ACCESS: The Ten-Year Window for Digital Health Investment That Everyone Missed While Arguing Abou Drug Pricing

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Abstract

CMS announced the ACCESS model (Advancing Chronic Care with Effective, Sc Solutions) on December 1, 2024, creating a ten-year payment pathway for techno enabled chronic disease management in Original Medicare. The model launches 1, 2026 and represents the most significant Medicare payment innovation for dig health since the program's inception. This essay examines the structure, mechan and investment implications of ACCESS based on the limited public informatio available, explores the parallel FDA TEMPO pilot for device enforcement discre and analyzes opportunities across the digital health stack from infrastructure to solutions. Key findings: ACCESS targets conditions affecting two-thirds of Medi FFS beneficiaries (approximately 26 million people), introduces outcome-aligned payments that waive patient cost-sharing, and creates the first sustainable

reimbursement model for prescription digital therapeutics and remote monitori solutions that have struggled under traditional fee-for-service. The model arrive commercial RPM coverage contracts, suggesting federal payment may become th primary revenue source for chronic care technology companies over the next dec

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What CMS Actually Built and Why It Matters

Let me start with what this is not. ACCESS is not about drug pricing, not about outcomes-based pharma rebates, not part of IRA implementation. It's a pure dig health play focused on chronic disease management using technology as the prir care delivery mechanism. CMS dropped this December 1st with surprisingly litt fanfare given it's basically creating a new $10B+ market category over ten years.

The model targets four clinical tracks covering conditions that hit roughly two-t of Medicare fee-for-service beneficiaries. That's about 26 million people if you d math on current FFS enrollment. Track one is early cardio-kidney-metabolic stu hypertension, high cholesterol, prediabetes, and obesity with central adiposity markers. Track two is more advanced CKM including diabetes, CKD stages 3a a and atherosclerotic cardiovascular disease. Track three is chronic musculoskelet pain lasting more than three months. Track four is behavioral health covering depression and anxiety.

The tracks are smart groupings because they cluster conditions that get manage similar intervention types and care delivery models. Someone participating in th eCKM track needs to handle all qualifying conditions in that track for any given patient, which forces integrated care rather than siloed point solutions. This is basically CMS saying we're done with the fragmented approach where you've go seven different vendors each monitoring one thing with no coordination.

Payment structure is what they're calling Outcome-Aligned Payments which is a way of saying you get recurring revenue tied to actually moving clinical outcome rather than billing for specific activities. So instead of billing for RPM codes or codes or whatever alphabet soup of billing codes you're currently wrestling with get paid to manage the condition and full payment depends on hitting outcome targets across your patient population. CMS hasn't released the actual dollar am yet which is driving everyone nuts from a business planning standpoint, but the structure is you get paid per enrolled patient per time period and the payment is higher initially then drops to a maintenance rate once patients hit control.

The outcome targets are based on clinical guidelines and measure things like blo pressure reduction of 10 mmHg for hypertension, A1C control for diabetes, pati reported outcome measures for depression and anxiety, pain scores for MSK. Th design choice is CMS will pay based on the overall share of your enrolled popula that meets targets rather than individual patient success. So if you enroll 100 hypertension patients and 75 of them hit their BP targets, you get full payment e though 25 didn't make it. This is actually pretty generous compared to some of t

outcome-based models we've seen and recognizes that not everyone responds to interventions.

Patient cost-sharing gets waived which is huge. Traditional Medicare requires c and deductibles for most Part B services but ACCESS participants can waive all that. This removes a massive enrollment friction point and probably increases participation rates by 30-50% based on what we've seen in other programs when eliminate out-of-pocket costs. CMS is offering the patient incentive safe harbor this which gives regulatory cover under anti-kickback statute.

The other piece that's interesting is the referring provider co-management paym PCPs or other clinicians who refer patients into ACCESS programs can bill a ne code for reviewing progress updates and coordinating care like adjusting meds c updating problem lists. The service is billable approximately every four months no beneficiary cost-sharing. CMS has not yet released the specific payment amou though based on comparable care coordination codes this could range from $20- per service. This is CMS's attempt to keep primary care engaged rather than just handing patients off to a digital health vendor and never hearing from them agai

Care delivery can happen any way that works which is the whole point. In-perso virtual, asynchronous, through FDA-authorized devices or software, whatever ge results. CMS is explicitly not mandating care delivery models which is smart bec the whole value prop of digital health is flexibility and innovation in how you en patients. The requirements are around outcomes and safety not process.

Organizations have to enroll in Medicare Part B as providers or suppliers which big deal for tech companies that haven't traditionally operated in the healthcare provider space. You can't just be a software vendor or device manufacturer participating indirectly. You need to be a Medicare-enrolled provider accepting assignment which means you can't balance bill patients and you're subject to all compliance obligations that come with provider enrollment. This is going to be barrier for some companies but CMS seems to think it's necessary to maintain q oversight and beneficiary protections.

Every participant needs to designate a physician Clinical Director responsible fo clinical oversight and compliance. This can't just be a medical director role whe some doc reviews stuff once a quarter. The Clinical Director has real accountabi for care quality and safety and CMS can come after them if things go sideways. F tech companies this means either hiring a physician into a senior operational rol partnering with physician groups who can provide that oversight.

The compliance requirements are actually pretty reasonable given how much flexibility CMS is offering on care delivery. You need to meet state licensure requirements for wherever you're providing care, maintain HIPAA compliance a covered entity, comply with applicable FDA requirements or be subject to enforcement discretion through TEMPO, exchange data bidirectionally with ref clinicians and integrate with a health information exchange, and report outcome to CMS on their timeline. The data exchange piece is probably the heaviest lift f companies that don't already have robust interop infrastructure.

CMS is going to maintain a public directory of all ACCESS participants showing which tracks they operate in, what tools they use, and their risk-adjusted clinica outcomes. This is transparency on steroids compared to most Medicare program means your performance data is going to be out there for competitors and poten partners to see. It also means patients and referring providers can comparison sh which should drive quality competition but also creates reputation risk if your outcomes suck.

The directory is paired with an ACCESS Tools Directory where technology vend can list their solutions even if they're not direct participants. So if you make blo pressure cuffs or glucose monitors or digital therapeutic apps or interoperability platforms, you can get listed in the directory as a resource for ACCESS organiza This is basically CMS creating a marketplace and it's going to become a key disc channel for tech vendors trying to reach the organizations that are participating.

Applications open January 12, 2026 with a first deadline of April 1, 2026 for the cohort launching July 1, 2026. Then rolling applications through 2033 which giv multiple entry points. The model runs ten years through June 30, 2036 and if it s

it can improve quality without increasing costs or reduce costs without harming quality, the HHS Secretary can make it permanent or expand it through rulemak So this could become the standard way Medicare pays for chronic care long-term

The Payment Mechanics We Know and the Huge Questions That Remain

Important note: CMS has not released actual payment amounts for outcome-alig payments or other ACCESS-specific payment rates. All dollar figures in this sect are educated speculation based on comparable programs and economic modelin confirmed rates.

CMS has been frustratingly vague on the actual payment amounts and we won't the real numbers until the Request for Applications comes out sometime in the few weeks. But we can make some educated guesses based on what we know abo similar programs and what would make economic sense.

The payment structure is recurring per-enrolled-patient-per-month or per-quar however they decide to periodically pay out. Most tracks include an initial care p at a higher rate followed by an optional continuation period at a reduced rate aft patients achieve control. The MSK track is different because the goal is to resolv chronic pain during the initial period so there's no maintenance phase. For the c tracks you've got something like 12 months at full rate then ongoing at maybe 6(of the initial rate.

If I had to guess on dollar amounts based on comparable programs like chronic management, remote patient monitoring, and Medicare Advantage care manager fees, CMS might be considering something in the range of $150-300 per membe month for the initial period depending on track complexity, then $75-150 for maintenance. The behavioral health track is probably at the higher end because depression and anxiety management requires more intensive engagement. The e track is probably lower because early-stage conditions need less intervention. Th numbers would need to be high enough to fund the technology, clinical oversigh

patient engagement, and data infrastructure required but not so high that they b up Medicare's budget. Again, this is pure speculation until official rates are rele

The benchmark for what works economically is probably CCM and RPM codes v pay around $40-70 per patient per month depending on time spent and what you billing. But those programs have been criticized for low uptake and questionabl outcomes so CMS likely wants to pay more to drive better results. On the other h MA plans pay anywhere from $100-500 PMPM for comprehensive chronic care management depending on risk and complexity. So the range I'm guessing feels reasonable.

CMS will apply a discount if a patient enrolls in multiple tracks with the same organization which makes sense because there are administrative efficiencies fro managing someone's diabetes and hypertension together versus separately. How the discount is matters a lot for business planning. If it's 10-20% you can still ma decent margin on multi-condition patients. If it's 40-50% you're basically getting for one condition and throwing in the rest for free.

Payment is tied to meeting minimum performance thresholds that CMS says wil increase over time. So year one might be 50% of your population hitting targets, two is 55%, year three is 60%, and so on. This ramp is critical because it determi how quickly you need to improve outcomes to maintain full payment. Too aggres and you create a death spiral where organizations can't hit targets and revenue d and they can't invest in improvement. Too lenient and CMS doesn't get the outc improvements they're paying for.

The risk adjustment methodology is undefined but CMS says outcomes will be r adjusted and publicly reported. This matters because patients come in at differe baseline risk levels and you need to account for that in outcome calculations. If y serving a healthier population you should be expected to hit higher outcome rat than someone serving sicker patients. The question is how sophisticated the risk adjustment is and whether it actually captures the meaningful differences in pat populations.

What we don't know is how payment works if a patient drops out mid-period or they move into a control group for evaluation purposes. CMS is randomly assign some patients to control groups which is required for their evaluation methodol under Section 1115A. If you enroll someone and they get randomized to control, you still get paid? Do you provide care anyway? This is a huge operational quest that affects your economics significantly.

We also don't know how payment reconciliation works timing-wise. Is it monthl arrears? Quarterly? Annual with interim payments? How long do you have to rep outcomes before payment adjustments kick in? The cash flow implications are massive especially for smaller organizations that can't float months of receivable while waiting for Medicare to pay up.

The other big unknown is what happens at the organization level if you consiste underperform. CMS says they can disenroll participants who fail to meet quality safety, or outcome standards but they haven't defined the thresholds or the proc Getting kicked out of ACCESS after you've built your whole business around it v be catastrophic so understanding the downside scenario is critical.

There's no downside financial risk which distinguishes this from ACO models. Y not on the hook for total cost of care and you're not going to get clawed back if utilization goes up. The worst case is you don't meet outcome thresholds and you lower payment or you get disenrolled, but you're not writing checks back to Mec This makes the model way more accessible for organizations that aren't big enou take insurance risk.

The upside is capped at full payment for meeting outcome targets. There's no bo for exceeding targets which is actually kind of weird given CMS's focus on incentivizing excellence. If you get 90% of your patients to goal versus 75% you g same money. This creates interesting strategic questions about whether to invest getting marginal patients to goal versus just hitting the threshold and allocating resources elsewhere.

The TEMPO Pilot: FDA's Companion Bet on Uncleared Devices

This is where things get really interesting from an investment standpoint. FDA launched the TEMPO pilot alongside ACCESS specifically to handle devices tha aren't yet authorized for the intended uses needed for ACCESS. So if you've got digital health device that could help manage diabetes or hypertension or chronic but you haven't gone through the premarket authorization process yet, you can a to TEMPO and potentially get enforcement discretion to offer the device to ACC participants while collecting real-world data.

FDA is selecting up to 10 manufacturers in each of the four ACCESS clinical use for a total of 40 devices. That's actually a pretty significant number given FDA typically moves slowly on these kinds of pilots. Applications open January 2, 202 with the first decisions expected by March.

The enforcement discretion covers premarket authorization requirements, investigational device exemption requirements, informed consent and IRB requirements under 21 CFR parts 50 and 56, and potentially other applicable requirements. Basically FDA is saying we'll look the other way on regulatory requirements that would normally apply while you collect real-world evidence, b exchange you need to collect robust data and share it with us and eventually seel proper marketing authorization.

This is huge for early-stage device companies that have been stuck in a catch-22 they need data to get FDA clearance but can't generate data at scale without reimbursement and can't get reimbursement without FDA clearance. TEMPO cr a pathway to break that cycle by allowing real-world use with payment through ACCESS while building the evidence base for eventual authorization.

The criteria for TEMPO participation include having a device intended for outp use in conjunction with a clinician, demonstrating safety and patient benefit bas preliminary data, having a plan for mitigating risks, proposing performance goal a timeline for data collection, and committing to eventually seek premarket

authorization using the data collected. FDA wants manufacturers of all sizes and maturity levels to apply to get diverse representation.

The devices can be software as a medical device, connected hardware, wearables, enabled diagnostics, basically anything that qualifies as a medical device under F jurisdiction. The key is they need to be targeted at improving patient outcomes i of the ACCESS clinical use areas and they need to be appropriate for the lower-a outpatient setting where ACCESS operates.

From an investment perspective TEMPO changes the calculus for backing medi device companies focused on chronic disease. Previously you needed to budget f long FDA clearance process before you could start generating revenue. Now you got a path to revenue while you're still building your regulatory package. This compresses time to market and reduces the capital required to get to cash flow positive.

The catch is TEMPO is limited to 40 devices and it's competitive. FDA is going t prioritize devices that address unmet needs, have compelling preliminary data, c from manufacturers with credible teams, and demonstrate a clear plan for collec quality real-world evidence. If you're a me-too glucose monitor with nothing nov you're probably not getting in. If you're a AI-powered digital therapeutic for treatment-resistant depression with solid pilot data you've got a shot.

The other consideration is TEMPO participation creates obligations. You're committing to collect and share data with FDA on an ongoing basis, you're agree seek proper authorization eventually, and you're subject to FDA oversight even though you don't have formal clearance. If your device causes safety issues FDA pull your enforcement discretion immediately and you're done. So there's regula risk that needs to be managed carefully.

For investors the question is whether to back companies applying to TEMPO or to see who gets in. Getting accepted into TEMPO is basically FDA validation tha your device is promising and addresses a real need. It also means you've got a ne term path to revenue through ACCESS. So TEMPO acceptance becomes a key

inflection point for valuations and a derisking event that should unlock follow-o funding.

The Market Sizing Exercise Everyone Should Be Doing

Important disclaimer: The following market size estimates are analytical projections b on assumptions about uptake rates, payment levels, and program participation. These not CMS projections or official market size estimates. They represent a framework for thinking about the potential opportunity scale.

Let's get concrete on the actual opportunity here because the numbers are bigge most people realize. Medicare FFS covers about 39 million beneficiaries current Two-thirds have one of the qualifying conditions per CMS's estimates so that's 2 million people who could theoretically be eligible for ACCESS.

Not all 26 million are going to enroll obviously. Uptake in voluntary Medicare m typically runs 5-15% in the first few years depending on how well it's marketed a how compelling the value prop is. Let's be conservative and assume 5% uptake ir one ramping to 15% by year five. That's 1.3 million enrollees in year one and 3.9 million by year five.

If average payment per enrollee across all tracks is $200 PMPM blended betwee initial and maintenance phases, that's $3.1B in annual payments in year one and by year five. That's not pocket change and it's all incremental to existing Medica spending because these services aren't well-reimbursed under traditional fee-fo service.

Now not all of that flows to tech companies because a lot goes to the provider organizations participating in ACCESS. But tech companies capture revenue thr several channels. Direct participation as Medicare-enrolled provider organizatio you're set up that way. Software licensing to participating organizations. Hardwa sales for connected devices. Data and analytics services. Interoperability and

integration services. Care coordination platforms. The technology stack is proba 30-40% of the total spend so call it $1-3B annually for tech vendors by year five.

The market splits across different categories. Infrastructure companies providin EMRs, care coordination platforms, data exchange, analytics, and interop probal capture $300-500M annually. Remote monitoring and connected device manufac probably get $400-800M depending on how much hardware gets deployed. Digit therapeutic companies providing the actual interventions could see $800-1500M they can demonstrate outcomes. Telehealth and virtual care platforms enabling clinical delivery probably get $200-400M. Patient engagement and activation toc might see $100-200M.

These are rough estimates but directionally correct based on how spend typicall distributes across the stack in value-based care programs. The key insight is the meaningful revenue opportunity at multiple layers not just for the point solutio vendors but for everyone enabling the ecosystem.

The other way to think about market sizing is from the condition perspective. Hypertension affects about 32 million Medicare beneficiaries. If 10% enroll in ACCESS through the eCKM or CKM tracks that's 3.2 million people. At $150 PI that's $5.8B annually just for hypertension management. Diabetes affects 13 mil Medicare beneficiaries. Ten percent uptake at $250 PMPM is $3.9B annually. Depression affects 6 million at maybe 5% uptake and $200 PMPM is $720M ann Chronic MSK pain affects 17 million at 10% uptake and $200 PMPM is $4.1B annually.

The total addressable market across all conditions if you achieve meaningful penetration is probably $20-30B annually which is enormous. Obviously we're n getting there in year one or even year five but over the ten-year model timeline t become realistic numbers if ACCESS succeeds and gets expanded or made perm

For investors the question is which slice of this you want to own. Do you want infrastructure plays that capture a small percentage of every dollar flowing throu the system? Do you want category-leading point solutions that own a specific

condition? Do you want horizontal tools that work across multiple conditions? E has different risk-reward profiles and different capital requirements to achieve s

Infrastructure Plays: Plumbing Before Applications

The infrastructure layer is where some of the most capital-efficient opportunitie probably exist because everyone participating in ACCESS needs the same basic plumbing and most organizations don't want to build it themselves.

Care coordination platforms are probably the highest-value opportunity in infrastructure. Organizations need tools to enroll patients, track them across the journey, coordinate with referring providers, manage interventions, collect outc data, report to CMS, and handle all the operational workflow. This is basically ca management software purpose-built for outcomes-based chronic care.

The platform needs to handle multi-condition patients, integrate with referring provider EMRs, connect to devices and patient apps, support clinical decision support, track guideline adherence, manage staff tasking and workflows, genera reports for Clinical Directors, and submit data to CMS in whatever format they require. That's a lot of functionality and building it from scratch would take yea millions of dollars.

Existing EMR vendors are going to try to extend their platforms to support ACC but most EMRs are built for episodic acute care not longitudinal chronic disease management. They're not great at patient engagement, outcomes tracking across or coordinating with external partners. This creates an opening for purpose-buil chronic care platforms that integrate with EMRs but provide better workflows f specific ACCESS use case.

The business model is probably SaaS subscription per provider seat or per enrol patient PMPM. Pricing probably ranges from $10-30 PMPM depending on featu richness and level of support. If you can sign up 100 ACCESS organizations each

1000 patients on average that's 100k patients at $20 PMPM or $24M annual recu revenue on $2-3M in infrastructure costs for a really healthy margin profile.

Data exchange and interoperability is the other big infrastructure play. Every AC participant has to exchange data with referring providers, integrate with a healtl information exchange, report to CMS, and potentially share data with partners. organizations don't have robust interop capabilities and the existing HIE ecosyst fragmented and hard to work with.

Companies that can provide turnkey interoperability services wrapping FHIR A HL7 feeds, Direct messaging, TEFCA-aligned exchange, and whatever other star CMS ends up requiring are going to be in high demand. This is plumbing that n wants to build but everyone needs.

The challenge with interop is it's not clear how much organizations will pay bec there's a perception that data exchange should just work and be cheap. But the r is healthcare interop is hard and getting clinical data in and out of systems relia requires significant engineering and ongoing support. Pricing probably needs to bundled into broader platform offerings rather than sold standalone.

Analytics and outcomes measurement is another infrastructure need. Organizati need to calculate risk-adjusted outcomes, benchmark against peers, identify pati falling behind on targets, flag safety issues, and generally make sense of all the d flowing through their programs. Most lack internal analytics capabilities and ne external tools.

This is probably a thin layer on top of the care coordination platform rather tha standalone product. But there's opportunity for analytics-first companies that ca ingest data from multiple sources, apply sophisticated risk adjustment and ML models, and provide actionable insights. The key is the analytics need to be operationalized into workflows not just pretty dashboards that nobody looks at.

Patient engagement tools are infrastructure in the sense that every program nee them but they're also differentiators in terms of which ones actually move the ne on outcomes. Apps for symptom tracking, medication reminders, educational co

behavior change support, and communication with care teams are table stakes. E most patient apps have terrible engagement rates and don't drive sustained beha change.

Companies that have cracked patient engagement through behavioral science, gamification, personalization, or other approaches are going to command premi pricing. The challenge is proving your engagement tools actually improve outcor not just get downloaded and forgotten. If you can show patients using your app l targets at 10-15% higher rates than patients not using it, you've got a compelling story for ACCESS organizations.

Device integration platforms that can connect multiple types of connected devic through a single API are valuable because programs are going to use blood press monitors from multiple manufacturers, different CGM vendors, various weight s and activity trackers, and whatever else. Managing integration with 15 different device APIs is a pain and creates fragility. A unified device integration layer sim this and ensures data flows reliably.

The market for device integration is probably smaller than care coordination or analytics but it's defensible if you can become the standard integration layer and embedded deeply in organizations' workflows. Pricing is probably per connected device per month at something like $1-3 per device which adds up quickly when you've got tens of thousands of devices deployed.

Identity verification and fraud prevention are requirements for ACCESS given beneficiaries can enroll directly rather than being attributed by claims. Organiza need to verify someone actually is the Medicare beneficiary they claim to be and prevent duplicate enrollments or bad actors trying to game the system. This is a straightforward B2B SaaS play selling identity verification as a service.

The compliance and regulatory support layer is also infrastructure. Organizatior need help navigating Medicare enrollment, maintaining provider compliance, understanding changing requirements, managing audits, and staying current on ACCESS program rules. Legal and compliance consultancies will make money h

but there's also opportunity for tech-enabled compliance platforms that automa
lot of the heavy lifting.

Point Solution Positioning: Who Wins i
Each Track

Let's walk through each clinical track and think about which types of companie
best positioned to win.

In the eCKM track you've got hypertension, dyslipidemia, obesity, and prediabe
These are relatively early-stage conditions where the primary interventions are
lifestyle modification, medication adherence, and monitoring. Digital therapeuti
hypertension and prediabetes have shown decent outcomes in clinical trials and
their chance to prove value at scale with Medicare patients.

Companies like Omada Health, Virta Health, and Noom have built business mod
around metabolic health and weight management and should be well-positioned
the eCKM track. They've got the clinical programs, the patient engagement plat
the outcomes data, and the operational capabilities to scale. The question is whe
they can make the Medicare FFS economics work compared to their existing B2
employer and MA contracts.

For hypertension specifically you need reliable BP monitoring which means con
blood pressure cuffs and consistent patient measurement. Companies making
consumer-grade connected BP monitors that are validated and reliable should se
significant volume if they can get embedded in ACCESS programs. The challeng
BP monitors are relatively cheap commodities so margins are thin unless you ca
provide additional value through software or services.

Diabetes prevention programs for the prediabetes component are well-establish
CDC-recognized DPPs have been delivering for years through Medicare's existi
DPP benefit. ACCESS creates an alternative pathway that might be more attract
the payment is better and the administrative burden is lower. Companies operat

DPPs should evaluate whether to migrate to ACCESS or stay in the traditional D structure.

The CKM track with diabetes, CKD, and cardiovascular disease is higher acuity requires more intensive management. CGM for diabetes is obviously a huge opportunity and the major manufacturers like Dexcom and Abbott already have strong Medicare presence. The question is whether ACCESS creates incrementa growth beyond traditional DME channels or whether it just shifts volume betwe reimbursement pathways.

For diabetes management more broadly you need comprehensive programs that combine monitoring, medication management, coaching, and lifestyle interventi Digital diabetes management platforms like Virta, Livongo/Teladoc, and others proven models but need to show they can hit outcome targets with Medicare populations which tend to be older, sicker, and more complex than commercial populations.

CKD is interesting because it's underserved and there aren't many established d health solutions. Companies that can demonstrate they can slow CKD progressi reduce complications should find a receptive market. The clinical interventions mostly medication optimization, blood pressure control, and dietary modificatio which are all amenable to digital support.

Cardiovascular disease is the hardest part of the CKM track because these are si patients at high risk for acute events. Cardiac rehab delivered virtually or throu digital tools could work but you need strong clinical oversight and probably nee partner with cardiology practices rather than operate standalone. Remote monit for heart failure patients is well-established and should translate to the ACCESS model.

The MSK track for chronic pain is wide open because most current pain manage is either opioids which we're trying to reduce or physical therapy which has acce and adherence challenges. Digital MSK companies like Hinge Health, Sword He

and Kaia Health have shown they can reduce pain and improve function through based exercise therapy and coaching.

The MSK track has no maintenance phase which is interesting because the goal resolve pain during the initial care period not manage it chronically. This favors interventions that work relatively quickly like PT-based approaches versus slow acting modalities. It also means your revenue per patient is time-limited so you high throughput and efficient patient acquisition.

For chronic pain you probably also need multimodal approaches that combine exercise, behavioral health, sleep optimization, and potentially medication taper for patients on opioids. Companies that can integrate across these domains will see better outcomes than point solutions addressing just one aspect.

The behavioral health track covering depression and anxiety is potentially the bi opportunity because these conditions are prevalent, undertreated, and highly amenable to digital intervention. The evidence base for digital CBT is strong an companies like Big Health, Woebot, and others have validated approaches.

The challenge with behavioral health in Medicare is most of the existing digital mental health companies have focused on younger commercial populations and i not clear their products and engagement models translate to elderly Medicare beneficiaries. Companies that have experience serving older adults or that can ac their offerings for this demographic are going to have an edge.

For anxiety and depression you need longitudinal engagement because these are chronic relapsing conditions. The initial care period is probably focused on gett remission but the maintenance phase is critical for preventing relapse. Compani with strong retention and engagement models that keep patients connected over are going to see better outcomes and more sustainable revenue.

Measurement-based care using validated tools like PHQ-9 for depression and G for anxiety is table stakes for the behavioral health track. Companies need to int regular assessment into their programs and show they're actually moving scores just providing access to therapy or coaching.

The Primary Care Integration Problem That Could Sink Everything

Here's the thing that keeps me up at night about ACCESS: the model is predicat integration with primary care but the incentives for PCPs to participate are wea the operational burden is high.

PCPs are supposed to refer patients to ACCESS organizations, review progress updates, coordinate care, and bill the co-management code. In exchange they get recurring payments for care coordination, though the specific payment amount l been released yet. Whatever the payment level, it needs to be compelling enough justify the time required to review updates and coordinate across at least three b occasions per year.

Most PCPs are buried in patient panels, administrative tasks, and quality metric They don't have time to actively manage referrals to a new program and track outcomes for patients who are technically receiving care from someone else. The management payment is supposed to compensate for this but it's probably not e to get meaningful engagement.

If PCPs don't refer actively, ACCESS organizations will struggle with patient acquisition and the model doesn't scale. If PCPs refer but don't engage with the management piece, you lose care coordination and continuity which probably lea worse outcomes and potential safety issues.

The other problem is PCPs may see ACCESS organizations as competitors rathe partners. If you're a primary care practice and you refer your hypertension patie a digital health vendor who then manages their BP and sends you updates, you've outsourced a core part of primary care. Why wouldn't you keep those patients a for managing their hypertension yourself?

The answer is supposed to be that PCPs don't have the tools and time to provide intensive technology-enabled management that ACCESS organizations can deliv And the co-management payment is on top of their regular E&M revenue so they

not losing money by referring. But culturally and professionally it's still a shift t
may feel threatening.

For this to work ACCESS organizations need to position themselves as extensior
the primary care team not replacements. They need to make the referral process
simple, provide updates in formats that integrate with PCP workflows, and
demonstrate clear value in terms of improved outcomes and reduced PCP burde

The integration needs to be bidirectional and real-time. If a PCP adjusts a patie
hypertension medication, the ACCESS organization needs to know immediately
they can adjust monitoring and follow-up. If the ACCESS organization identifies
patient whose depression is worsening, they need to alert the PCP right away. Tl
requires robust data exchange and communication infrastructure that most
organizations don't have today.

The other integration challenge is with specialists. Patients in the CKM track m
seeing cardiologists, nephrologists, endocrinologists who also need to be in the l
Coordinating care across multiple specialists plus primary care plus the ACCES
organization gets complicated fast. Somebody needs to be the hub coordinating
these spokes and it's not clear who that is.

CMS's answer is the Clinical Director at the ACCESS organization should provi
that coordination but that only works if everyone else is willing to communicate
through that channel. If specialists keep siloing their care and not sharing
information, the coordination breaks down.

There's also the question of what happens when patients have acute issues or ne
urgent care. They're going to go to their PCP or ER not the ACCESS organizatio
How does the ACCESS organization stay informed about these events and how d
factor into outcome measurement? If a diabetic patient ends up hospitalized for
that's relevant to the ACCESS organization's performance but they may not find
about it.

The EMR integration burden is significant. ACCESS organizations need to excha
data with dozens or hundreds of different PCPs using different EMR systems. So

will be on Epic, some on Cerner, some on random small-vendor EMRs with limit interop capabilities. Building and maintaining all those integrations is expensive brittle.

HIE integration is supposed to solve some of this but the HIE landscape is a mes There are hundreds of regional and state-level HIEs with different technical spe governance models. National networks like Carequality and CommonWell are improving but still have gaps in coverage and data quality. Realistically you're g to need multiple integration strategies and a lot of manual workarounds.

The other question is who owns the primary relationship with the patient. Is it t PCP or the ACCESS organization? When patients have questions or concerns, w they contact first? If you create confusion about where patients should go for wh you end up with fragmented experience and things falling through the cracks.

My gut says the successful ACCESS organizations will be ones that figure out th primary care integration piece early and invest heavily in making it work. The o that treat primary care as an afterthought or try to go direct-to-consumer witho strong PCP relationships are going to struggle with both patient acquisition and term outcome management.

Business Model Implications and Unit Economics

Let's talk about what it actually takes to make money in ACCESS because the un economics are going to determine who survives and thrives.

On the revenue side you've got the OAP from Medicare which we're guessing is 300 PMPM depending on track and phase. Patient cost-sharing is waived so you getting copays. For some organizations there may be additional revenue from sel technology or services to other ACCESS participants but for most your revenue OAP.

On the cost side you need to account for patient acquisition, technology infrastructure, clinical labor, device costs if you're providing connected devices, and analytics, regulatory compliance, overhead. Let's walk through each piece.

Patient acquisition is probably the biggest variable cost and the hardest to estim you're getting most patients through PCP referrals your acquisition cost is low, $50-100 per patient to cover marketing to providers and referral coordination. If you're going direct-to-consumer with advertising your acquisition cost could eas $200-500 per patient depending on competition and channel efficiency.

The lifetime value calculation depends on how long patients stay enrolled. If ave tenure is 18 months and you're getting $200 PMPM, that's $3600 in LTV. If acquisition cost is $150 and your contribution margin is 40% after variable costs you're making $1440 per patient minus acquisition for $1290 net contribution. T a payback period of about 3 months which is pretty healthy.

But if acquisition costs are $500 and contribution margin is only 25% because yo paying high clinical labor costs, you're making $900 per patient minus acquisitio $400 net contribution. That's a payback period of 14 months which is marginal a doesn't leave much room for error.

Technology infrastructure costs depend on whether you're building or buying. If you're using off-the-shelf care coordination platforms and device integration ser you're probably paying $10-20 PMPM in software costs. If you're building custo you need to amortize development costs across your patient base which works if you've got scale but kills you if you're small.

Clinical labor is the biggest ongoing cost for most models. You need coaches or or health educators engaging with patients, you need clinicians reviewing cases a making care decisions, you need the physician Clinical Director providing overs Depending on intervention intensity you might need 5-20 hours of clinical time patient per year. At blended labor rates of $60-100 per hour that's $300-2000 per patient per year in clinical costs.

The key to making the economics work is driving efficiency through technology you need less clinical time per patient while maintaining or improving outcomes Companies that can deliver effective interventions with 5 hours of clinical time 20 hours have a massive cost advantage.

Device costs vary hugely depending on what you're providing. Connected BP cu cost $40-80, CGMs cost $150-200 per month if you're not getting them through insurance, weight scales cost $30-50. If you're providing devices upfront you nee factor in that capital cost and either amortize it or write it off if patients churn e

Some organizations will probably opt not to provide devices and instead require patients to bring their own or pay out-of-pocket. This shifts the cost burden but reduce enrollment and engagement if patients don't want to pay for devices.

Data and analytics costs are probably $5-10 PMPM if you're using external platf and services. This covers outcomes measurement, risk adjustment, reporting to and any predictive analytics or decision support tools you're using.

Regulatory compliance and overhead is hard to estimate but probably runs 15-2 revenue just covering all the administrative costs of being a Medicare provider. includes coding and billing, compliance, legal, finance, HR, and general overhea Lean organizations might get this down to 15% but 20% is more realistic for mos

If you put it all together, a well-run organization might have a cost structure lik $20 PMPM for technology, $50 PMPM for clinical labor, $10 PMPM for devices amortized over the patient lifetime, $8 PMPM for data and analytics, and $40 P for overhead and compliance. That's $128 PMPM in total costs against $200 PM revenue for a 36% operating margin before patient acquisition costs.

A less efficient organization might look like: $30 PMPM for technology because built custom and have low patient volume to amortize over, $100 PMPM for clin labor because their model is high-touch, $15 PMPM for devices, $10 PMPM for and $50 PMPM for overhead. That's $205 PMPM in costs against $200 PMPM i revenue for a negative margin before you even account for patient acquisition.

The path to profitability is achieving scale to amortize fixed costs and driving operational efficiency through better technology and care models. You probably at least 5000-10000 patients to get to break-even and more like 25000-50000 to achieve attractive margins.

This means early-stage companies are going to burn cash for a while before getti profitability. Investors need to underwrite enough capital to get to scale and sust losses during the growth phase. How much capital that takes depends on growth and efficiency but it's probably $10-30M for most companies to get to cash flow positive.

The other lever is expanding into multiple tracks which increases revenue per pa and improves efficiency by leveraging the same infrastructure and clinical team conditions. If you can enroll a diabetes patient into both the CKM track and the behavioral health track, you're getting paid for both while only having marginal incremental costs.

The challenge is delivering high-quality integrated care across multiple conditic harder than it sounds. You need clinical protocols that address interactions betv conditions, you need staff who can work across domains, and you need coordinat avoid conflicting recommendations. But if you can pull it off the economics are r better than single-condition models.

Investment Thesis by Company Stage and Type

For seed and Series A investors the opportunity is probably in infrastructure and horizontal tools that will be needed by many ACCESS participants rather than b on specific point solutions. The infrastructure thesis is lower risk because you d need to prove clinical outcomes, just that your product solves a real operational point and organizations are willing to pay for it.

Care coordination platforms, device integration layers, patient engagement tools analytics services are all seed/Series A scale opportunities. You're talking about

rounds to build MVP product, sign up early design partners, and prove product-market fit with a few dozen organizations.

The exit path for infrastructure plays is probably acquisition by larger health IT vendors or platforms that want to expand their chronic care capabilities. Epic, C Meditech, and others will likely buy their way into ACCESS-related functionalit rather than building everything in-house. Typical M&A outcomes might be $50- for successful infrastructure companies that achieve meaningful market penetra

For Series B and C investors the thesis shifts to point solutions that have proven clinical outcomes and are ready to scale into ACCESS. By this stage companies s have FDA clearance if required, strong evidence of clinical impact, initial Medic contracting experience, and a playbook for operational execution.

Digital therapeutics for hypertension, diabetes, behavioral health, or pain are Se B/C opportunities if they've already demonstrated outcomes in clinical trials or commercial programs. You're talking about $10-30M rounds to build sales and marketing, expand clinical operations, and acquire the first few thousand Medic patients.

The exit path for point solutions is either growth equity and eventual IPO if the get to $100M+ revenue or strategic acquisition by large healthcare systems, paye pharma/med device companies. Outcomes in the $300M-1B range are achievable category-winning digital health companies that capture significant market share their condition focus.

For growth equity and late-stage investors the opportunity is in scaled platforms are already operating successful programs and want to expand aggressively into ACCESS. Companies like Omada, Virta, Hinge Health, and others that have buil substantial businesses in commercial markets are logical candidates if they deci pursue Medicare FFS seriously.

These are $50-150M+ rounds to fund national expansion, build out multi-track capabilities, and invest in technology infrastructure for hundreds of thousands c

patients. The return profile is lower risk because the companies are proven but t capital requirements are much higher.

For strategics the opportunity is both organic participation in ACCESS as a prov organization and M&A of companies that have built ACCESS-relevant capabiliti Large health systems with primary care networks should be evaluating whether t participate directly and what technology they need to acquire or partner with. H plans may want to acquire digital health companies to offer similar programs to MA members.

Pharma and device companies are interesting strategic players because they have aligned incentives around improving outcomes for their products. If you're Novo Nordisk and your GLP-1s are being used for diabetes and obesity management i CKM and eCKM tracks, you want those patients to have good outcomes. Partner with or acquiring digital health companies that improve adherence and outcome makes strategic sense.

The risky bets are companies that are betting entirely on ACCESS without diver revenue. If you're building a business that only works if ACCESS succeeds and s you're taking regulatory and policy risk that could kill you. Smarter play is comp that have commercial traction and see ACCESS as incremental opportunity not t whole strategy.

The other risk is companies that launch into ACCESS without having proven the care model works with Medicare populations. Taking a digital health program designed for 35-year-old tech workers and trying to deploy it with 70-year-old Medicare beneficiaries is harder than it looks. Companies that have already serv older adults or that invest in understanding the unique needs of this population going to have higher success rates.

What Gets Built Between Now and July 2026

We've got 18 months until ACCESS launches which sounds like a lot of time but go fast. Here's what needs to happen.

CMS needs to release the full Request for Applications with all the details on pa amounts, performance thresholds, data submission requirements, application pr and compliance expectations. This should come in the next few weeks and will c clarity for everyone trying to decide whether to participate.

Companies that want to participate need to make build-buy-partner decisions o technology stack. Are you building a care coordination platform in-house or lice one? Are you integrating devices directly or using a device integration platform? you building your own analytics or buying? These architectural decisions take m to implement so you can't wait until the last minute.

Organizations not currently enrolled in Medicare Part B need to start that proce now because it typically takes several months to complete and there will be a su applications leading up to the July 2026 launch. CMS's enrollment infrastructur going to be stressed by the volume and you don't want to be stuck in the queue.

Companies planning to apply to the FDA TEMPO pilot need to start assembling applications now for the January 2 opening. This means getting preliminary safe efficacy data organized, developing a real-world evidence collection protocol, de performance goals, and putting together a credible regulatory strategy.

Technology vendors positioning to get into the ACCESS Tools Directory need to engaging with CMS to understand the listing requirements and make sure their products meet whatever criteria CMS establishes. Getting listed early creates fir mover advantage for discovery by ACCESS organizations.

Primary care practices and health systems need to start educating their provider about ACCESS and thinking through their referral strategy. Do they want to be referring partners and bill the co-management code? Do they want to stand up t own ACCESS programs and participate directly? Do they want to stay out of it entirely? These strategic decisions affect how primary care orgs should prepare.

Investors need to start evaluating which companies in their portfolio or pipeline well-positioned for ACCESS and which need to pivot or partner. This is a massiv market opportunity but it's not going to lift all boats equally. The companies tha move fast and execute well will capture disproportionate value.

We also need to see what happens with TEMPO applications and who FDA selec Those decisions will signal which types of devices and interventions FDA thinks promising and will create follow-on opportunities for investors to back the comp that get enforcement discretion.

The other unknown is whether commercial payers start launching ACCESS-like programs for their fully insured populations. If United, Cigna, Aetna, and other CMS creating an outcomes-based payment pathway for tech-enabled chronic car they may want to do the same thing. That would dramatically expand the market beyond just Medicare and create more sustainable business models for digital he companies.

There's also going to be a lot of partnership deal-making over the next 18 month Technology vendors partnering with provider organizations to deliver ACCESS programs. Device manufacturers partnering with digital health platforms to inte their products. Large health systems partnering with tech-enabled care compani expand their chronic care capacity. These partnerships will shape who ends up w strategic advantages when the model launches.

The policy risk is that ACCESS could get delayed or modified before it launches We've got an election year happening and depending on how that plays out there could be pressure to revisit or scale back CMS Innovation Center initiatives. Bu ACCESS seems relatively bipartisan in that technology-enabled care and outcom based payment have support across the political spectrum.

The bigger policy question is what happens if ACCESS succeeds. Does it becom default way Medicare pays for chronic care? Does it expand to more conditions? it get rolled into Medicare Advantage? The ten-year timeline gives CMS a long

runway to evaluate and iterate but if early results are promising we could see rap expansion that creates even larger opportunities.

From an investment timing perspective, the next 6-12 months are probably the s spot for backing companies positioning for ACCESS. Valuations haven't fully pr in the Medicare opportunity yet and there's still time to build or acquire capabil before the model launches. Once we get to 2026 and early results start coming ir valuations will adjust quickly and the best opportunities will be harder to acces

The one thing I'm confident about is that ACCESS is going to reshape the digita health landscape regardless of how successful the specific model is. CMS has essentially validated that technology-enabled chronic care is something Medicar willing to pay for in a sustainable way. That signal is going to drive investment, innovation, and market development for years to come. Companies and investors recognize this early and position accordingly are going to capture significant val over the next decade.

Discussion about this post

Comments Restacks

Write a comment...

Christian Pean MD, MS Techy Surgeon Dec 10

Really nice deep dive! Truly a generational opportunity for digital health companie
think a lot of folks are not thinking about all the intricacies and benefits here.

Also nice image of the ACCESS program in there ☺

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