted required outcome data. The Innovation Payme Contractor issues quarterly payments based on validated monthly claims from tl prior quarter.

Here is where the withholding structure creates working capital exposure. Duri twelve-month care period, the IPC pays only up to fifty percent of the total annu OAP in quarterly installments. The remaining fifty percent is withheld until afte care period concludes. This is not a small holdback on a bonus. It is half the exp revenue for that beneficiary locked up for up to twelve months pending perform assessment.

The payment amount varies by track and tier. Each track has an Initial Period ra a Follow-On Period rate. The FAQ clarifies that "most tracks include an optiona continuation period, with CMS paying a reduced payment rate to the organizati that reflects lower resource needs once care is established. The MSK track is foc on resolving chronic pain during the initial care period and does not include an optional follow-on period." This is a critical economic detail that was unclear in RFA alone.

The Initial Period applies when it is the first time the participant is treating the beneficiary in that track within the past two years and at least one required outc measure is not at target at baseline. This tier receives higher payment reflecting resource needs for onboarding, relationship establishment, and achieving initial clinical improvement. The Follow-On Period applies when continuing to manag beneficiaries previously treated by the participant for the same track within the two years, or when initiating care for beneficiaries whose outcome measures are target at baseline. This tier receives lower payment reflecting reduced resource n for maintenance care.

For eCKM and CKM tracks, if a beneficiary is referred by another clinician for t qualifying condition, the participant qualifies for the full Initial Period payment if baseline measures are already at target. In these cases, the participant must in the referring clinician's NPI on the claim when billing. This exception recognize accepting referred patients who are already well-controlled still requires onboar and coordination work.

The RFA does not specify actual payment amounts, stating that payment rates ar related model parameters will be announced in 2026 in advance of the initial application deadline. Payment amounts will vary by clinical track to reflect expe resource needs for integrated care. For eCKM and CKM tracks, rates account fo expected device cost of a cellular network-connected blood pressure cuff used fo condition management and outcome reporting, with a fixed add-on payment for beneficiaries to account for higher distribution costs. When a beneficiary enrolls multiple tracks with the same participant, CMS applies a payment discount to th total OAP amount to reflect administrative and operational efficiencies from integrated care delivery.

After the twelve-month care period concludes, CMS conducts semi-annual reconciliation assessing performance across all beneficiaries whose care periods during the prior six-month assessment window. Two potential downward adjust exist: the Clinical Outcome Adjustment and the Substitute Spend Adjustment. C applies only the larger of the two in each reconciliation period, preventing compounding penalties while maintaining accountability across both performan dimensions.

The Clinical Outcome Adjustment compares the participant's Outcome Attainm Rate against the Outcome Attainment Threshold. The OAR is the percentage of aligned beneficiaries who completed their twelve-month care period and met all required OAP measure targets for their track. In the model's first performance y the OAT is set at fifty percent. If a participant's OAR equals or exceeds fifty perc the participant earns full payment with no adjustment. If the OAR falls below fi percent, payment is reduced proportionally calculated as OAR divided by OAT multiplied by the full OAP amount. For example, if forty percent of aligned

beneficiaries met all OAP measures, the participant earns forty divided by fifty, eighty percent of the full OAP amount, with a Clinical Outcome Adjustment of twenty percent. The adjustment is capped at fifty percent reduction, so a partici with only twenty percent outcome attainment would still retain fifty percent of OAP payment under this floor. Participants falling short of minimum threshold be subject to termination under the Participation Agreement.

The FAQ clarifies that "CMS determines payment based on the overall share of patients who meet their defined outcomes, compared to a minimum threshold th increases with each participation year. This balances accountability with accessi and rewards strong overall performance." The OAT remains at fifty percent for participants in their first year of model participation or when initiating a new tr then increases in subsequent participation years up to a defined upper limit. CM publish OATs for later model years in 2026 in advance of the initial application and may adjust values for subsequent years based on operational experience and overall model goals.

The Substitute Spend Adjustment compares the participant's Substitute Spend I against the Substitute Spend Threshold. The SSR is the percentage of aligned beneficiaries who did not receive listed substitute services from other Medicare providers or suppliers for the same condition during their ACCESS care period. clinical track includes a Substitute Spend List identifying Medicare Physician F Schedule services considered substitutes if provided by another entity for the sa condition. The initial lists focus on new service initiations representing duplicat care, such as new physical therapy evaluations for low back pain while an MSK participant manages the same condition, or diabetes self-management training w CKM participant treats diabetes.

In the model's first performance year, the SST is set at ninety percent. If a participant's SSR equals or exceeds ninety percent, the participant earns full pay with no adjustment. If the SSR falls below ninety percent, payment is reduced proportionally calculated as SSR divided by SST multiplied by the total annual C amount. For example, if eighty percent of aligned beneficiaries did not receive li substitute services, the participant earns eighty divided by ninety, or approximat

eighty-nine percent of the full OAP amount, with a Substitute Spend Adjustmen eleven percent. The adjustment is capped at twenty-five percent reduction. This adjustment applies only to payments made to ACCESS participants, while care provided by non-ACCESS entities for services on the Substitute Spend List cont to be reimbursed under standard Medicare payment rules.

CMS nets the larger of the two adjustments against the participant's withheld payments and issues any remaining amounts owed through a subsequent quarter payment. If additional recovery is needed beyond available withheld payments, C may offset against future payments or initiate formal overpayment recovery proc including standard Medicare recoupment mechanisms.

## The Substitute Spend Trap: CMS Pricin Your Ability to Stay Primary

The Substitute Spend Adjustment deserves separate analysis because it represen fundamentally different risk than clinical outcomes. Clinical outcomes are withi participant's direct control through care delivery quality, patient engagement, a protocol optimization. Substitute spend is partially outside the participant's con because it depends on beneficiary behavior, other clinician decisions, and care coordination effectiveness.

The specific services on each track's Substitute Spend List create the economic exposure. For eCKM and CKM, the list includes Ambulatory Blood Pressure Monitoring (CPT codes 93784, 93786, 93788, 93790), Ambulatory Continuous G Monitoring (95249-95251), Remote Physiologic Monitoring device setup (99453, 99473), Diabetes Self-Management Training (G0108), Intensive Behavioral Thera Cardiovascular Disease (G0446), Intensive Behavioral Therapy for Obesity (G044 Medical Nutrition Therapy individual initial visit (97802), Remote Therapeutic Monitoring patient education and device setup (98975), and Medicare Diabetes Prevention Program services (G9880, G9881, G9886, G9887).

For MSK, the list includes Physical Therapy Evaluation (97161-97163), Occupati Therapy Evaluation (97165-97167), and Remote Therapeutic Monitoring patient

education and device setup (98975). For BH, the list includes Digital Health Medication Therapy supply of digital device and monthly treatment (G0552-G05 initial individual psychotherapy (90832-90834, 90836-90838), and Remote Thera Monitoring patient education and device setup (98975).

These are not obscure codes. They represent common Medicare services that beneficiaries with chronic conditions frequently receive. A beneficiary with diab seeing an endocrinologist might receive diabetes self-management training. A beneficiary with chronic low back pain might get referred to physical therapy by primary care physician. A beneficiary with depression might start therapy sessio with a local clinician. Each of these events potentially triggers substitute spend represents a new service initiation for the same condition the ACCESS participa managing.

The ninety percent threshold means participants can tolerate substitute services only ten percent of their aligned panel before payment reductions begin. In prac this requires extremely tight care coordination, rapid response to patient needs, comprehensive service offerings that reduce the reasons beneficiaries would seel duplicate care elsewhere.

Participants have access to Medicare claims data through the Beneficiary Claims API to monitor for substitute services, but this is retrospective detection not prevention. By the time substitute spend appears in claims data, the service has already been delivered and the revenue impact is locked in. The operational resp has to be prospective: designing care models that meet beneficiary needs comprehensively enough that outside initiation rates stay below threshold.

This creates several strategic implications. First, participants need robust care coordination with primary care physicians and referring clinicians to ensure tho clinicians understand the ACCESS participant's role and do not initiate duplicat services. Second, participants need rapid access and responsiveness so beneficia not seek care elsewhere due to access barriers. Third, participants need comprehensive service scope covering the full range of needs within their track beneficiaries do not require outside services to address gaps. Fourth, participant

need monitoring and intervention capabilities to detect early warning signs of beneficiary dissatisfaction or unmet needs before external utilization occurs.

The care coordination requirements CMS imposes support this, but they are not sufficient by themselves. Sending standardized updates to primary care physicia informs them of the participant's involvement but does not prevent them from ordering services if they believe clinical need exists. The real defense against substitute spend is becoming the trusted primary pathway for that condition in beneficiary's and clinician's minds.

## Measurement as Infrastructure: Device Provenance, PROMs, and FHIR Plumbin

ACCESS is unusually aggressive about data quality and provenance. CMS requir that clinical biomarker and patient-reported outcome data be submitted via FHI enabled APIs with standardized data elements, and specifies acceptable data collection methods to prevent gaming and ensure comparability.

For blood pressure, CMS requires use of validated upper arm cuffs supporting timestamped, source-verifiable transmission. Manual entry of values is explicitly prohibited. Each submission to CMS must reflect an average of at least three rea Data collection should follow the 2025 AHA/ACC Hypertension Guidelines for c blood pressure, ambulatory blood pressure monitoring, or home blood pressure monitoring, including appropriate cuff size, seated rest period, and multiple rea per occasion. This single requirement has cascading implications for device sele inventory management, distribution logistics, beneficiary onboarding, technical support, data integration, identity matching, time series storage, and audit readi

For lipid panels and HbA1c, CMS accepts values from accredited labs, CLIA-compliant point-of-care devices, health information exchanges, or lab networks. lipids, CMS recommends using assays and labs participating in CDC standardiz programs (Lipid Standardization Program or Cholesterol Reference Method Laboratory Network) for accuracy. Reporting should include total cholesterol, H cholesterol, triglycerides, and calculated LDL cholesterol, with either nonfastin

fasting samples acceptable. For HbA1c, if used for baseline eligibility to establis qualifying condition of prediabetes or diabetes, a lab-validated HbA1c is require For diagnosis of diabetes, CMS requires use of NGSP-certified HbA1c assays. A of-care A1c can be used for initial diagnosis only if FDA cleared and performed CLIA-certified moderate or high-complexity lab setting. For ongoing monitoring glycemic control for quality reporting, point-of-care HbA1c devices that are FDA cleared and CLIA-waived are acceptable.

For urine albumin-creatinine ratio, point-of-care semi-quantitative urine album tests, urine protein-to-creatinine ratio tests, or total urine protein are not consic compliant for measure reporting. These tests may be used as an initial screen, bu positive protein result must be confirmed by quantitative uACR. uACR on a first morning spot urine is preferred, but if unavailable, a random spot uACR is acceptable. For estimated glomerular filtration rate, CMS requires use of serum creatinine-based eGFR using the CKD-EPI Creatinine Equation 2021, or when creatinine is unreliable, use of cystatin C-based eGFR. When precision is needed combined creatinine and cystatin C eGFR is allowable.

For weight and BMI, weight may be reported by the patient using a home scale. is calculated as weight in kilograms divided by height in meters squared. Partici must retain documentation of the date and method of reporting (clinic versus se report).

For patient-reported outcome measures, PROMs can be administered using web portals or web-first mixed-mode approaches using web followed by phone (voice and/or paper/mail. Participants cannot make changes to the wording, response options, order, or layout conventions of any PROMs required in the model. PRO must be collected in a format that preserves scoring fidelity and allows CMS aud CMS will release additional specific guidance for each PROM and will request screenshots and copies of the patient-facing version in use. For electronic administration, specific best practices are required including testing across brov and devices to ensure readability and assistive technology compatibility, providi device instructions and training, not presenting default response selections, capt data points for all items while preventing out-of-range or illogical responses,

providing ability to go back to previous screens without auto-advancing, and providing progress indication with a final save and submit screen.

For all measures, participants must retain documentation of the data source, dat method of collection. These data are required for submission via FHIR-based pr following the Person-Centered Outcomes HL7 FHIR Implementation Guide. CM will monitor suspicious patterns and may require documentation and device log Participants may be subject to audit, corrective action, or payment recoupment i reported values cannot be substantiated. CMS reserves the right to audit any submitted values and withhold or recover payment if data quality, measurement protocol, or provenance cannot be verified.

This measurement infrastructure requirement is not decorative. It is foundation the model's functioning. Without reliable, auditable, comparable outcome data, cannot assess performance, distribute withheld payments, or publicly report risk adjusted results. Participants that treat measurement as an afterthought or atter use convenience-oriented approaches like self-reported values will fail complian requirements and lose billing eligibility.

## Care Coordination Requirements That Actually Have Teeth

ACCESS has unusually explicit and mandatory care coordination requirements. Participants must support care coordination by making reasonable efforts to ide beneficiaries' existing care team members (specifically any primary care practitic and referring clinician if applicable) and share standardized clinical updates at k points in care.

To identify the care team, participants must make a good-faith effort by asking t beneficiary during enrollment to provide the name and contact information of th current PCP and any clinician who referred them for ACCESS services, reviewin CMS-supplied information if made available at alignment which may include Medicare providers or suppliers associated with the beneficiary, optionally revie clinical data from health information exchanges to identify the PCP or referring

clinician, and documenting all steps in the beneficiary's record. If the beneficiar not identify a current PCP or referring clinician, or none can be confirmed throu CMS data, the participant's obligation under this section is considered met.

Before sharing updates, participants must obtain the beneficiary's consent to proactively share care updates with their identified care team, meeting all applic requirements under federal and state law. If the beneficiary declines, the partici obligation to share updates is satisfied.

Participants must make reasonable good-faith effort to proactively share care up with each beneficiary's identified care team using secure, nationally recognized exchange methods to the extent permitted by law. This requirement is met when participant proactively sends or attempts to send the minimum required update through a secure electronic method such as Direct Secure Messaging, an HIE-supported push mechanism, or a HIPAA-compliant exchange method. The FAQ emphasizes that "ACCESS participants will be required to send electronic updat health information exchanges or CMS Aligned Networks to patients' referring o primary care providers at initiation, completion, and clinical milestones."

To meet this obligation, participants must make reasonable effort to determine l reach the identified PCP or referring clinician by checking at least one trusted s for valid contact or routing information such as an HIE or state/regional directo DirectTrust directory, or NPPES endpoint listing. Accessing such information through a Health Information Service Provider is acceptable but not required. Participation in query-only exchange does not by itself satisfy this requirement.

Before transmitting any beneficiary information, participants must take reasona steps to ensure that information is sent only to the intended recipient, consisten requirements under federal and state law. This may include confirming the iden and secure endpoint of the receiving provider by verifying the provider's name, l and practice affiliation in a trusted exchange directory such as an HIE, DirectTr NPPES listing or by using a HIPAA-compliant data-sharing network. If the participant cannot confirm the provider's identity or secure endpoint or no valid contact information is available, the participant's obligation under this care

coordination requirement section is considered satisfied. Participants must docu
the outcome of the attempt, whether the message was successfully delivered or r
as no secure address available.

Participants must also make each standardized care plan and update reasonably
accessible to the beneficiary. CMS provides a concise, standardized care plan an
update template that participants must use to ensure consistency and minimize
burden. The template includes fields for beneficiary identifiers, contact informa
for the ACCESS participant including a monitored clinical contact who can resp
to care-related inquiries within a reasonable timeframe and the Clinical Directo
name (the FAQ uses this terminology rather than Medical Director) for oversight
purposes, baseline measures and treatment goals, active medications and relevan
laboratory results, narrative summary of progress or outcomes, and treatment pl

CMS defines minimum required updates at specific coordination reporting mom
when ACCESS participants must send updates to the identified care team. All
participants must transmit updates at care initiation within ten days of care init
communicating care plan, baseline measures, responsible contact, and initial goa
care completion within thirty days after the end of the twelve-month care period
sooner if the beneficiary disenrolls or transitions care summarizing achieved
outcomes, medications, and follow-up recommendations; and care escalation wit
ten days of any transition of the beneficiary to another clinician or care setting d
clinical needs exceeding the scope of ACCESS services.

These requirements create real operational cost and complexity. Someone has to
identify care team members, validate contact information, manage beneficiary
consent, configure and maintain secure messaging infrastructure, generate
standardized updates at specified moments, handle delivery failures and bounce
document all attempts, and maintain audit trails. For organizations already oper
like clinical delivery entities with EHR infrastructure and care coordination
workflows, these requirements are incremental work. For organizations operatin
consumer technology companies with light clinical staffing, these requirements
represent fundamental capability gaps that require buildout.

The FAQ provides critical clarification on the co-management payment mechani
“To support ongoing care coordination and encourage continued engagement be
referring health care providers and ACCESS participants, clinicians who co-mar
ACCESS beneficiaries with an ACCESS participant may bill a new ACCESS Mod
Co-Management service for documented review of ACCESS updates and care
coordination activities. The service will be paid at approximately thirty dollars p
service, subject to the geographic adjustment and standard Medicare payment
adjustments. To bill the Co-Management code, the consulting clinician must rev
the ACCESS Care Update and place a brief written note in the EHR documentin
assessment and any care coordination action, such as a medication change or
reconciliation, updated problem list, monitoring instruction, or referral. Clinici
who assist a beneficiary with onboarding and initial setup activities may also bil
Co-Management code with a CMS-specified modifier the first time they bill for
beneficiary to receive an additional payment of approximately ten dollars. The
payment will be limited to once every four months per beneficiary per track, up
approximately one hundred dollars per year. There will not be Part B beneficiary
sharing for this service and advance consent from beneficiaries would not be req
The ACCESS Co-Management Payment G-code, modifier, and additional billing
guidance will be shared in 2026.”

This co-management payment is not about the money. Thirty dollars quarterly is
changing anyone’s practice economics. The payment is about alignment and poli
feasibility. It gives primary care physicians and specialists a formal billing mech
for the work of reviewing updates and coordinating care, which legitimizes the
ACCESS participant’s role in the care ecosystem and creates a paper trail of
coordination that CMS can monitor.

## Eligibility, Enrollment, and the Evaluat
## Randomization Problem

Beneficiary eligibility and alignment mechanics create both opportunity and fric
Eligible beneficiaries include Original Medicare beneficiaries with Medicare Pa
and B as primary payer who have qualifying chronic conditions within the four

clinical tracks and are not enrolled in Medicare Advantage, PACE, or Medicare hospice benefit.

Beneficiaries can align with only one ACCESS participant in a given track at a ti but can simultaneously align with the same or different participants in multiple different tracks. The FAQ clarifies that "people can sign up in multiple different tracks from the same or different organizations." An exception applies to eCKM CKM: because CKM encompasses all eCKM clinical measures and care, benefici may not be enrolled in both tracks simultaneously. If a beneficiary is already alig to eCKM and later elects to enroll in CKM, the beneficiary may switch tracks immediately without the standard three-month lock-in period.

Clinical validation is the participant's responsibility. Participants must validate document each beneficiary's qualifying condition before initiating services throu clinical assessment by the participant, referral from another licensed clinician fo specific condition, or evidence of the qualifying diagnosis in the beneficiary's cli record or claims history within a clinically relevant timeframe.

For beneficiaries who qualify only on the basis of a reported hypertension diagn CMS recognizes that temporary blood pressure elevation in clinical settings (wh coat hypertension) can make an initial diagnosis appear valid when subsequent readings show otherwise. To accommodate this, participants may align and begi services based on patient-attested information of a hypertension diagnosis. If fol up ambulatory or home blood pressure readings confirm the beneficiary does no hypertension, the beneficiary is not on antihypertensive medication, and the beneficiary does not otherwise meet the track's qualifying conditions, the benefi will be disenrolled. Participants that submit these non-qualifying readings to Cl may retain payments for up to two months of services furnished. Participants th not submit the non-qualifying readings will have all payments for that beneficia recouped. Participants with a high rate of such non-qualifying alignments may b subject to CMS audit and corrective action.

The alignment process requires that the participant first verify coverage by quer the CMS ACCESS Eligibility API to verify that the beneficiary meets coverage cr

excluding clinical eligibility. The participant then validates that the beneficiary clinical eligibility requirements for the track. Once clinical eligibility is confirm the participant provisionally aligns the beneficiary through the CMS Alignment

Before initiating alignment, the participant must obtain and document the beneficiary's informed consent. Consent may be provided verbally or in writing a must be documented in the patient's record. Documentation must reflect that th beneficiary agreed to participate in the ACCESS Model, was informed that participation is voluntary, that only one ACCESS participant may provide servic a given track during an enrollment period, that the beneficiary may end particip or switch participants any time ninety days after enrolling, and any cost-sharing applies unless the participant has elected to offer cost-sharing support.

Within a defined number of days of enrollment, participants must submit baseli clinical and PRO measures through CMS's ACCESS Reporting API. These basel data establish the analytic starting point for outcome measurement and are requ to maintain enrollment.

To balance beneficiary choice with operational stability for participants, benefic may switch to a different participant or voluntarily disenroll any time after ninet days from the start of alignment. Beneficiaries remain aligned to the participant they become ineligible or after they have completed the ninety-day minimum alignment period and choose to switch or disenroll. Participants may initiate disenrollment only under limited circumstances as listed in the Participation Agreement, such as relocation outside the ACCESS participant's service area, documented loss of contact despite good-faith efforts, or loss of Medicare eligib

Here is where the evaluation design creates an operational wrinkle. ACCESS inc a randomized controlled trial with beneficiary-level randomization to support rigorous impact evaluation. The FAQ provides critical clarification: "Because th model's new payment approach is being tested, a small share of people who try t enroll in a specific ACCESS track may be randomly assigned to a control group f that track. This process helps CMS evaluate the model's impact, consistent with Innovation Center's authority. Individuals in a control group continue to have fu

access to all regular Medicare services and can work with their usual health care providers."

CMS will conduct the randomization and communicate assignment results to participants through the CMS Eligibility API. The randomization rate starts at n to ten intervention to control ratio in the first year and may be adjusted or elimi in future years depending on the number of beneficiaries enrolled and the evalu ability to detect model impact on improved quality and reduced Medicare spend

Before querying the API to verify a beneficiary's eligibility, participants must in the beneficiary that the service is offered as part of a new CMS payment model t and that as part of model evaluation their data may be shared with CMS subject federal privacy and security protections, that they may be randomly assigned to a comparison group and therefore ineligible to participate in the clinical track wh continuing to have access to all usual Medicare benefits and services, and that su assignment will not affect their Medicare benefits, rights, or coverage. If a benef is assigned to the control group, they will not be eligible to participate in the mo for the following twelve-month period. To preserve evaluation integrity, particip will be required to use standardized language provided by CMS when informing beneficiaries of assignment to the control group.

This randomization creates friction in the enrollment funnel. Participants must recruit and engage beneficiaries, obtain consent, complete clinical validation, an then discover that ten percent (in year one) are randomized to control and canno enroll. Those beneficiaries may feel disappointed or confused. The standardized language requirement limits participants' ability to manage this interaction with own messaging. The twelve-month exclusion means those beneficiaries cannot be enrolled later in the same year even if they remain interested.

From an underwriting perspective, investors should assume that effective conver rates will be lower than in non-randomized programs and that acquisition costs enrolled beneficiary will be higher because recruitment effort is expended on so beneficiaries who cannot ultimately enroll. The ninety to ten ratio means this is

modest headwind in year one, but if CMS adjusts the ratio to increase the contro group size in later years, the impact on growth economics becomes more materia

## The FDA TEMPO Pilot and What It Mean for Device Regulation

The FAQ introduces major new information about FDA requirements and a nove regulatory pathway specifically designed for ACCESS. The section on FDA compliance and the TEMPO pilot represents one of the most strategically signif elements for investors evaluating device-dependent digital health companies.

The FAQ clarifies that "some digital tools and connected devices used in ACCES such as mobile applications, wearables, or remote monitoring equipment, may m the definition of a device under the Federal Food, Drug, and Cosmetic Act if the intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the stru or any function of the body. These devices are generally subject to FDA oversigh provide a reasonable assurance of safety and effectiveness."

The FAQ distinguishes between regulated and non-regulated software: "Softwar functions focused only on general wellness, data storage, or administrative supp are typically not regulated as medical devices. For products that are regulated, F may require premarket authorization such as clearance of a premarket notificati (510k), or approval of a premarket approval application (PMA), depending on the device's classification and risk."

The compliance obligation is clear: "ACCESS participants are responsible for ensuring that medical devices used in the model are legally marketed with an intended use for which the device is used in the model (for example, appropriate cleared, approved, 510k-exempt, or otherwise in compliance with applicable FDA requirements), except to the extent the device is subject to FDA enforcement discretion."

Then comes the TEMPO pilot, which is a genuinely novel regulatory mechanism FAQ states: "The Technology-Enabled Meaningful Patient Outcomes (TEMPO) f Digital Health Devices Pilot is an FDA initiative for manufacturers of certain di health devices that wish to offer their devices in connection with the ACCESS m for an intended use that would generally require FDA premarket authorization, have not yet obtained such authorization."

Under TEMPO, "manufacturers may request that FDA exercise enforcement discretion and not enforce certain applicable requirements, such as FDA premar authorization requirements, when their device is offered to or by ACCESS participants for an intended use to improve patient outcomes, to be used in prov care expected to be covered by the ACCESS model. Under the ACCESS model, ACCESS participants may use a device consistent with any plan for mitigating ri patients and collecting, monitoring, analyzing, and reporting real-world perform data that the manufacturer has discussed with FDA in connection with FDA's determination that it is appropriate to exercise enforcement discretion for the d under the TEMPO pilot."

The data collection requirement is explicit: "During ACCESS participation, use devices under the TEMPO pilot will generate real-world data that may support assessment of safety, performance, and potential future FDA marketing submiss and additional data collection beyond what is ordinarily reported in the ACCES be provided to FDA as agreed upon with FDA."

The FAQ emphasizes that "TEMPO pilot participation is optional. It may be particularly valuable for organizations developing certain digital health devices would generally require FDA premarket authorization, by facilitating the use of devices in a controlled context while real-world data are collected under FDA oversight."

The beneficiary consent requirement is stricter for TEMPO devices: "ACCESS participants that choose to use a device in the TEMPO pilot must obtain enhanc consent from enrolled beneficiaries, informing them that the device is participat

an FDA pilot and that certain data will be shared with FDA, consistent with all applicable federal privacy and security requirements."

The application process is separate: "Manufacturers interested in TEMPO shoul apply directly to FDA once the application process opens."

This TEMPO mechanism is strategically important for several reasons. First, it creates a viable path for digital health devices that have not yet obtained FDA clearance to participate in ACCESS, which significantly expands the addressable company universe. Second, it shifts real-world evidence generation into a reimbu clinical setting rather than requiring companies to fund expensive RCTs before market access. Third, it creates a structured pathway from pilot use under enforcement discretion to eventual marketing authorization using the same real· data.

For investors, TEMPO creates both opportunity and complexity. Companies wit devices that would benefit from this pathway gain market access they otherwise not have, but they also take on FDA oversight, enhanced consent requirements, a data submission obligations beyond standard ACCESS reporting. The enhanced consent requirement may reduce enrollment conversion rates compared to participants using already-cleared devices. The data sharing with FDA creates regulatory risk if performance data reveals safety or effectiveness concerns.

Companies should evaluate whether TEMPO participation makes strategic sens based on their device regulatory status, their confidence in device performance u real-world conditions, and their ability to manage the enhanced compliance and reporting burden. For some companies, TEMPO is a lifeline enabling ACCESS participation that would otherwise be impossible. For others with already-cleare devices, avoiding TEMPO and its enhanced requirements is the cleaner path.

## ACO Benchmark Treatment and Cross-Payer Alignment Mechanics

The FAQ provides critical clarification on how ACCESS interacts with Accounta Care Organizations and other payers, information that was not detailed in the R

On ACO benchmark treatment, the FAQ states: "ACCESS is designed to comple existing ACO and risk-bearing arrangements by incentivizing ACOs to leverage technology-enabled care to meet quality and savings goals. For 2026 and 2027, C will be making system changes to support model operations and CMS anticipate there will be no impact from ACCESS Outcome-Aligned Payments on ACO benchmark and performance year calculations for the Medicare Shared Savings Program and ACO REACH. Beginning in 2028, expenditures associated with AC OAPs will be included in ACO benchmark and performance year calculations."

This two-year exclusion period is strategically important. It creates a window wh ACOs can experiment with ACCESS participants and evaluate their impact on q and total cost of care without the spending immediately affecting their benchma ACCESS participants prove effective at managing chronic conditions and reduci downstream utilization, ACOs benefit from the savings without the payment am raising their benchmarks. Starting in 2028, the spending gets incorporated, whic means ACOs need to demonstrate that the ACCESS payments plus any remainin utilization for those beneficiaries are lower than what would have occurred with ACCESS.

For investors, this creates a favorable window for companies to establish relatio with ACOs and demonstrate value before the benchmark incorporation happens ACOs have strong incentive to test ACCESS participants in 2026-2027 since the downside risk is limited (they can terminate relationships if outcomes are poor) the upside potential from improved chronic disease management and reduced ac utilization is not offset by benchmark increases. After 2028, the calculus change ACOs will be more selective, favoring only those ACCESS participants who can demonstrate total cost of care reduction net of the OAP amounts.

The FAQ also addresses cross-payer alignment extensively. For Medicare Advant the guidance is clear: "ACCESS is being tested in Original Medicare, but Medica Advantage organizations may independently adopt similar outcome-aligned payı

arrangements with their contracted providers. MA plans do not need a waiver to implement such arrangements and have flexibility to structure payments under existing program requirements."

The medical loss ratio treatment is important: "Outcome-based payments for pa care would generally be considered medical expenses in the MLR numerator wh benefits and payment arrangements satisfy the requirements under 42 CFR 422.2420(b)(2) and 422.2430(a), to qualify as incurred claims or quality improvem activities and are not claims or activities that are otherwise excluded under regulations. Therefore, no MLR policy changes are needed to support these type payments."

This MLR clarification removes a major barrier to MA plan adoption of ACCES models. Plans can treat the outcome-based payments as medical expenses that c favorably in their MLR calculations rather than administrative costs that do not, making the economics more attractive.

For Medicaid, the FAQ states: "States may allow Medicaid managed care plans t voluntarily implement ACCESS-like approaches through the In Lieu of Services Settings (ILOS) authority under 42 CFR 438.3(e)(2) and 438.16. Under this autho plans have the option to provide services or settings that are medically appropri and cost-effective substitutes for services or settings covered under the state pla willing beneficiaries if authorized by the state. States have flexibility to determi whether and how an ACCESS-like model qualifies as an ILOS and how it is refle in managed care contracts, as long as the state complies with all of the requirem in 42 CFR part 438. Because the ILOS authority is part of existing managed care regulations, states typically do not need a separate CMS waiver to implement su model."

This guidance makes clear that Medicaid managed care plans can adopt ACCES payment models without needing state plan amendments or waivers, significantl reducing the regulatory friction for multi-payer alignment. States still need to authorize the approach, but the pathway exists within current regulations.

The cross-payer alignment strategy is explicit in CMS's approach. The FAQ note "ACCESS is designed to promote consistent, outcome-based payment structures across payers. CMS will make available payer implementation resources, includi reference provider agreements, source code, and technical documentation, to he payers optionally align their contracting and performance models with ACCESS

For investors, this multi-payer alignment potential is critical to long-term value creation. Companies that can demonstrate strong outcomes in Medicare ACCES become attractive partners for MA plans and Medicaid MCOs looking to adopt similar approaches. The standardized G-codes, outcome measures, and reporting infrastructure create interoperability across payers, reducing the administrative burden of multi-payer participation compared to fully custom contracts with ea plan.

However, the timing and extent of actual multi-payer adoption remains uncertai plans and Medicaid MCOs will watch Medicare ACCESS performance data befo committing to similar arrangements. If early ACCESS participants demonstrate outcomes and cost savings, adoption will accelerate. If performance is mixed or are not well-controlled, payers will remain cautious. Investors should model mu payer revenue as upside opportunity rather than base case, with realization depe on demonstrated Medicare performance.

## The ACCESS Tools Directory and What I Signals About CMS Strategy

The FAQ introduces a previously undisclosed element that reveals important information about CMS's implementation approach and market-building strateg The ACCESS Tools Directory represents CMS taking on an active market-makin rather than simply defining payment rules and letting participants figure out execution.

The FAQ states: "To further support participation, CMS will launch an ACCESS Directory, a CMS-hosted informational resource within the ACCESS application participant portal. The directory will help organizations identify optional softwa

and hardware tools that may support model participation and compliance, such
data exchange and interoperability solutions, identity verification systems, optio
connected clinical devices like blood pressure cuffs, and tools that support HIPA
compliance."

The inclusion of promotional offers is notable: "Vendors listed in the directory r
also choose to include optional promotional offers, such as product discounts or
service credits, for ACCESS participants. Any such offers must comply with all
applicable federal and state laws, including those governing beneficiary inducem

The liability and endorsement disclaimers are careful: "Participation in the dire
would be voluntary and non-endorsing. Vendors would submit their own listings
self-certify that their products meet all applicable federal and state requirement
including applicable FDA requirements or are otherwise subject to FDA enforce
discretion. CMS would conduct a basic review for completeness and relevance b
would not independently verify, approve, or endorse any listed products. No
proprietary, confidential, or beneficiary information would be collected or share
connection with this directory."

The interest mechanism is already open: "Vendors interested in being notified w
the application form becomes available can sign up using the ACCESS Interest F

This directory serves multiple strategic purposes for CMS. First, it lowers barrie
entry for smaller participants who might struggle to identify compliant vendors
critical infrastructure like HIE connectivity, FHIR APIs, or validated devices. Se
it creates competitive pressure on vendors to offer favorable pricing to ACCESS
participants, which indirectly subsidizes participation costs. Third, it provides C
with market intelligence about which vendors are actively supporting ACCESS a
what their pricing looks like. Fourth, it creates a curated ecosystem that reduces
fragmentation and improves interoperability across participants.

For vendors, inclusion in the directory is valuable marketing and distribution. B
listed signals CMS recognition of relevance to the model even without explicit
endorsement. Promotional offers can be used to acquire customers who might n

otherwise consider the vendor's products. However, vendors take on self-certific liability and need to ensure their products actually meet the requirements they c

For ACCESS participants, the directory is primarily useful for organizations bui infrastructure from scratch. Established digital health companies with existing c supply chains, data infrastructure, and HIE connectivity may not need the direct But for provider organizations or smaller technology companies entering the ma the directory reduces the research and procurement burden for critical compliar infrastructure.

For investors, the existence of the directory signals that CMS expects a meaning number of participants will need to build or acquire infrastructure capabilities t currently lack. This validates the thesis that ACCESS creates market opportunit also confirms that operational complexity is real and not all applicants will be re execute even if accepted into the model.

## What Has to Be True Operationally for Anyone to Make Money

ACCESS rewards a very specific operating model and punishes everything else. T simplest characterization is that CMS is turning chronic care into a receivables business where clinical KPIs function as the collection mechanism and compliar infrastructure is the price of admission.

Working capital has to be available because half the annual payment is withheld released only after the care period ends pending performance reconciliation. A participant enrolling one thousand beneficiaries at three thousand dollars annua payment per beneficiary has one point five million dollars in withheld payments steady state assuming uniform enrollment throughout the year. Scaling to ten thousand beneficiaries creates fifteen million dollars in withheld payments. This working capital requirement scales linearly with patient volume, creating increa capital needs as companies grow rather than the improving cash conversion dyna typical of SaaS businesses. Companies must finance the withheld amount throug

equity capital, venture debt, or strong operating cash flow from the fifty percent quarterly.

Panel management has to be rigorous because outcomes are assessed at the pane not individual patient level. The Outcome Attainment Rate measures the percen of completed care periods meeting all targets, so performance depends on achiev consistent outcomes across a meaningful share of the population. The FAQ emphasizes that "CMS determines payment based on the overall share of patient meet their defined outcomes, compared to a minimum threshold that increases v each participation year." Small panels create statistical noise where a few patient missing targets can drop the OAR below threshold. Large panels without proces discipline create operational quality problems where care delivery becomes inconsistent and outcome rates deteriorate. Companies need to find the scaling window where panels are large enough to smooth variance but not so large that clinical quality collapses.

Measurement operations have to be bulletproof because missing data is not neut Claims submissions are attestations that required measures have been submitted billing eligibility depends on timely measure reporting. If device integrations fai PROM completion rates drop, or data pipelines break, revenue is at risk even if care delivered was clinically sound. Companies need monitoring systems, except handling workflows, technical support infrastructure, and audit-ready documen to ensure measurement completeness and provenance.

Care pathway design has to align to guideline-based targets CMS specified and produce measurable change not just engagement. In CKM and eCKM, blood pre control and lipid management are not optional nice-to-haves. They are revenue determinants. In MSK, functional outcomes measured via PROMs are what matt not patient satisfaction with the coaching experience. In BH, symptom reduction validated scales and functional improvement on WHODAS are the outcomes CM pays for. Companies built around engagement metrics, NPS scores, or self-repor satisfaction will discover those metrics do not translate to ACCESS revenue unle they also drive the specific clinical and functional outcomes CMS measures.

Leakage control has to be managed because the substitute spend adjustment per parallel care initiation. Meeting the ninety percent threshold requires that at lea ninety percent of aligned beneficiaries do not receive listed substitute services fr other Medicare providers for the same condition during the care period. This re coordination with primary care, rapid access to prevent beneficiaries from seeki care elsewhere due to access barriers, comprehensive scope to address the full ra of needs within the track, and monitoring plus intervention to detect early warn signs before external utilization occurs.

Device logistics for eCKM and CKM tracks create operational complexity and ca intensity. Participants must purchase, provision, ship, and support cellular-conn blood pressure cuffs for all enrolled beneficiaries, with the payment rate incorporating expected device costs rather than allowing separate billing. Comp need inventory management, shipping workflows, technical support, pairing and onboarding processes, identity resolution to match devices to patients, and devic failure replacement protocols. The trade-off between device cost and quality ma because cheaper devices with higher failure rates reduce upfront capital but inc support costs and potentially impact outcome measurement reliability.

The ACCESS Tools Directory may help here by connecting participants with dev vendors offering promotional pricing, but participants still own the operational execution and capital outlay.

Clinician staffing and Clinical Director oversight have to be real. The Clinical Director role (the FAQ consistently uses this term rather than Medical Director the RFA) carries explicit accountability for clinical policies and procedures, pati safety plans, outcome monitoring and validation, corrective action, and regulato compliance. The FAQ emphasizes that “organizations must enroll in Medicare as providers or suppliers and designate a physician Clinical Director to oversee cli quality and compliance.” This is not a figurehead position. CMS requires the Cli Director to be a Medicare-enrolled physician who is an employee or under contr with the participant.

All physicians and non-physician practitioners furnishing or supervising care m individually Medicare-enrolled participating providers or suppliers who have reassigned their Medicare billing rights to the participating TIN and are practic within applicable licensure and scope of practice standards. This reassignment requirement effectively prohibits use of contractors or 1099 arrangements for cc clinical staff unless those individuals have formally reassigned billing rights, wh typically requires employment or more structured contractual relationships thar simple independent contractor agreements.

FDA compliance infrastructure becomes necessary for any participant using dev that meet the definition of medical devices under the FD&C Act. The FAQ is cle that "ACCESS participants are responsible for ensuring that medical devices use the model are legally marketed with an intended use for which the device is usec the model." For companies using devices not yet cleared, the TEMPO pilot provi path but adds FDA oversight, enhanced consent requirements, and data submiss obligations beyond standard ACCESS reporting.

Medicare enrollment must be completed before participation. The FAQ directs organizations to the Provider Enrollment, Chain, and Ownership System (PECO emphasizes that "because ACCESS applications cannot be approved until Medic enrollment is complete, organizations that are not yet enrolled are encouraged t begin the Medicare enrollment process as early as possible to avoid delays in mo participation."

# Underwriting Framework for Investors

For venture investors evaluating ACCESS-focused companies, the traditional dig health underwriting framework requires significant modification. Standard SaaS metrics around annual recurring revenue, net dollar retention, customer acquisi cost, and lifetime value remain relevant but insufficient for assessing businesses where fifty percent of revenue is withheld for up to twelve months and final payı depends on achieving specific clinical outcome thresholds for a percentage of patients.

The first underwriting question is whether the company can actually be the participant. ACCESS participation requires Medicare Part B enrollment as prov or supplier excluding DMEPOS and laboratory suppliers. The FAQ clarifies the enrollment process and timeline implications. If the company is a pure software vendor or platform operator, it cannot directly participate without building or acquiring a provider entity, which changes compliance posture, governance, liab exposure, and cost structure fundamentally. Investors should treat this as a core capability question not a minor operational detail.

The second underwriting question is clinical outcomes track record with the spe rigor ACCESS requires. The FAQ emphasizes that "full payment depends on ach measurable health outcomes, such as improvement or control of blood pressure hypertension." Rather than evaluating published studies or customer testimonia supporting evidence for product effectiveness, investors must assess clinical out data as direct predictors of revenue realization. A company with strong user engagement metrics and customer satisfaction but inconsistent clinical outcome faces significantly impaired revenue potential compared to one with modest engagement but reliable outcome achievement.

The distribution of patient outcomes across the population matters more than a outcomes because the Outcome Attainment Rate measures the percentage of pat meeting all required targets rather than average improvement. A company achie fifteen mmHg average blood pressure reduction but with high variance such tha forty percent of patients meet the ten mmHg threshold faces a twenty percent re reduction via the Clinical Outcome Adjustment in year one. A company achievir eleven mmHg average reduction with lower variance such that fifty-five percent threshold receives full payment despite lower average improvement. Investors sh request outcome distribution data not just means and ask what percentage of th current patient population would meet ACCESS targets if enrolled today.

The ability to predict which patients will achieve outcomes before enrollment significantly impacts unit economics and potentially creates adverse selection dynamics. Companies that can identify likely responders and focus enrollment o those patients could achieve higher Outcome Attainment Rates and capture full

payments, while those with less selective enrollment or emphasis on serving challenging patients may face payment reductions despite delivering valuable ca The required clinical exclusions prevent the most severe selection, but substanti room remains for variation in patient population risk. Investors should understa patient selection criteria, assess whether they constitute cherry-picking or appropriate matching of clinical capability to patient need, and model how aggr selection affects addressable market size.

Working capital implications of fifty percent payment withholding create substa capital intensity beyond typical digital health models. Investors should model withheld balances at target enrollment milestones and ensure sufficient capital i raised to finance working capital needs through projected growth. The withhold mechanics also create asymmetric risk: companies that grow quickly accumulate withheld balances before outcome data from early cohorts is available, creating exposure if early performance is weaker than projected. Conservative underwrit should stress test scenarios where year one outcome attainment lands at forty pe triggering twenty percent revenue reductions and model the impact on cash run and follow-on funding needs.

The FFS exclusion creates revenue displacement risk for companies that current derive Medicare revenue from fee-for-service billing or operate through provide entities that do. The exclusion prevents participants and affiliated entities from billing Medicare FFS for aligned beneficiaries during active care periods. Affilia is defined as five percent or greater ownership interest, operational control or da day management, or reassignment relationships. For provider groups currently monetizing chronic care management codes, remote patient monitoring codes, a episodic visits, shifting patients into ACCESS represents revenue migration not revenue. Investors should model the displacement impact and assess whether OA payments more than compensate for lost FFS revenue.

Measurement provenance readiness is critical. Programs relying on self-reporte values will fail compliance requirements. Investors should assess what percentag the target population currently uses connected devices meeting CMS requireme how often readings are taken and whether protocols align with CMS standards,

logistics including procurement, provisioning, shipping, pairing, technical supp and failure replacement, data integration architecture including timestamping, s verification, identity resolution, and audit trails, and PROM administration infrastructure including mode of delivery, response rate monitoring, and scorin fidelity. The ACCESS Tools Directory may provide vendor options, but participa still own execution and costs.

Care coordination capability determines substitute spend performance. The nin percent threshold allows only minimal external service initiation before paymen reductions begin. Investors should assess the company's health information exch connectivity and Direct Messaging infrastructure (or ability to access vendors th the Tools Directory), monitoring of beneficiary claims data via BCDA API to det external utilization, protocols for coordinating with primary care and referring clinicians, rapid access and responsiveness to reduce beneficiary incentive to see elsewhere, and comprehensiveness of service offerings relative to track scope.

FDA compliance infrastructure requires evaluation for any company using devic meeting the medical device definition. The FAQ makes clear that participants ar responsible for ensuring devices are legally marketed for their intended use. Companies with FDA-cleared devices have straightforward compliance. Compar with devices not yet cleared must evaluate whether TEMPO participation makes strategically. TEMPO provides market access but adds FDA oversight, enhanced beneficiary consent requirements reducing conversion rates, and data submissio obligations. Investors should model the impact of enhanced consent on enrollme conversion and assess whether the company can manage the additional regulator burden.

The regulatory and compliance infrastructure required for Medicare participati creates both barriers to entry and potential moats. Companies already participat Medicare through other pathways have significant advantages, while pure consu or commercial-only companies face twelve to eighteen month buildout timelines FAQ guidance on Medicare enrollment through PECOS provides a clear path bu timeline is long enough that companies should start immediately. Investors shou assess whether the company has existing Medicare enrollment and billing

infrastructure, prior experience with CMS models or Medicare Advantage, compliance and program integrity capabilities including documentation, audit preparedness, and internal controls, and health information technology infrastru including FHIR APIs, HIE connectivity, and care coordination workflows.

ACO relationship strategy becomes important given the two-year benchmark exclusion period for ACCESS spending. Companies should evaluate opportuniti partner with ACOs in 2026-2027 to demonstrate value before the spending gets incorporated into benchmarks in 2028. ACOs have incentive to test ACCESS participants during the exclusion window since downside is limited while upsid improved chronic disease management is not offset by benchmark increases. Aft 2028, only ACCESS participants demonstrating total cost of care reduction net c OAP amounts will be attractive ACO partners. Investors should assess the comp ACO relationships and strategy for demonstrating total cost of care value.

Multi-payer alignment potential depends on Medicare performance. The FAQ cl that MA plans can adopt similar arrangements without waivers and that Medica MCOs can use ILOS authority. CMS providing reference payer implementation resources further reduces friction. However, other payers will wait for Medicare performance data before committing. Investors should model multi-payer revenu upside dependent on strong Medicare outcomes rather than base case.

The talent and organizational capability requirements are distinct from typical c health hiring needs. Clinical Directors qualified to oversee virtual chronic disea management programs and willing to assume the accountability and liability the entails may be limited particularly for smaller or earlier-stage companies. Clinic staff capable of delivering effective technology-enabled care while meeting documentation and compliance requirements need training and management. Technology and operations teams must develop FHIR integration, HIE connectiv and care coordination capabilities many digital health companies lack.

## Twenty Company Examples: Who Fits, Who Gets Wrecked, and Why

These examples are based on the representative organizations image showing companies that submitted intent to apply to ACCESS. Analysis focuses on publi available information about business models, clinical focus areas, and operation capabilities to assess fit with ACCESS requirements including the new informat from the FAQ. These are not claims that any specific company is definitely apply predictions of success, but rather illustrations of how different business models capabilities map to ACCESS underwriting considerations.

Omada Health operates a comprehensive digital care platform for cardiometabol conditions including diabetes prevention, diabetes management, hypertension, a musculoskeletal health. Founded in 2011 with over 250 million raised, the comp serves more than 1900 employers and health plans reaching over 15 million eligi members. Omada reports published outcomes data showing A1c reductions, wei loss, and blood pressure improvements in their commercial population.

For ACCESS underwriting with the new FAQ information, Omada's strengths in direct clinical focus alignment with eCKM and CKM tracks, existing connected device operations for blood pressure monitoring and weight scales that could me timestamped source-verifiable transmission requirements, established care deliv infrastructure with coaches and clinicians, and demonstrated outcomes in target conditions. The key diligence questions are whether Omada has completed Med Part B enrollment or has timeline to complete before their target cohort start (th

FAQ emphasizes starting this process immediately), how their Clinical Director structure and physician oversight will satisfy ACCESS requirements given their historic coach-centric model, whether outcome distributions in their commercia population translate to Medicare populations and meet ACCESS thresholds, hov will manage the FFS exclusion if they operate through or alongside provider ent that currently bill Medicare, and whether their devices meet the validation and connectivity requirements or need to be upgraded.

The device cost integration for eCKM and CKM where the payment rate incorpo blood pressure cuff costs rather than separate billing may work in Omada's favo they already distribute connected devices and have optimized supply chain and logistics. The ACCESS Tools Directory could provide alternative device vendors their current suppliers do not meet requirements. Their challenge is demonstrat that their care model can achieve outcome targets across the full bundle of requi measures including blood pressure, lipids, weight, and A1c, not just the subset t have historically emphasized in marketing.

Omada likely does not need TEMPO since they focus on lifestyle intervention ar coaching rather than novel medical devices requiring FDA clearance, but they st need to ensure any devices used meet FDA requirements.

Virta Health focuses specifically on type 2 diabetes reversal through continuous remote care combining medical, nutritional, and behavioral support with an emp on nutritional ketosis. Founded in 2014 with over 370 million raised, the compa publishes peer-reviewed clinical outcomes data demonstrating A1c reductions, medication discontinuation, and weight loss with two-year data showing sustain diabetes reversal for a meaningful percentage of patients.

Virta's physician-led care model with continuous remote monitoring maps closel ACCESS CKM track requirements. Their strength is demonstrated clinical outc in diabetes specifically, with published data that could directly support ACCESS underwriting. The questions are whether their intensive nutritional ketosis intervention can achieve outcomes across the full CKM measure set including bl pressure and lipid control which may not be as central to their current protocol,

whether their emphasis on medication reduction creates tension with CMS outc targets that allow any path to control including medication use, how they will m patients with CKD or ASCVD in addition to diabetes given their historic diabet focus, and whether their care intensity and cost structure works under ACCESS payment rates that will be announced in 2026.

Virta's emphasis on diabetes remission is clinically valuable but not what ACCE explicitly pays for. ACCESS measures A1c control or reduction, not remission or medication freedom. If Virta's model achieves A1c targets but requires higher ca intensity than payment rates support, the unit economics fail even if clinical out are strong.

Virta likely needs to add blood pressure cuff distribution for their CKM patient not already doing so, and ensure the devices meet the timestamped source-verifi transmission requirements. They may be able to source these through the ACCE Tools Directory if needed. They do not appear to need TEMPO since their intervention is primarily nutritional and behavioral with physician oversight rat than depending on novel medical devices.

Teladoc Health via their Livongo acquisition operates connected device program diabetes and hypertension reaching millions of members through employer and plan contracts. As a large publicly traded incumbent with over ten billion marke capitalization at various points, Teladoc has resources for Medicare infrastructu buildout and regulatory compliance.

The underwriting concerns for an incumbent are strategic alignment and execut focus. ACCESS requires the participant to own Medicare compliance, outcome accountability, and care coordination in ways that large platforms typically dele payer partners. If Medicare is a strategic priority with dedicated product and operations teams, Teladoc could leverage existing device distribution and coachi infrastructure. If Medicare is treated as a small experimental channel, execution quality will suffer and outcome performance may lag.

The FFS exclusion is particularly important for Teladoc if they operate through own provider entities that currently bill Medicare for telehealth visits, chronic c management, or other services. Shifting patients into ACCESS could cannibalize existing revenue streams. Investors should model this as a portfolio optimizatior problem not pure incremental opportunity.

Teladoc's Livongo devices likely meet basic connectivity requirements but may r upgrades to ensure timestamped source-verifiable transmission with manual ent prohibited. The ACCESS Tools Directory is probably not necessary for Teladoc g their scale and existing vendor relationships. TEMPO is unlikely to be relevant u they are developing novel device capabilities.

The two-year ACO benchmark exclusion period creates opportunity for Teladoc partner with ACOs for ACCESS participant services in 2026-2027 without imme benchmark impact, then demonstrate total cost of care value before the spendin incorporated in 2028.

Hinge Health and Sword Health represent the digital MSK category with physica therapy programs combining exercise therapy, wearable sensors or computer vis and PT oversight. Hinge Health founded in 2014 has raised over 800 million and serves more than 1200 employer and health plan customers. Sword Health found 2015 has raised over 300 million serving over 2000 enterprise customers. Both companies publish outcomes data showing pain reduction and function improve

For ACCESS MSK, these companies have clear clinical alignment and existing outcome measurement via PROMs. Their challenges are substitute spend manag and Medicare population characteristics. MSK is the track where substitute serv are most common because beneficiaries with chronic pain frequently receive phy therapy, imaging, injections, and specialty consultations from other providers. Keeping substitute PT and OT evaluations below ten percent of the panel requi tight primary care coordination and rapid access.

The FAQ clarification that "the MSK track is focused on resolving chronic pain during the initial care period and does not include an optional follow-on period"

critical for unit economics. Unlike eCKM, CKM, and BH where participants can generate recurring revenue from Follow-On Period payments, MSK participants get one twelve-month bite per patient. This means customer lifetime value is capped at the Initial Period payment, and participants need continuous new patient acquisition rather than building a stable recurring revenue base from retained patients.

This single-period structure makes MSK economics fundamentally different and potentially less attractive than other tracks unless the Initial Period payment rate is substantially higher to compensate for lack of continuation revenue. Investors should carefully model customer acquisition costs against single-period revenue and assess whether the unit economics work without Follow-On Period payments.

The Medicare population also differs from employer populations in important ways. Older adults have more comorbidities, mobility limitations, and potentially cognitive issues affecting exercise therapy adherence. Programs designed for working-age adults may need significant protocol modifications for Medicare populations. Investors should assess whether the companies have Medicare-specific outcome data or will be extrapolating from commercial experience.

The MSK PROM-based outcome measures mean revenue depends entirely on patient-reported pain and function scores, not on clinical biomarkers. This creates different measurement challenges around PROM completion rates, response validity, and potential for gaming. CMS's requirement that PROMs be collected without modification and with audit-ready documentation is designed to prevent this, but participants still need robust measurement operations.

Neither Hinge nor Sword likely needs TEMPO since their wearable sensors and computer vision systems for exercise tracking are likely not classified as medical devices requiring premarket authorization, or if they are, the companies likely already have appropriate clearances. The ACCESS Tools Directory may be useful for HIE connectivity or identity verification systems if these companies do not already have these capabilities.

Noom, known for psychology-based weight management with over 650 million r and tens of millions of users globally, represents the consumer behavior change category. For ACCESS eCKM where obesity is a qualifying condition, Noom's hi strength in engagement and habit change could be relevant.

The fundamental question is whether Noom has or can build the clinical entity a biomarker monitoring infrastructure ACCESS requires. Their consumer model v subscription pricing and app-based content differs substantially from Medicare' enrollment, payment, and compliance requirements. The FAQ emphasizes that participants must be Medicare Part B enrolled providers or suppliers with physi Clinical Directors and compliance with HIPAA as covered entities. If Noom has expanded into clinical weight management with prescribing, device-connected monitoring, and outcome measurement, ACCESS could be viable. If they remain primarily a consumer engagement app with light clinical staffing, the gap to AC requirements is large.

The eCKM track requires not just weight management but integrated manageme hypertension, dyslipidemia, and prediabetes with blood pressure, lipid, weight, a A1c outcome targets. Noom would need to demonstrate capability across this fu clinical scope, not just weight loss, to succeed in ACCESS.

Noom would need to add blood pressure cuff distribution meeting the timestam source-verifiable transmission requirements, likely source these through the AC Tools Directory since device logistics are not their current core competency, con Medicare Part B enrollment, hire or contract a physician Clinical Director, build connectivity for care coordination, and implement FHIR reporting infrastructur This is a substantial buildout suggesting ACCESS is not a near-term opportunity unless they have been quietly developing these capabilities.

TEMPO is unlikely to be relevant for Noom unless they are developing novel me devices for metabolic monitoring or intervention.

Headspace represents the consumer meditation and mindfulness category that h expanded into clinical behavioral health through acquisitions. Their Ginger

acquisition and subsequent merger created Headspace Health combining on-der mental health coaching and therapy with the consumer mindfulness app.

For ACCESS BH, the clinical behavioral health platform from Ginger could potentially support participation while the consumer Headspace app would not directly generate ACCESS revenue. The FAQ clarifies that participants must be Medicare Part B enrolled providers or suppliers with physician Clinical Directo The key questions are whether Headspace Health operates as a Medicare-enrolle clinical entity capable of being the participant, whether their care model can ach PHQ-9, GAD-7, and WHODAS outcome targets in Medicare populations, how th will manage Clinical Director oversight and physician involvement given their h coach and therapist focus, and whether their digital-first asynchronous model provides sufficient clinical touchpoints for older adults with depression and anx who may have complex medication regimens and comorbidities.

The BH requirement that all patients receive both PHQ-9 and GAD-7 assessmer regardless of primary diagnosis, plus WHODAS functional assessment, creates measurement burden. Programs built for employer populations accustomed to a based surveys may face lower completion rates in Medicare populations with les digital fluency.

Headspace likely does not need TEMPO since therapy and coaching delivered by licensed clinicians does not involve medical devices requiring FDA clearance. Th would need to ensure Medicare enrollment, Clinical Director designation, HIE connectivity for care coordination, and FHIR reporting infrastructure. The ACC Tools Directory may be useful for these compliance infrastructure pieces.

The two-year ACO benchmark exclusion creates opportunity for Headspace to p with ACOs seeking behavioral health management without immediate benchma impact, which could be a valuable go-to-market channel.

Brightside, Meru Health, Grow Therapy, and SonderMind represent different BH operating models. Brightside offers psychiatry and therapy with medication management for anxiety and depression. Meru Health provides a structured digi

program with therapist support and biofeedback. Grow Therapy and SonderMir marketplace and network models helping people find therapists and navigate insurance.

Brightside's medication management focus aligns with BH track requirements a their psychiatry involvement could support Clinical Director designation. The questions are Medicare enrollment status, outcome attainment rates in their cur population, and care coordination infrastructure for interacting with primary ca physicians. They likely do not need TEMPO and could use the Tools Directory f HIE connectivity if needed.

Meru Health's structured program with biofeedback introduces operational que about hardware logistics and whether the biofeedback component is necessary t achieve outcomes or creates friction that hurts retention. Their model would ne demonstrate that the structure and biofeedback translate to measurable PHQ-9 GAD-7 improvement meeting CMS thresholds. Depending on how their biofeed hardware is classified, they might need FDA clearance or could potentially use TEMPO if the device improves outcomes but is not yet cleared.

Grow Therapy and SonderMind face the hardest path because marketplace mod structurally misaligned with ACCESS. The FAQ emphasizes that participants m have physician Clinical Directors overseeing care delivery and achieving outcom ACCESS pays a participant entity to manage outcomes across a panel with standardized protocols and measurement. Marketplaces connect people to independent clinicians who practice autonomously. To participate in ACCESS, t companies would need to transform into clinically governed care delivery organizations with centralized measurement, quality oversight, and accountabili That is a different business requiring different capabilities and economics. The ACCESS Tools Directory does not solve this structural problem.

Biofourmis operates remote patient monitoring and analytics with FDA-cleared algorithms for detecting clinical deterioration, historically focused on heart fail and post-discharge monitoring. For ACCESS, their FDA clearances and clinical validation studies could support regulatory compliance, but their traditional ho

and health system customer base differs from the direct-to-patient enrollment m
ACCESS requires.

If Biofourmis has expanded into continuous chronic disease monitoring for cardiometabolic conditions, their sensor technology and analytics could support eCKM or CKM track participation. The questions are whether they have built th patient enrollment, care delivery, and engagement infrastructure required for longitudinal chronic disease management versus their historic acute monitoring focus, and whether their device costs and clinical staffing models work under ACCESS payment rates.

Biofourmis likely already has FDA clearances for their devices so TEMPO is pro not needed, though they could potentially use it if developing new device capabi specifically for ACCESS. Their existing FDA regulatory experience is an advanta The ACCESS Tools Directory may be useful for HIE connectivity and identity verification systems to support the direct-to-patient model.

Cadence, Somatus, and Monogram Health represent value-based kidney care and home specialty provider models. CKD is explicitly part of the CKM track and CI includes eGFR and uACR submission requirements in the measure set.

These operators are already built to handle complex Medicare populations, mult clinician care coordination, and outcome accountability through existing value-b contracts. Their advantage is operational maturity in Medicare and comfort with based payment. The unique challenge is the FFS exclusion and how it interacts v existing billing patterns. If they currently bill for nephrology visits, chronic care management, transitional care, or other services, shifting beneficiaries into ACC could suppress those claims during active care periods.

The FAQ clarification on ACO benchmark treatment is particularly relevant for companies. The two-year exclusion period means they can partner with ACOs fo ACCESS-based kidney care management in 2026-2027 without the spending affe ACO benchmarks immediately. If they demonstrate value in reducing total cost

care through better CKD management and progression prevention, ACOs will continue the relationship after the spending gets incorporated in 2028.

Investors should model ACCESS as a portfolio optimization question: where doe sit relative to existing kidney-focused value-based contracts, does the OAP compensate for displaced FFS revenue plus the incremental cost of meeting AC requirements, and does the fifty percent withholding create working capital stra given their existing capital structure.

These companies likely do not need TEMPO and probably already have most rec compliance infrastructure. The ACCESS Tools Directory may not add much valu these mature Medicare participants.

Hello Heart focuses on blood pressure tracking and cardiovascular risk reductio which maps directly to eCKM and CKM hypertension management. However, as device and app company rather than a clinical provider entity, Hello Heart faces structural challenges becoming an ACCESS participant directly. The FAQ is clea participants must be Medicare Part B enrolled providers or suppliers with physi Clinical Directors. The more plausible pathway is serving as measurement infrastructure for participants via inclusion in the ACCESS Tools Directory.

If Hello Heart has built or acquired clinical operations to become a provider ent ACCESS could be viable. Investors should assess whether they have Medicare enrollment, physician Clinical Director designation, care delivery staff, and the f clinical scope to manage the eCKM or CKM measure bundle beyond just blood pressure.

Alternatively, Hello Heart could position as a vendor in the ACCESS Tools Direc providing validated blood pressure cuffs and monitoring infrastructure to ACCE participants. This is probably the more natural fit given their current business n

AliveCor and iRhythm operate in cardiac monitoring with FDA-cleared devices f arrhythmia detection. These are not directly aligned with initial ACCESS tracks cardiac arrhythmia monitoring is not part of eCKM or CKM. Their relevance is indirect: arrhythmia detection can support cardiometabolic risk management, bu

ACCESS payments are tied to the track outcomes CMS defines (blood pressure, l
weight, A1c), not broader risk detection.

Unless CMS adds cardiac-specific tracks in future years, these companies are be
positioned as monitoring tools used by other participants than as participants
themselves. They could potentially list in the ACCESS Tools Directory as option
cardiac monitoring vendors for participants who want enhanced cardiovascular
oversight beyond the required measures.

Their existing FDA clearances mean TEMPO is not needed, and they already
understand medical device regulatory compliance.

Whoop and Oura are consumer wearables with continuous sensing for activity, s
heart rate variability, and recovery metrics. While these devices generate rich
physiological data, ACCESS does not pay for those metrics. CMS is paying for bl
pressure measured via validated upper arm cuffs, lab values from accredited sou
weight, and validated PROM scores. Consumer wearables could play a role in
engagement, adherence monitoring, or supplemental data, but the core reimburs
measures require different devices and workflows.

Investors should not assume that general-purpose wearables capture ACCESS re
unless CMS expands track definitions or measurement requirements in future ye
include metrics like heart rate variability, sleep quality, or activity levels as outc
measures or risk adjusters.

These companies could potentially list in the ACCESS Tools Directory as option
engagement and adherence monitoring tools for participants, but they would no
core to the payment and measurement model. They likely do not need TEMPO s
consumer wearables are generally not classified as medical devices requiring
premarket authorization.

## What to Watch Before Rate Cards Drop 2026

The structural analysis above is complete with information available in the RFA FAQ, but the economic analysis is incomplete without payment rates and future threshold trajectories. CMS states that payment rates and related model parame will be announced in 2026 in advance of the March 20, 2026 initial application deadline.

When rates are published, investors should immediately assess whether they cov all-in cost of compliant ACCESS participation including clinical staffing at level needed to achieve outcomes, Clinical Director oversight, device procurement an distribution for eCKM and CKM, care coordination infrastructure, FHIR report and HIE connectivity, program integrity and audit preparedness, potential TEM participation costs if using devices under enforcement discretion, and working c carrying cost for the fifty percent withholding.

If rates only support minimal clinical staffing or automated intervention models companies will face a choice between underinvesting in care delivery and missin outcome thresholds, or overinvesting and operating at negative margin. Neither sustainable. Rates need to support the full operational stack CMS describes in tl requirements or the model selects for corner-cutting and eventual failure.

The second critical piece of information is the future Outcome Attainment Thre trajectory. CMS says the threshold starts at fifty percent in year one and increase later years up to a defined upper limit, with the schedule to be published in 202 slope of that increase determines how quickly participants must improve perfor and how much operational leverage exists.

If the threshold rises to sixty percent in year two, seventy percent in year three, a eighty percent in year four, companies face extreme pressure to optimize clinical protocols, refine patient selection, and scale operational quality rapidly. If the threshold rises more gradually to fifty-five percent in year two and sixty percent year three, the learning curve is more forgiving. Investors should model multiple scenarios with different threshold trajectories and assess how sensitive their uni economics are to threshold assumptions.

The third piece is the Substitute Spend Threshold trajectory and the specifics of track's Substitute Spend List. The RFA includes initial lists in Appendix E, but C may modify these over time to reflect changes in billing codes, utilization patter and model goals. The breadth of the lists determines how hard the ninety percer threshold is to achieve.

If the lists are narrow and include only obvious duplicates like new PT evaluatio while an MSK participant is active, many participants will clear the threshold. If lists are broad and include common services like lab orders, care coordination c or specialist consultations that primary care physicians routinely initiate for pat with chronic conditions, the ninety percent threshold becomes very difficult and Substitute Spend Adjustment becomes the binding constraint on revenue for ma participants.

Investors should also watch for CMS clarification on several operational details fully specified in the RFA or FAQ. The Implementation Guide promised for publication will include technical specifications for FHIR APIs, data submissior standards, alignment and eligibility workflows, and reconciliation processes. Companies need this level of detail to build systems and cannot finalize technica architecture without it.

Another important signal will be the volume and composition of actual applican after the March 20, 2026 deadline for the first cohort. If hundreds of organizatio apply across all four tracks, CMS has successfully created a competitive market the model has achieved ecosystem buy-in. If only a handful apply, it suggests pay rates are too low, operational requirements are too burdensome, or market perce is that the model is not viable. The presence or absence of large incumbents like major health systems, Medicare Advantage plans launching provider entities, or established digital health platforms will signal whether sophisticated organizati view ACCESS as strategic opportunity or regulatory science experiment.

Investors should watch CMS communication about benchmark setting and risk adjustment methodology for public outcome reporting. The FAQ states that "CM will maintain a public directory of ACCESS participants, including the conditio

they treat and their risk-adjusted clinical outcomes, so patients and referring providers can make informed choices." The specific risk adjustment approach determines how fairly performance is compared across participants serving diffe patient populations. If risk adjustment is inadequate, participants serving sicke more socioeconomically disadvantaged populations will appear to perform wors if their clinical care is equivalent, creating pressure to avoid complex patients. I adjustment is robust, comparisons will be more equitable but the methodology v complex and potentially controversial.

The TEMPO pilot timeline and application process need monitoring. The FAQ s that "manufacturers interested in TEMPO should apply directly to FDA once th application process opens" but does not specify when that will be. Companies w devices that would benefit from TEMPO need to understand the timeline and application requirements to plan whether this pathway is viable for their first co participation or requires waiting for a later cohort.

Finally, investors should monitor developments in multi-payer alignment. The F clarifies that MA plans can adopt similar arrangements without waivers and Me MCOs can use ILOS authority, with CMS providing reference payer implementa resources. If major Medicare Advantage plans announce they will align with AC payment methodology and outcome measures for their networks in 2026 or 2027 addressable market expands dramatically and the operational investment in ACO compliance pays dividends across multiple payer channels. If MA plans ignore ACCESS or develop competing frameworks, the model remains Medicare FFS or and the total opportunity is more limited.

The ACO benchmark incorporation timeline in 2028 creates a natural evaluation point. If ACCESS participants demonstrate strong outcomes and total cost of ca reduction during the 2026-2027 exclusion period, ACO relationships will streng and expand. If performance is mixed or total costs are not well-controlled, ACO enthusiasm will cool. Investors should track early performance data and ACO adoption patterns to assess whether ACCESS becomes embedded in ACO strateg remains peripheral.

ACCESS represents CMS attempting to build a functioning market for technolo enabled chronic care where payment is tied to outcomes, measurement is standa and auditable, competition is based on demonstrated clinical performance, and regulatory compliance creates both barriers and moats. The FDA TEMPO pilot a novel dimension enabling device innovation under enforcement discretion while collecting real-world evidence under FDA oversight. The ACO benchmark exclu period creates favorable conditions for early adoption and value demonstration. ACCESS Tools Directory signals CMS commitment to reducing barriers and bui an ecosystem.

If the payment rates announced in 2026 are adequate and the operational requirements are calibrated correctly, ACCESS could become the primary reimbursement pathway for digital health companies serving Medicare populati and potentially influence commercial payer approaches through multi-payer alignment. If the rates are inadequate or the operational burden is excessive rela payment, ACCESS will select for either well-capitalized organizations willing to operate at low or negative margin to establish market position, or for lower-qual operators who cut corners on care delivery, measurement integrity, or compliance until CMS enforcement catches them.

The investor challenge is determining which scenario will unfold before commit capital to ACCESS-dependent business models. The structural design is now ful visible through the RFA and FAQ. The economic viability depends on parameter CMS will announce in 2026. Companies and investors have until March 20, 2026 decide whether to participate in the first cohort or wait for later cohorts with m operational clarity and market performance data.

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