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

Request for Applications

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Model Summary

This Request for Applications (RFA) introduces the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model, a new Center for Medicare and Medicaid Innovation (Innovation Center) model from the Centers for Medicare & Medicaid Services (CMS). The ACCESS Model will test whether an alternative payment methodology—Outcome-Aligned Payments (OAPs)—for technology-enabled chronic care reduces expenditures while preserving or enhancing quality of care for Medicare beneficiaries.

The ACCESS Model is designed to expand choice for patients and clinicians by offering a new payment option that removes payment barriers to technology-enabled care, while maintaining accountability for clinical and patient reported outcomes. The model is expected to reduce Medicare expenditures by enabling efficient care that achieves improved clinical outcomes and prevents avoidable utilization.

Key Model Elements

1. **Scope and Duration:** The ACCESS Model will be a 10-year voluntary model offered nationwide, running from July 5, 2026 through June 30, 2036 ("Model Performance Period"). Applications will be accepted on a rolling basis from the release of this RFA through April 1, 2033 to facilitate at least three years of participation for each participant. To participate in the first cohort, which begins July 5, 2026, applications are due on April 1, 2026. Applications received after this date will be processed in subsequent cohorts as outlined in Section 2: Scope and Duration.

2. **Participants:** ACCESS participation will be defined at the organizational level, with each ACCESS Participant identified by a single Medicare Part B–enrolled Taxpayer Identification Number (TIN) eligible to bill under the Medicare Physician Fee Schedule (PFS) (“ACCESS Participant”). Eligible entities will include Medicare Part B-enrolled providers or suppliers, excluding Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and laboratory suppliers. Organizations not enrolled in Medicare Part B must enroll to participate in ACCESS. Applicants should start the Medicare enrollment process, described here, as early as possible, as applications will not be fully approved for participation until the Medicare enrollment process is complete.

3. **Beneficiary Eligibility and Alignment:** Eligible beneficiaries will include Original Medicare beneficiaries, including those dually eligible for Medicare and Medicaid, who have qualifying chronic conditions. Beneficiaries will voluntarily and prospectively align to ACCESS Participants by enrolling directly with them. ACCESS

enrollment will not affect beneficiaries' freedom of choice or access to any covered Original Medicare services.

4. **Clinical Tracks:** The model will include four initial clinical tracks: Early Cardio-kidney-metabolic (eCKM[1]), Cardio-kidney-metabolic (CKM), Musculoskeletal (MSK), and Behavioral Health (BH), with additional tracks and conditions to be considered for future model years. Qualifying conditions within each track are listed in Table 1. Each track groups clinically related, frequently comorbid conditions that are often addressed with similar care activities and intensity. Participants will be responsible for managing all qualifying conditions a beneficiary has within the track in which they are enrolled, supporting integrated, patient-centered care. Initial tracks were chosen based on: condition prevalence; unmet patient need; demonstrated fit for technology-enabled care, as reinforced by the presence of many technology-enabled health care providers outside of Medicare actively treating these conditions; and suitability for outcome-aligned payment, including outcome measures that met CMS' measure selection criteria as described in *Performance Measurement*.

5. **Outcome-Aligned Payments:** ACCESS Participants will receive fixed payments for managing beneficiaries' qualifying conditions over 12-month periods, with full payment contingent on achieving track-specific clinical outcome (OAP Measure) targets. Targets are defined relative to each beneficiary's baseline and focus on improvement or control, such as a 15-mmHg reduction in systolic BP or final systolic BP below 130 mmHg for hypertension. CMS will publish outcome targets for each OAP Measure, informed by clinical guidelines.

   The ACCESS Model's predictable, recurring payments—with clear success criteria—are designed to provide revenue stability and support investment in innovative care models. The model emphasizes accountability for outcomes rather than specific activities, allowing ACCESS Participants to adapt their care delivery approach to achieve results. This flexibility supports the use of Federal- and State- compliant

[1] Cardiovascular-kidney-metabolic (CKM) syndrome is defined as a health disorder attributable to connections among obesity, diabetes, chronic kidney disease (CKD), and cardiovascular disease (CVD), including heart failure, atrial fibrillation, coronary heart disease, stroke, and peripheral artery disease. CKM syndrome includes those at risk for CVD and those with existing CVD. See Ndumele et al., "Cardiovascular-kidney-metabolic health: A Presidential Advisory from the American Heart Association," Circulation 148, no. 20 (October 9, 2023): e1–e34, https://doi.org/10.1161/cir.0000000000001184

technologies, including Food and Drug Administration (FDA)-cleared Software as a Medical Device (SaMD),[2] under appropriate clinical oversight.

Payment amounts will vary by clinical track and include two payment tiers: a higher rate for initial care and clinical improvement, and a lower rate for continued management or clinical maintenance. Payments will be subject to Clinical Outcome Adjustments and Substitute Spend Adjustments to ensure accountability for outcomes and coordinated care delivery. Each ACCESS Participant may adopt a uniform policy, which complies with ACCESS requirements for beneficiary engagement incentives and is applied consistently across all beneficiaries, to waive the beneficiary cost-sharing component.

6. **Oversight and Guardrails:** All ACCESS Participants must be Medicare Part B–enrolled providers or suppliers (excluding DMEPOS and laboratory suppliers) in good standing; hold valid state licensure and practice within their scope to ensure care is delivered by qualified professionals under state authority; comply with applicable Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security standards, as covered entities, to safeguard protected health information (PHI); comply with FDA requirements to ensure that software devices used in care meets appliable safety and effectiveness standards; and undergo CMS program integrity and enrollment screening. Furthermore, ACCESS adds additional model-specific guardrails, including requiring each participant to designate a Medicare-enrolled physician as a Medical Director to oversee care delivery and regulatory compliance; making full payment contingent on achieving clinical thresholds to align incentives with patient health outcomes; CMS' publishing participants' risk-adjusted aggregate clinical performance to promote transparency and inform patient and referring clinician choice; and monitoring outcomes, claims, and related data to support program integrity.

7. **Care Coordination**: To support care coordination with beneficiaries' existing care teams, ACCESS Participants will be required to electronically share clinical updates with their aligned beneficiaries' primary care and referring health care providers, as applicable, as described in *Care Coordination Requirements*. Participants will also be eligible to request certain Medicare claims data for aligned beneficiaries through the Beneficiary Claims Data (BCDA) Application Programming Interface (API) to further support care coordination and monitoring. Finally, primary care practitioners (PCPs) and referring clinicians will qualify for a new ACCESS Co-Management

[2] Definition of SaMD, per the FDA: https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

Payment, billed without cost-sharing, for documented review of patient updates from ACCESS Participants. Overall, this structure is designed to support the integration of care delivered by ACCESS participants into the broader healthcare system and collaboration with healthcare organizations, including Accountable Care Organizations (ACOs), to manage their beneficiaries' chronic conditions and total cost of care.

8. **Data Sharing:** ACCESS will use APIs for data exchange between ACCESS Participants and CMS. ACCESS Participants will check eligibility and enroll beneficiaries via CMS Eligibility and Alignment APIs, respectively, and will report OAP Measures data to CMS via a Fast Healthcare Interoperability Resources® (FHIR®)-based Data Reporting API.
9. **Billing and Model Scalability:** Monthly billing will occur through standard claims using new track-specific G-codes, supporting potential adoption of aligned payment approaches by other payers including Medicare Advantage (MA), Medicaid, and commercial plans.[3]

[3] CMS will also make available reference payer implementation resources to further support multi-payer alignment.

Table 1. Initial Tracks Overview

Track	Qualifying Conditions[4]	OAP Measure[5]
eCKM	Hypertension (HTN), or two or more of the following conditions: dyslipidemia, obesity or overweight with a marker of central obesity,[6] prediabetes	- Control or minimum improvement in blood pressure (BP), lipids, weight, and hemoglobin A1c (HbA1c)
CKM	One or more of the following conditions: diabetes mellitus, chronic kidney disease (CKD),[7] atherosclerotic cardiovascular disease (ASCVD)	- Control or minimum improvement in BP, lipids, weight, and HbA1c - Submission of estimated glomerular filtration rate (eGFR) and urine albumin-creatinine ratio (UACR) data
MSK	Chronic musculoskeletal (MSK) pain[8]	- Minimum improvement in pain intensity, interference, and overall function (assessed via validated PROMs)
BH	One or more of the following conditions: depression, anxiety	- Control or minimum improvement in symptoms (assessed via PHQ-9 for depression and GAD-7 for anxiety)- Optional: Submission of WHODAS 2.0 12-item, a validated PROM of overall function

Background

Strategic Alignment with CMS Innovation Center Priorities

The ACCESS Model aligns with CMS Innovation Center's Strategy to Make America Healthy Again, including:

- **Promoting evidence-based prevention** by holding participants accountable for validated clinical outcomes associated with slowing disease progression and avoidance of disease.

[4] Fixed payment amount is for integrated treatment of all conditions in the track, as relevant to the patient, not per-diagnosis.
[5] Submission requirements vary based on qualifying condition. Outcome measures and targets are guideline-based and defined in consultation with experts. Control refers to meeting guideline-directed targets or remission.
[6] Obesity defined as Body Mass Index (BMI) greater than or equal to 30. Overweight defined as BMI 25 – 29.99 along with marker of central obesity, specifically waist circumference greater than 40 inches (102 cm) for men or 35 inches (88cm) for women.
[7] Stage 3a and 3b only.
[8] Chronic is defined as pain lasting more than three months. Musculoskeletal disorders are defined broadly to include conditions affecting bones, joints, muscles, and connective tissues.

- **Empowering people** to achieve their health goals with accessible health technology solutions, alongside publicly available risk-adjusted outcomes for each participant to inform patient choice.
- **Driving choice and competition** by expanding choice for patients and clinicians by removing payment barriers to high-value, innovative care delivery models for chronic conditions.
- **Protecting federal taxpayers** by reducing downstream spending by conditioning full payment on clinical outcomes.

Overview of Technology-Enabled Care

There are more than 10,000 technology-enabled care organizations, also known as digital health and digital therapeutics companies,[9] with over $10 billion invested in 2024.[10] The sector is expected to grow rapidly, supported by advances in artificial intelligence.[11]

Technology-enabled care organizations deeply integrate technology into care delivery to deliver continuous, high-value care to prevent and manage chronic disease. Their care delivery models include clinician-led, technology-augmented approaches, where clinicians use tools such as virtual visits,[12] remote monitoring,[13] and artificial intelligence (AI)-assisted care delivery support;[14] and technology-led, clinician-supervised approaches, where software applications—also known as digital therapeutics—deliver treatment directly, under the oversight of a clinician. Examples of technology-enabled practices include:

- A virtual musculoskeletal (MSK) program using AI-guided exercise therapy and wearable monitoring overseen by a licensed physical therapist.
- A cardiometabolic clinic delivering app-based lifestyle and dietary coaching along with remote medication management.

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[9] Digital Health 50: The Most Promising Digital Health Startups Of 2024. CB Insights. Dec 2024.

[10] 2024 Year-End Market Overview: $10.1b Raised Across 497 Deals. Rock Health. Jan 2025.

[11] AI Startups Boost Digital Health Funding in H1: Rock Health. Healthcare Dive. July 9, 2025

[12] HHS Telehealth website: https://telehealth.hhs.gov/

[13] HHS Telehealth and Remote Patient Monitoring (RPM) best practices: https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-and-remote-patient-monitoring

[14] Based on stakeholder interviews, such care includes "technology-native" care organizations that use technology to: A) enhance clinician capacity—including AI-assisted documentation (AI scribing), pre-visit care planning, risk stratification, remote monitoring, clinical decision support, and point-of-care imaging; B) provide continuous patient support—across clinical (e.g., medication adherence), behavioral (e.g., diet, exercise, smoking cessation), social (e.g., transportation, housing, food security), and care navigation domains—an approach that is evidence-based but historically difficult to scale; C) improve practice operations—such as AI-enabled scheduling, telehealth workflows, billing, and practice management.

- A virtual health care provider group overseeing use of an FDA-cleared cognitive behavioral therapy application.

These organizations typically offer integrated care that may include a combination of clinician consultation, lifestyle support (such as nutrition, exercise, and smoking cessation), therapy and behavioral counseling, patient education, care coordination, medication management, remote monitoring via connected devices, access to social needs support (such as housing, food, and transportation connections), and oversight of labs and imaging when applicable.

Continuous support is well-suited to chronic disease management but has been difficult to deliver within traditional visit-based healthcare systems and payment models. Technology-enabled health care providers use digital tools to deliver this care more efficiently, with emerging evidence that many interventions are achieving lower costs and comparable or improved outcomes, as supported by independent analyses.[15] Most digital health companies currently serve the commercially insured populations, where more flexible payment arrangements make participation feasible.

Barriers to Technology-Enabled Care

Despite emerging evidence on the effectiveness of technology-enabled care solutions, Medicare patients have limited access to them because of a lack of viable payment pathways. Relatedly, Medicare-enrolled practitioners who want to offer technology-enabled care delivery models are often constrained by existing payment structures.

Fee-for-service (FFS) payment approaches cover a limited set of activities and items that are typically poorly aligned with evolving technology-enabled care, which is often continuous and remote.[16] Furthermore, adapting FFS for technology-enabled care—including removing time-constraints from activity-based codes—risks significant cost inflation, since FFS rewards activity volume while technology-enabled care is less supply-constrained.

Value-based care (VBC) models with shared savings better align incentives, but their complexity presents challenges for technology-enabled care organizations. For example, since ACO and MA plans often have significant size and local concentration, they may select a single digital health vendor for a given clinical condition, creating a "winner-take-all" dynamic. Additionally, some ACOs and MA plans struggle to contract with digital health

[15] See, for example, assessments from Peterson Health Technology Institute, which demonstrate cost and quality effectiveness of many digital health solutions.
[16] An additional challenge with FFS is that approval of new reimbursable activities occurs through a centralized process, which can be slow and inaccessible to innovators.

solutions due to difficulties in attributing condition-specific savings especially when beneficiaries are enrolled in multiple interventions. Finally, custom contracts increase implementation costs and make vendor comparisons difficult, limiting competition. As a result, many high-value technology-enabled care organizations are unable to support Medicare patients. This results in a missed opportunity to improve outcomes, expand patient choice, and reduce program expenditures.

Payment Policy Context

The ACCESS Model tests OAPs as a new payment option to increase patient access to technology-enabled care with outcome accountability. ACCESS's OAP approach draws on emerging outcome-based pricing models in the commercial insurance market and aligns with broader trends in AI-enabled services pricing, where low marginal costs make at-risk payment models more viable.[17] It also builds on CMS's experience with bundled payments, condition-specific quality measures, and patient-reported outcomes.

Scope and Duration

The ACCESS Model will be a 10-year voluntary national model offered in all states, U.S. territories, and the District of Columbia. The Model Performance Period will begin on July 5, 2026 and end on June 30, 2036.

Applications will be accepted on a rolling basis from the release of this RFA through April 1, 2033, allowing each participant the potential for at least two years of engagement. The first application deadline, for participation beginning July 5, 2026, will be 11:59 PM Pacific Daylight Time (PDT) on April 1, 2026. Applications received after that date and before October 1, 2026 will be considered for participation beginning on January 1, 2027, with subsequent applications considered for later cohorts as described in Table 2. Application deadlines for each cohort will be announced on the CMS Innovation Center's Website and through the ACCESS Model's listserv. Those that wish to follow updates on the ACCESS Model can fill out the Model Interest Form here.

Table 2. Model Timeline

Milestone	Date
Applications Open	January 12, 2026
Initial Application Deadline	April 1, 2026

[17] See "AI Is Driving A Shift Towards Outcome-Based Pricing." Dec 2024. Andreesen Horowitz.

Milestone	Date
First Cohort Begins	July 5, 2026
Subsequent Cohorts Begin	January 1, 2027, and quarterly thereafter through July 1, 2033
Applications Close	April 1, 2033
Model Performance Period Ends	June 30, 2036

ACCESS Application and Participation Requirements

Application

Application questions, including deadlines and contact information, can be found in Appendix A. Applicants must submit all application materials via an online portal available on the ACCESS Model website at https://innovation.cms.gov/innovation-models/access. It is the responsibility of the applicant to ensure that they include all required information in their application. CMS may update or clarify application questions over time, and the most current version will be maintained on the online portal.

Applicants seeking to withdraw their application must submit an electronic withdrawal request to CMS via the following mailbox: ACCESSModelTeam@cms.hhs.gov. The request must be submitted as a PDF on the organization's letterhead and must be signed by a corporate official authorized to bind the applicant. It should include: the applicant organization's registered name; the organization's primary point of contact; the full and correct address of the organization; and a description of the reasons for the withdrawal. Further information will be available in the Participation Agreement (PA).

Participant Eligibility Criteria

To be eligible to participate in ACCESS, each ACCESS Participant must meet each of the following criteria:

- Be a Medicare Part B–enrolled organizational entity, identifiable by a single TIN, that is eligible to bill under the Medicare Physician Fee Schedule (PFS). Eligible entities are Medicare Part B–enrolled providers or suppliers, excluding DMEPOS suppliers and laboratory suppliers. Participation is defined at the organizational TIN level, not the individual practitioner level.

- Be a legal entity formed under applicable state, federal, or Tribal law, and authorized to conduct business in each state in which it operates.
- Maintain active Medicare Part B enrollment under a single TIN.
- Designate and maintain a Medicare-enrolled physician as Medical Director, responsible for oversight of care delivery and model performance, as described in *Care Delivery*.
- Ensure that all physicians and non-physician practitioners furnishing or supervising care are individually Medicare-enrolled, participating providers or suppliers who have reassigned their Medicare billing rights to the participating TIN and practicing within applicable licensure and scope-of-practice standards.
- Submit and maintain an up-to-date roster of all Medicare-enrolled practitioners (with NPIs) furnishing or supervising care under the TIN.
- Successfully complete CMS program integrity screening and any other reviews conducted under Medicare's Conditions for Medicare Payment as described in 42 C.F.R. Part 424.

As a condition of ongoing participation, each ACCESS Participant must meet each of the following criteria:

- Submit claims for ACCESS services using CMS-defined, model-specific G-codes.
- Transmit electronic clinical updates to beneficiaries' other health care providers (including referring and primary care practitioners), and support other healthcare technology requirements, as described in *Care Coordination Requirements* and *Health Information Technology Requirements*.
- Submit OAP Measures via CMS' FHIR®-based API, as described in *Performance Measurements*.
- Comply with all applicable federal and state laws and regulatory requirements, including licensure and scope-of-practice standards under 42 C.F.R. § 424.516; HIPAA obligations as a covered entity; and FDA requirements for any technologies used that qualify as medical devices under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act.
- Attest to ongoing compliance with model, regulatory, care delivery, and program integrity requirements through monthly billing.
- Disclose to CMS any material changes in ownership, licensure, or exclusion status.
- Meet minimum clinical outcome performance, as will be defined in the Participation Agreement.
- Comply with the terms of the Participation Agreement, with failure subjecting the Participant to corrective action or termination.

Participant Withdrawal Policy

An ACCESS Participant may terminate its participation in the ACCESS Model upon advance written notice to CMS, which must specify the effective date of termination. The ACCESS Participant must provide advance written notice at least 180 days prior to the effective date of termination. Until the effective date of termination, the ACCESS Participant must continue to provide model services to aligned beneficiaries and may not accept the voluntary alignment of new beneficiaries. The ACCESS Participant must also notify its aligned beneficiaries of its withdrawal from the ACCESS Model and refer beneficiaries to suitable health care providers as appropriate to ensure continuity of care for the remainder of the care period.[18] Any waivers or protections issued under Section 1115A of the Social Security Act (42 USC § 1315a) and the CMS-Sponsored Model Patient Incentives (42 CFR § 1001.952(ii)(2)) to the ACCESS Participant are no longer applicable as of the effective date of termination.

Beneficiary Eligibility, Outreach and Alignment

The ACCESS Model is designed to serve Original Medicare beneficiaries, including beneficiaries dually eligible for Medicare and Medicaid, who have qualifying chronic conditions in the four initial clinical tracks.

Initial tracks were selected based on condition prevalence, unmet patient need, suitability for technology-enabled care, and suitability for outcome-aligned payment, including the existence of outcome measures that met CMS' measure selection criteria, as described in *Performance Measurement*. Conditions are grouped into clinically related, frequently comorbid categories with shared interventions and care intensity, to support integrated, patient-centered care delivery.

Additional clinical tracks and conditions may be considered for future years of the ACCESS Model.

Beneficiary Eligibility

A beneficiary must meet the following criteria to be eligible for voluntary alignment to an ACCESS Participant:

1. **Clinical Eligibility:** Meet the track-specific Qualifying Conditions described below.
2. **Medicare Coverage:** Be enrolled in Original Medicare Parts A and B, with Medicare as the primary payer
3. **Program Exclusions:**

[18] A "care period" refers to the defined duration during which an ACCESS Participant is responsible for delivering care for the attributed conditions and achieving specified clinical outcomes, defined as 12 months for all tracks

a. Not be enrolled in Medicare Advantage, Program of All-Inclusive Care for the Elderly (PACE), or the Medicare hospice benefit. See *Program Overlaps* for more information, including other track-specific exclusions.

b. Not be actively aligned to another ACCESS Participant for the same track starting within the past 3 months.

c. Not be assigned to the control group. See *Section 10: Evaluation*, for additional information on the model's randomized evaluation.

Participants are responsible for validating clinical eligibility, as described in *Clinical Validation*, and CMS will support validation of Medicare coverage and exclusion criteria through the ACCESS Eligibility API, as described in *Beneficiary Alignment* and shown in *Figure 1*.

Beneficiaries can align with only one ACCESS participant in a given track at a time. However, beneficiaries can simultaneously align with the same or different participants in multiple different tracks. An exception applies to eCKM and CKM. Because CKM encompasses all eCKM clinical measures and care, beneficiaries may not be enrolled in both tracks at the same time. If a beneficiary is already aligned to eCKM and later elects to enroll in CKM, the beneficiary may switch tracks immediately.[19]

Qualifying Conditions:

1. **ACCESS - eCKM:** Hypertension, or two or more of the following conditions: 1) dyslipidemia, 2) obesity or overweight with marker of central obesity[20] , 3) prediabetes.
2. **ACCESS - CKM:** One or more of the following conditions: 1) diabetes mellitus, 2) chronic kidney disease stage 3a or 3b, 3) atherosclerotic cardiovascular disease.
3. **ACCESS - MSK:** Chronic musculoskeletal (MSK) pain.[21]
4. **ACCESS - BH:** One or more of the following conditions: depression, anxiety.

[19] In this case, no three-month lock-in applies. See more information below on patient switching.

[20] Obesity defined as Body Mass Index (BMI) greater than or equal to 30. Overweight defined as BMI 25 – 29.99 along with marker of central obesity, specifically waist circumference greater than 40 inches (102 cm) for men or 35 inches (88cm) for women. Sources: 1) American College of Cardiology/American Heart Association Task Force on Practice Guidelines; The Obesity Society. (2014). 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Journal of the American College of Cardiology, 63(25 Pt B), 2985–3023. doi:10.1016/j.jacc.2013.11.004; 2) Garvey, W. T., Mechanick, J. I., Brett, E. M., Garber, A. J., Hurley, D. L., Jastreboff, A. M., Nadolsky, K., Pessah-Pollack, R., & Plodkowski, R., et al. (2016). American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity (Supplement 3). Endocrine Practice, 22(Suppl. 3), 1–203. https://doi.org/10.4158/EP161365.GL.

[21] Chronic defined as pain lasting more than three months. Musculoskeletal disorders are defined broadly to include conditions affecting bones, joints, muscles, and connective tissues.

CMS will publish additional guidance on qualifying conditions, including ICD-10 codes.

Participants must provide care for all qualifying conditions that a beneficiary has within the track in which they are enrolled, supporting comprehensive, patient-centric care.

Clinical exclusions include:

- **Required Clinical Exclusions:** A beneficiary must not have any of the clinical conditions defined within the Required Clinical Exclusions list in Appendix D
- **Additional Clinical Exclusions:** As part of their application, Participants may propose additional exclusions for CMS review and approval, based on their service model, but may not exclude an entire condition from a track. This policy ensures participants provide comprehensive care for aligned beneficiaries while allowing flexibility for different care delivery models.

Clinical Validation

ACCESS Participants must validate and document each beneficiary's qualifying condition before initiating services. Validation may be established through any one of the following:

1. Clinical assessment by the Participant;
2. Referral from another licensed clinician for the specific condition; or
3. Evidence of the qualifying diagnosis in the beneficiary's clinical record or claims history within a clinically relevant timeframe.

For beneficiaries who qualify only on the basis of a reported hypertension diagnosis, CMS recognizes that temporary blood pressure elevation in clinical settings ("white-coat hypertension") can make an initial diagnosis appear valid when subsequent readings show otherwise. To accommodate this circumstance, Participants may align and begin services based on patient-attested information of a hypertension diagnosis. If follow-up ambulatory or home blood pressure readings confirm that the beneficiary does not have hypertension, the beneficiary is not on antihypertensive medication, and the beneficiary does not otherwise meet the track's qualifying conditions, the beneficiary will be disenrolled. Participants that submit these non-qualifying readings to CMS may retain payments for up to two months of services furnished. Participants that do not submit the non-qualifying readings will have all payments for that beneficiary recouped.[22] Participants with a high rate of such non-qualifying alignments may be subject to CMS audit and corrective action.

[22] The policy described in this paragraph applies only to beneficiaries initially aligned to the eCKM track solely on the basis of a reported hypertension diagnosis, reflecting the unique and common phenomenon of "white-coat hypertension." It does not apply to other tracks or qualifying conditions, for which Participants are expected to complete clinical validation before initiating services.

Beneficiary Outreach

CMS will support patient and referring health care provider awareness of the ACCESS Model and Co-Management Payment, including by maintaining a CMS-hosted public directory of ACCESS Participants. ACCESS participants may engage in direct outreach to potentially eligible beneficiaries, in compliance with standard CMS marketing rules.[23] Beneficiaries may decide, in their sole discretion, which ACCESS Participants to contact if they are interested in the ACCESS Model.

Beneficiary Alignment

Alignment is voluntary and prospective, with patients aligning, or enrolling, with an ACCESS Participant directly. The ACCESS Participant first verifies coverage by querying CMS' ACCESS Eligibility API to verify that the beneficiary meets the coverage criteria (excluding clinical eligibility) as described in *Beneficiary Eligibility*. The ACCESS Participant is then responsible for validating that the beneficiary meets clinical eligibility requirements for the track, as described in this section and Appendix C. Once the ACCESS Participant has confirmed clinical eligibility, they may provisionally align the beneficiary through the CMS Alignment API.

Before initiating alignment, the ACCESS Participant must obtain and document the beneficiary's informed consent. Consent may be provided verbally or in writing and must be documented in the patient's record. Documentation must reflect that the beneficiary agreed to participate in the ACCESS Model, was informed that participation is voluntary, that only one ACCESS Participant may provide services for a given track during an enrollment period, that the beneficiary may end participation or switch participants any time 90 days after enrolling, and any cost-sharing that applies (unless the Participant has elected to offer cost-sharing support in accordance with *Beneficiary Cost-Sharing Support*).

Within a defined number of days of enrollment, Participants must submit baseline clinical and PRO measures through CMS's ACCESS Reporting API, as described in *Performance Measurement*. These baseline data establish the analytic starting point for outcome measurement and are required to maintain enrollment. To balance beneficiary choice with operational stability for participants, beneficiaries may switch to a different participant or voluntarily disenroll any time after 90 days from the start of alignment.[24] Beneficiaries remain aligned to the Participant until they become ineligible or after they have completed

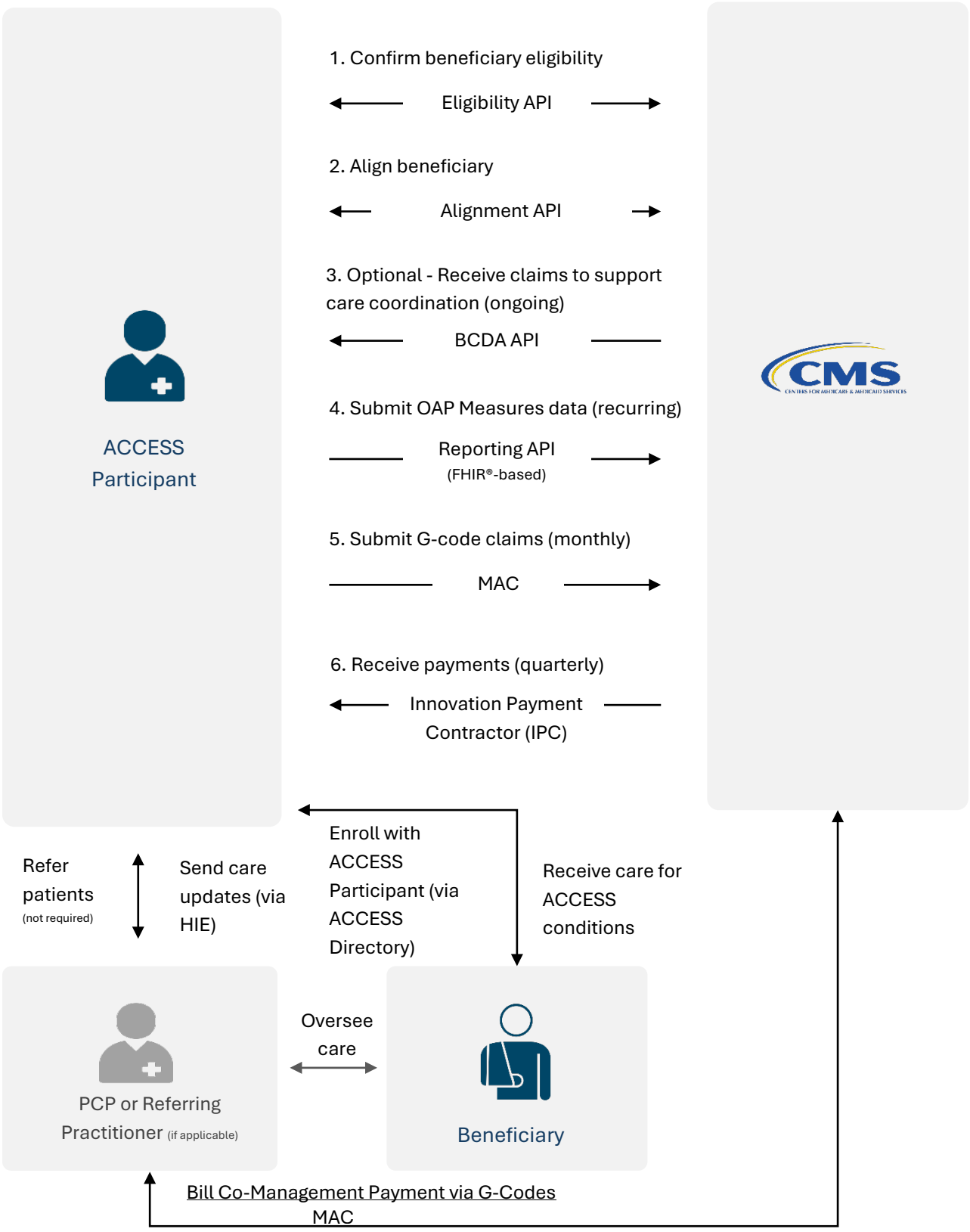
[23] Marketing rules may be updated and are listed here: https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/medicare-guidelines

[24] Beneficiary switching and disenrollment is facilitated via CMS' APIs. More information will be provided in the Participation Agreement and forthcoming Implementation Guide. A new care period begins upon switching.

the 90-day minimum alignment period and choose to switch or disenroll. Participants may initiate disenrollment only under limited circumstances as will be 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 eligibility.

To support an organized wind-down of model operations and ensure that all aligned beneficiaries receive meaningful support from the ACCESS Model, new beneficiaries may not be aligned during the final year of the ACCESS Model, which is July 1, 2035 to June 30, 2036. CMS will publish a detailed Implementation Guide with operational specifications for these processes, including use of FHIR® APIs, data submission standards, and technical workflows. See Figure 1 with an overview of the end-to-end implementation flow, including applicable APIs.

Figure 1. ACCESS Participant End-to-End Flow



Care Delivery

The ACCESS Model emphasizes accountability for outcomes rather than specific activities, allowing ACCESS Participants to adapt their care delivery approach to achieve required clinical outcomes. This structure gives participants more flexibility and less administrative burden to deliver an array of integrated services than is possible under traditional FFS. Examples of services that may be provided by ACCESS Participants include but are not limited to:

- Clinician consultations
- Lifestyle support services such as nutrition counseling, exercise support, and smoking cessation interventions
- Remote monitoring via connected medical devices
- Therapy and behavioral health counseling
- Patient education and care coordination
- Medication prescription and management
- Ordering and interpretation of laboratory and diagnostic tests
- Connected device deployment and monitoring
- Deployment and oversight of FDA-cleared, authorized, or approved software devices

These services may be delivered in-person, virtually, asynchronously, or through other technology-enabled modalities, when permitted under applicable law and clinically appropriate.

Care Delivery Requirements

In addition to the requirements as outlined in *Participant Eligibility Criteria,* ACCESS Participants must:

1. Deliver care that is reasonably designed and implemented in good faith to be safe, high-quality, and consistent with nationally recognized clinical guidelines and standards of practice. For purposes of this application, "consistent with nationally recognized clinical guidelines and standards of practice" means the ACCESS Participant will use reasonable clinical judgment to incorporate applicable guidelines into care, recognizing that guidelines may conflict, evolve during the course of the model, and require individualized application to specific patient circumstances based on current clinical evidence.
2. Identify when a beneficiary's clinical needs exceed the scope of ACCESS services and facilitate transition to an appropriate clinician and care setting to support

continuity and patient safety. Participant's obligations are limited to making a good-faith referral to a qualifying clinician with capacity to manage the patient's clinical needs and provisioning relevant clinical data to the extent exchangeable through existing systems under Participant's control; responsibility for subsequent prescribing or treatment lies with the new qualified clinician.

Clinical Quality Monitoring

CMS will monitor participant performance using claims and FHIR®-based clinical submissions for quality and patient safety, including patterns of care suggesting excessive treatment intensity. CMS may take corrective action or remove Participants that demonstrate persistent or significant overtreatment inconsistent with safe, evidence-based care.

Medical Director[25]

Each ACCESS Participant must designate a physician to serve as Medical Director and be responsible for the delivery of patient care and outcomes under the ACCESS Model. The Medical Director must be a Doctor of Medicine or Osteopathy who is an employee or is under contract with the Participant. The Medical Director is accountable for the quality of medical care provided to aligned beneficiaries. Medical Director responsibilities include, but are not limited to, the following:

- Policies and procedures. The Medical Director must:
    - Participate in the development, periodic review and approval of the Participant's clinical policies and procedures for ACCESS care, including a documented written patient safety plan that establishes protocols for identifying, reporting, and addressing patient safety concerns, including care escalation pathways and management of adverse events associated with the Participant's treatment plans, consistent with all *Care Delivery Requirements*;
    - Ensure that all policies and procedures related to patient care, data reporting, and safety, consistent with all *Care Delivery Requirements,* are adhered to by all individuals who furnish ACCESS services, including physicians and nonphysician practitioners;

[25] This section adapts existing CMS requirements for medical directors in hospice (42 CFR § 418.102) and end-stage renal disease facilities (42 CFR § 494.150).

- Monitor patient outcomes, reasonably validate OAP Measure data, and guide corrective action plans to improve clinical results and compliance; and
- Ensure adherence to all applicable federal and state laws, including licensure, scope-of-practice, and HIPAA privacy and security standards.

A Participant may contract with either of the following - (i) A self-employed physician; or (ii) A physician employed by a professional entity or physicians' group. When contracting for medical director services, the contract must specify the physician who assumes the Medical Director responsibilities and obligations.

Performance Measurement

ACCESS Participants will earn full payment only if aligned beneficiaries meet their targets for applicable OAP Measures by the end of the care period. Track-specific OAP Measures include clinical measures calculated from clinical biomarker data and patient-reported outcome-based performance measures (PRO-PMs) calculated from survey assessment data (PROM data).

OAP Measure Selection Criteria

Each track includes a targeted set of condition-specific OAP Measures designed to reduce burden while holding Participants accountable for outcomes. OAP Measures were selected based on population specificity, clinical relevance, measure properties (validity, reliability, and responsiveness), and feasibility of collection (particularly low burden, commonality, and capacity to be exchanged via FHIR®-enabled APIs).[26]

OAP Measure Targets

Targets are defined relative to each beneficiary's baseline and focus on improvement or control. An example for hypertension would be a 15-mmHg reduction in systolic BP or a final BP below 130/80 mmHg. CMS will publish outcome targets for each OAP Measure, informed by clinical guidelines.

Outcome Measure Requirements by Track

- **eCKM:** Control or minimum improvement in BP, low-density lipoprotein cholesterol (LDL-C), weight, and hemoglobin A1c (HbA1c).
- **CKM:** Control or minimum improvement in BP, LDL-C, weight, and HbA1c; [CKD and diabetes-only] Submission of eGFR and uACR data.

[26] The design criteria aligns with CMS' Meaningful Measures 2.0 Framework and the CMS Innovation Center's Patient-Reported Measure Guidance.

MSK: Minimum improvement in pain intensity, interference, and overall function (assessed via validated PROMs).

- **BH:** Control or minimum improvement in symptoms (assessed via PHQ-for depression and GAD-7 for anxiety).

See Appendix B for detailed outcome measurements and requirements by track.

ACCESS Participants must submit to CMS a baseline value for each required measure in a track within a defined timeframe of aligning a patient, as well as follow-up values at defined, measure-specific intervals, via the CMS FHIR®-based Reporting API. Participants must also submit final OAP Measure results within a defined timeframe of the end of the 12-month care period, even if outcome targets were met earlier, to ensure outcomes are sustained through the conclusion of the care period. CMS may periodically update, add, or remove OAP Measures over the course of the model to reflect clinical evidence, stakeholder feedback, and operational experience.

Performance will be assessed at the participant level based on the share of completed periods where all outcome measure targets were met. Specific benchmarks will be set for each measure, and participant performance will be compared to those benchmarks. This approach balances accountability for results with model accessibility by allowing participants to earn full payment without meeting OAP Measure targets for all aligned beneficiaries. See *Performance-Based Payment Adjustments* for more information.

Payment Design

Outcome-Aligned Payment Overview

The ACCESS Model uses an OAP methodology that links payment to achieving measurable clinical and patient-reported outcomes rather than service volume.

Payment Structure

ACCESS Participants will receive a standard per-patient payment for managing all qualifying conditions a beneficiary has within a given track. This relatively flat payment structure reflects unique attributes of the model:

- Tracks include clinically related, often comorbid conditions that are typically addressed through similar care activities of similar intensity, such as remote monitoring, medication management, and lifestyle support.
- Delivering technology-enabled care generally has low incremental costs per activity, supporting flatter payment structures.

OAP rates will be calibrated to reflect expected resource needs to provide integrated care for each clinical track. OAPs will not include the cost of medications, laboratory tests, imaging, or DMEPOS, which may be coordinated by ACCESS Participants but are billed separately through Medicare FFS by financially unaffiliated entities, as described in *FFS Exclusion* below.

For the eCKM and CKM tracks, OAP rates will account for the expected device cost of a cellular network-connected blood pressure cuff used for condition management and outcome reporting, and for rural patients in these tracks a fixed add-on payment amount will be applied to payments to account for higher distribution costs associated with such devices.[27]

Initial and Follow-On Periods

To support sustained clinical outcomes, the ACCESS Model will include two payment tiers:

- **Initial Period (12 months)**: The Initial Period payment tier reflects the higher resource needs associated with onboarding, establishing care relationships, and achieving initial clinical improvement. Participants qualify for the Initial Period payment when it is the first time the organization is treating the beneficiary in the clinical track within the past two years and at least one required OAP Measure is not at target. Beneficiaries remain enrolled for the full 12-month care period, even if targets are achieved earlier, to ensure sustained results and end-of-period assessment.
- **Follow-On Period**: Follow-On Period payments reflect lower resource needs for continued management of beneficiaries already established in care or whose OAP measures are well controlled at baseline.[28],[29] Participants qualify for the Follow-On Period payment when continuing to manage beneficiaries previously treated by the organization for the same track within the past two years or when initiating care for beneficiaries whose OAP measures are all at target.

For the eCKM and CKM tracks, if a beneficiary is referred by another clinician for the qualifying condition, the Participant qualifies for the full Initial Period payment, even if

[27] Other tracks are not anticipated to include a device and therefore do not have a rural adjustment.
[28] CMS will not require ACCESS Participants to offer a Follow-On Period for continued care, although most are expected to do so. Where a Follow-On Period is offered, beneficiaries may only be denied enrollment under the same limited circumstances that apply to mid-Period disenrollment, such as relocation, loss of contact despite good-faith efforts, or loss of Medicare/track eligibility. If a Follow-On Period is not offered, Participants must still meet continuity-of-care obligations under the RFA and Participation Agreement, including making a good-faith referral to an appropriate clinician, with relevant clinical data shared as reasonably available, to ensure safe and continuous care.
[29] A beneficiary is eligible for a new Initial Period immediately upon enrolling with a different Participant, consistent with the switching rules.

baseline measures are already at target. In such cases, the Participant must include the referring clinician's NPI on the claim when billing.

At the start of each Follow-On Period, Participants must:

- Obtain and document beneficiary consent to continue no more than 60 days prior to the start of the Follow-On Period to remain eligible to bill, using the same documentation standards as initial enrollment;
- Validate and document that the ongoing intervention, including any medications, remains medically necessary and appropriate;
- Submit a new OAP measure baseline if the previous measure was collected outside the defined clinically relevant window.

Full payment remains contingent on meeting the applicable OAP Measure target. For example, if an eCKM beneficiary begins the Initial Period with a systolic blood pressure (SBP) of 165 mmHg and achieves 150 mmHg by the end of the 12-month period, the Follow-On Period target would again require improvement—such as an additional 15 mmHg reduction—relative to the new baseline. Conversely, if the beneficiary achieves guideline-directed control, defined as an SBP below 130 mmHg, by the end of the Initial Period, the Follow-On Period target would be maintenance of control, consistent with the OAP Measure framework.

OAP Rate Adjustments

OAP rates may be updated annually based on the Medicare PFS updates, regulatory changes, or other applicable update factors, including an efficiency adjustment based on the Medicare Economic Index (MEI) productivity adjustment percentage.

When a beneficiary is enrolled in multiple tracks with the same participant, CMS will apply a 5 percent payment discount to the OAP amount for the lower cost track(s) to reflect administrative and operational efficiencies associated with delivering integrated care.

Payment rates and related model parameters will be announced in 2026 in advance of the initial application deadline.

Payment Mechanics

Billing and Claims Processing

The ACCESS Model leverages existing Medicare FFS billing infrastructure and the Innovation Payment Contractor (IPC). Participants will submit monthly claims using new track-specific ACCESS G-codes through a process similar to submitting standard FFS claims for Part B Medicare services to the Medicare Administrative Contractors (MACs). Each claim must include, at the highest level of specificity, all qualifying condition(s) for the

ACCESS track in which the beneficiary is enrolled. CMS will issue additional implementation guidance with detailed billing instructions prior to model launch.

Participants must submit all OAP claims within 90 days of the date of service (DOS). These claims will be processed as "zero-paid" by MACs, with the IPC issuing monthly payments, net of applicable adjustments, based on validated claims for aligned beneficiaries.

Each claim submission will serve as an attestation of active care delivery and continued compliance with model requirements. Active care delivery refers to ongoing provision of services consistent with ACCESS Model requirements as described in this application, including patient engagement, monitoring, and timely collection and reporting of applicable OAP Measures. ACCESS Participants must submit required OAP Measure data within defined timeframes to remain eligible to bill. Further detail and documentation standards will be specified in the Participation Agreement.

Monthly Payment Distribution

CMS will issue monthly payments from the IPC based on valid monthly claims submitted and processed during the prior month. For each aligned beneficiary, 100% percent of the total annual OAP amount will be paid in monthly installments for validated claims during the first 6 months of the care period. The remaining 50 percent of the total annual OAP amount (months 7 to 12) will be withheld and reconciled after the 12-month care period concludes through the Clinical Outcome Adjustment and Substitute Spend Adjustment processes. This approach enables Participants to receive timely payments for care delivered while maintaining accountability for outcomes and minimizing administrative transactions and potential recoupments.

Example:

If an ACCESS Participant manages multiple beneficiaries, each beneficiary's payment is tracked independently. For a beneficiary midway through their 12-month care period—such as a seventh monthly claim—payment for that installment would be withheld pending end-of-period Clinical Outcome and Substitute Adjustment reconciliation, as described below. In contrast, for a newly enrolled beneficiary in their third month, payment would continue as part of the in-period installments. After each beneficiary's 12-month care period, CMS will release the withheld balance, in whole or in part, based on whether the required outcome thresholds were met. Any amount owed to the participant after reconciliation will be paid through a subsequent reconciliation payment.

Performance-Based Payment Adjustments

Payment amounts are subject to two potential downward adjustments, a Clinical Outcome Adjustment and a Substitute Spend Adjustment, applied during a semi-annual reconciliation. CMS will assess performance across each Participant's aligned patient panel, including all aligned beneficiaries whose 12-month care period ended during the prior six-month assessment window in the adjustment calculations.

Clinical Outcome Adjustment

To balance outcome accountability with model accessibility, CMS will determine payment based on achievement against applicable OAP Measures across each participant's full patient panel, rather than requiring every beneficiary to meet outcome targets. This approach will be implemented through a Clinical Outcome Adjustment.

Specifically, CMS will compare each participant's Outcome Attainment Rate (OAR)—the percentage of aligned beneficiaries who completed their 12-month care period and met all required OAP Measure targets and submission requirements—to a defined Outcome Attainment Threshold (OAT), which represents the minimum OAR needed to earn full payment.

In the model's first 18 months, the OAT will be set at 50 percent.

- If a Participant's OAR is equal to or above 50%, the participant will earn the full OAP.
- If a participant's OAR is below 50%, the participant will receive a proportional payment calculated as (OAR ÷ OAT) multiplied by the full OAP amount. For example, if 40 percent of aligned beneficiaries met all OAP Measures, the participant would earn 40 ÷ 50, or 80 percent of the full OAP amount. The Clinical Outcome Adjustment, defined as 1 – (OAR ÷ OAT), would be 20 percent in this case.

The Clinical Outcome Adjustment will be capped at a 50 percent reduction to the full OAP amount. For instance, if only 20 percent of a Participant's aligned beneficiaries met required outcomes and the OAT was 50 percent (which would otherwise yield 40 percent of the full payment), the Participant would still retain 50 percent of the gross OAP payment amount under this cap. Participants that fall short of the minimum threshold may be subject to termination under the Participation Agreement.

The OAT will remain lower for participants in their first year of model participation or when initiating a new track, to support accessibility, and will increase in subsequent participation years up to a defined upper limit. The OAT for the first 18 months of the model will be 50 percent. CMS may adjust the OAT value for subsequent years based on operational experience and overall model goals.

Substitute Spend Adjustment

The Substitute Spend Adjustment follows the same general approach as the Clinical Outcome Adjustment but focuses on reducing duplicative Medicare spending and encouraging comprehensive care delivery. This adjustment is designed to incentivize ACCESS Participants to minimize avoidable duplicative services reasonably within their control, while recognizing that some substitute services may be appropriate and outside the participant's direct influence.

Each clinical track includes a Substitute Spend List identifying services considered substitutes if provided by another Medicare entity for the same condition. The initial lists focus on new service initiations that duplicate care being managed under ACCESS—for example, a new physical therapy evaluation for low back pain while a MSK participant is managing the same condition. See Appendix E for detailed track-specific service lists.

CMS will compare each participant's Substitute Spend Rate (SSR)—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—to a defined Substitute Spend Threshold (SST), which represents the minimum SSR required to earn full payment.

In the model's first 18 months, the SST will be set at 90 percent.

- If a participant's SSR is equal to or above 90 percent, the participant will earn the full OAP.
- If a participant's SSR is below 90 percent, the participant will receive proportional payment calculated as (SSR ÷ SST) multiplied by the total annual OAP amount. For example, if 80 percent of aligned beneficiaries did not receive listed substitute services, the participant would earn 80 ÷ 90, or 89 percent of the full OAP amount. The Substitute Spend Adjustment, defined as 1 – (SSR ÷ SST), would be 11 percent in this case.

The Substitute Spend Adjustment will be capped at a 25 percent reduction to the full OAP amount. This adjustment applies only to payments made to ACCESS Participants. Care provided by non-ACCESS entities for services on the Substitute Spend List will continue to be reimbursed under standard Medicare payment rules.

To support substitute spend management and care coordination, participants will have access to their aligned beneficiaries' Medicare Parts A, B, and D claims data through the Beneficiary Claims Data (BCDA) API, as described in Data Reporting and Sharing. CMS may

adjust the SST value for subsequent years based on operational experience and overall model goals.

Semi-Annual Reconciliation

CMS will conduct payment reconciliations on a semi-annual basis, assessing performance across each participant's aligned patient panel, including all aligned patients whose care period ended during the prior six-month assessment window for both the Clinical Outcome Adjustment and the Substitute Spend Adjustment.

CMS will apply only one of the two potential downward adjustments per semi-annual reconciliation period – the larger of either the Clinical Outcome Adjustment or the Substitute Spend Adjustment – to prevent compounding penalties while maintaining accountability across both performance-based adjustment mechanisms. All adjustments are calculated based on total annual OAP amounts for the assessed patient panel.

CMS will net the reduction against the Participant's withheld payments, and CMS will issue any remaining amounts owed to the participant through a subsequent quarterly payment. If additional recovery is needed beyond available withheld payments, CMS may offset against future payments or initiate formal overpayment recovery processes – including using standard Medicare recoupment mechanisms.

Payment Examples

The following examples illustrate how ACCESS Model payment methodology works in practice. All examples are for illustration purposes only.

Payment Example 1: Successful Outcome Achievement

- **Clinical Outcome Adjustment:** 80% of completed care periods during the trailing 6 months meet all OAP Measure targets (above the 50% threshold).
- **Substitute Spend Adjustment:** 95% of patients did not receive listed substitute services (above the 90% threshold).
- **Final Payment Result:** Participant receives 100% of total annual OAP amount, and the full withheld amount is released in the next reconciliation payment.

Payment Example 2: Clinical Outcome Adjustment

- **Clinical Outcome Adjustment**: 40% of completed care periods meet OAP Measure targets (below the 50% threshold). The Clinical Outcome Adjustment would be 1 – (40 ÷ 50), or 20%.
- **Substitute Spend Adjustment:** 95% of patients did not receive listed substitute services (above the 90% threshold).

- **Final Payment Result:** Participant earns 80% of the total annual OAP amount, reflecting a 20% payment reduction due to the Clinical Outcome Adjustment. Since 50% of the total annual OAP amount was already paid during the care period, the remaining 30% from the withheld amount is released in the next reconciliation payment.

Payment Example 3: Substitute Spend Adjustment

- **Clinical Outcome Adjustment:** 95% of completed care periods meet all OAP Measure targets (above the 50% threshold).
- **Substitute Spend Adjustment:** 88% of patients did not receive listed substitute services (below the 90% threshold)**.** The Substitute Spend Adjustment would be 1 – (88 ÷ 90), or 2%.
- **Final Payment Result:** Participant earns 98% of the total annual OAP amount, reflecting a 2% payment reduction due to the Substitute Spend Adjustment. Because 50% of the total annual OAP amount was already paid during the care period, the remaining 48% from the withheld amount is released in the next reconciliation payment.

Co-Management Payment

To support ongoing care coordination and encourage continued engagement between referring health care providers and ACCESS participants, clinicians who co-manage ACCESS beneficiaries with an ACCESS participant may bill a new ACCESS Model Co-Management service for documented review of ACCESS updates and care coordination activities. The service will be paid at $30 per service, subject to the geographic adjustment[30] and all Medicare payment adjustments and penalties to which the billing practitioner's other Medicare FFS payments are subject, including but not limited to, sequestration, site-of service adjustments for facility and non-facility locations, and standard payment reductions for services furnished by non-physician practitioners. To bill the Co-Management code, the consulting clinician must review the ACCESS Care Update and place a brief written note in the EHR documenting the assessment and any care-

[30] To account for geographic variation in costs, CMS will adjust the ACCESS Co-Management Payment national base rate by the Medicare PFS Geographic Adjustment Factor (GAF) for each submitted claim. The GAF applied to the TEC Co-Management Payment is a weighed geographic adjustment based on all services in the Medicare PFS. It summarizes the combined impact of the three Geographic Practice Cost Index (GPCI) expense categories (work, practice expense, malpractice) on a locality's (state or metropolitan region's) physician payment level. The intent of the GAF is to ensure that the Medicare program does not overpay health care providers in certain areas and underpay in others because of geographic differences in prices of resources such as clinical and administrative staff salaries and benefits, office or hospital space (rent), medical supplies, and malpractice insurance. CMS publishes updated GAFs annually as part of the Medicare Physician Fee Schedule (PFS) Final Rule in Addendum D. The GAF applied to each TEC Co-Management Payment claim is based on the Service Facility Zip Code submitted on the claim form.

coordination action, such as a medication change or reconciliation, updated problem list, monitoring instruction, or referral. Clinicians who assist a beneficiary with onboarding and initial setup activities may also bill the Co-Management code with a CMS-specified modifier the first time they bill for that beneficiary to receive an additional payment of approximately $10, subject to the adjustments described above.

The payment will be limited to once every four months per beneficiary per track, up to approximately $100 per year. There will not be Part B beneficiary cost-sharing for this service and advance consent from beneficiaries would not be required. Documentation requirements ensure that co-management payments reflect genuine care coordination activities. The ACCESS Co-Management Payment G-code and its modifier will be shared with Medicare providers or suppliers in 2026. CMS may adjust the payment amount in later years based on operational experience related to utilization, care-coordination patterns, and overall model goals.

Beneficiary Cost-Sharing Support

CMS intends to offer the CMS-sponsored model patient incentive safe harbor (42 CFR § 1001.952(ii)(2)) to ACCESS participants who wish to forego collection of beneficiary cost-sharing for OAPs as a beneficiary engagement incentive. ACCESS Participants may indicate in the model application whether they will collect or forego collection of OAP cost-sharing. Participants must apply this policy uniformly to all beneficiaries, consistent with the requirements to be set forth in the applicable governing documentation and all applicable laws and regulation (see *Authority to Test the Model*). If an ACCESS Participant elects to collect OAP beneficiary cost-sharing, they must clearly disclose the expected beneficiary payment amount before beneficiary enrollment.

Medicare Participation

As described in *Participant Eligibility Criteria*, all physicians and non-physician practitioners furnishing or supervising care must be individually Medicare-enrolled, Medicare-participating providers or suppliers who have reassigned their Medicare billing rights to the Participant. As Medicare-participating providers and suppliers, they agree to accept claims assignment for all Medicare-covered services furnished to the Participant's aligned beneficiaries. By accepting assignment, they agree to accept the Medicare-allowed amounts as payment in full, which includes any beneficiary cost-sharing (unless the Participant has foregone collection of beneficiary cost-sharing, consistent with *Beneficiary Cost-Sharing Support*).

FFS Exclusion

The ACCESS Model offers an outcome-aligned payment option that replaces traditional fee-for-service billing. To preserve model integrity and prevent duplicative Medicare payments, ACCESS Participants and their affiliated entities may not submit Medicare FFS claims (directly, or indirectly through another organization for which they provide contracted services) for aligned beneficiaries during active care periods. Medicare claims processing systems will incorporate automatic controls that suppress FFS billing from ACCESS Participants for aligned beneficiaries during their care periods. Restrictions do not limit beneficiary choice in seeking care from other health care providers, with any applicable payment adjustments applied to Medicare payments rather than restrictions on beneficiary access.

For purposes of the FFS Exclusion, an affiliation means any of the following:

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of this paragraph, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
- Any reassignment relationship under 42 CFR § 424.80.

As described in *Participant Eligibility,* an ACCESS Participant is defined at the organizational, or TIN, level. The FFS Exclusion only applies in relation to the ACCESS Participant.

Data Reporting and Sharing

Data Reporting Requirements

In accordance with 42 CFR 403.1110(b), any entity participating in the testing of an Innovation Center model is required to collect and report such information, including "protected health information" as defined in 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate the model. ACCESS Participants will be required to collect and report to CMS clinical outcome data and other model-specific metrics. All clinical data must be submitted via a FHIR®-based API with standardized data elements.

Data Sharing

ACCESS Participants will have the opportunity to request access to certain Medicare claims data through the Beneficiary Claims Data API (BCDA).[31] to support care coordination for their aligned beneficiaries. Participants will receive regular reports on alignment, payment, and performance. CMS data sharing and data analytics in the ACCESS Model will be designed to comply with applicable federal laws, including the privacy and security requirements promulgated under HIPAA. ACCESS Participants that wish to receive beneficiary-identifiable data from CMS will be required to submit a HIPAA-Covered Data Disclosure Request and Attestation (DRA) form to request the specific types of data that ACCESS Participants will need to perform certain health care operations activities related to the ACCESS Model and attest that the data requested is the minimum necessary to perform those activities, consistent with HIPAA Privacy Rule requirements. CMS will provide the DRA to be completed by the Participant.

In the event the Innovation Center develops new, center-wide data sharing strategies, including data aggregation, during the Model Performance Period, CMS will strive to align ACCESS data sharing with these strategies as appropriate. The Innovation Center may also use existing platforms to create data dashboards and provide downloadable files to provide information back to the Participant as needed.

ACCESS Participant Directory

To promote transparency, beneficiary choice, and quality-based competition, CMS will maintain a public-facing directory of all ACCESS Participants. The directory will highlight each organization's tracks, the conditions they treat, and their risk-adjusted outcomes.[32] Risk-adjusted outcomes will be based on clinical information collected when administering the Outcome-Aligned Payments. This visibility is designed to highlight high-quality care, strengthen referral relationships, and create new opportunities for participants who demonstrate strong outcomes.

Care Coordination Requirements

ACCESS Participants are required to support care coordination by making reasonable efforts to identify beneficiaries' existing care team members—specifically any primary care practitioner (PCP) and referring clinician, if applicable—and to share standardized clinical

[31] https://bcda.cms.gov/

[32] The public directory will not include any beneficiary-identifiable information and will apply minimum case count reporting thresholds to protect patient privacy, in alignment with CMS Cell Size Suppression Policy (https://resdac.org/articles/cms-cell-size-suppression-policy), and to support statistical reliability of quality measure reporting. CMS will publish its reporting methodology (including data sources, calculation methods, and risk-adjustment approach) and maintain a process for Participants to request data corrections.

updates at key points in care. These requirements promote safe, coordinated, and transparent management of beneficiaries' conditions while minimizing administrative burden, reducing alert fatigue, and ensuring that only the minimum necessary information is shared to support patient care.

Identifying the Care Team

Participants must make a good-faith effort to determine whether each beneficiary has an existing PCP or referring clinician (collectively referred to as the "Identified Care Team"). This requirement is met when the Participant:

1. Asks the beneficiary during enrollment to provide the name and, if known, contact information of their current PCP and any clinician who referred them for ACCESS services;
2. Reviews any CMS-supplied information, if made available at the time of alignment, which may include Medicare providers or suppliers associated with the beneficiary;
3. (*Optional*) Reviews clinical data (for example, from an HIE) to identify the beneficiary's PCP or referring clinician;
4. Documents all steps in the beneficiary's record.

If the beneficiary does not identify a current PCP or referring clinician, or none can be confirmed through CMS data, the Participant's obligation under this section is considered met. CMS may also make available a national provider or supplier directory to assist Participants in identifying relevant provider or supplier information.

Before sharing updates, Participants must obtain the beneficiary's consent to proactively share care updates with their Identified Care Team. Such consent must meet all applicable requirements under federal and state law. If the beneficiary declines, the Participant's obligation to share updates under this entire section is satisfied.

Proactively Sharing Updates

Participants must make a reasonable, good-faith effort to proactively share care updates with each beneficiary's Identified Care Team using secure, nationally recognized exchange methods, to the extent permitted by law.

This requirement is met when a Participant:

- Proactively sends or attempts to send the minimum required updates through a secure electronic method such as Direct Secure Messaging, an HIE-supported push mechanism, or a HIPAA-compliant exchange method.

- To meet this obligation, Participants must make a reasonable effort to determine how to reach the identified PCP or referring clinician. Checking at least one trusted source for valid contact or routing information—such as an HIE or state/regional directory, a DirectTrust directory, or NPPES endpoint listing—fulfills this requirement. Accessing such information through a Health Information Service Provider (HISP) 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 reasonable steps to ensure that the information is sent only to the intended recipient, consistent with requirements under federal and state law. This may include confirming the identity and secure endpoint of the receiving provider by verifying the provider's name, NPI, and practice affiliation in a trusted exchange directory such as an HIE, DirectTrust, or 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.

Documents the outcome of the attempt—whether the message was successfully delivered or noted as "no secure address available" after performing the steps above.
Participants must also make each standardized care plan and update reasonably accessible to the beneficiary.

Standardized Care Plan Template

CMS will provide a concise, standardized care plan and update template that Participants must use to ensure consistency and minimize burden. The template will include fields for:

- Beneficiary identifiers;
- Contact information for the ACCESS Participant, including a monitored clinical contact (such as a care coordination team or clinician) who can respond to care-related inquiries within a reasonable timeframe, and the Medical Director's name for oversight purposes;
- Baseline measures and treatment goals;
- Active medications and relevant laboratory results;
- Narrative summary of progress or outcomes; and
- Treatment plan

Required Coordination Reporting — Minimum Required Updates

To promote effective care coordination while minimizing alert fatigue, CMS has defined a limited, standardized set of Required Coordination Reporting moments when ACCESS Participants must send updates to the Identified Care Team.

All Participants must transmit updates at the following core moments:

- Care Initiation: Within 10 days of care initiation. Communicates care plan, baseline measures, responsible contact, and initial goals.
- Care Completion: Within 30 days after the end of the 12-month care period, or sooner if the beneficiary disenrolls or transitions care. Summarizes achieved outcomes, medications, and follow-up recommendations.
- Care Escalation: Within 10 days of any transition of the beneficiary to another clinician or care setting due to clinical needs exceeding the scope of ACCESS services.

Additional communication for important clinical updates is encouraged but not required.

Health Information Technology Requirements

ACCESS Participants will not be required to utilize Certified Electronic Health Record Technology (CEHRT) as defined in 42 CFR 414.1305. However, to ensure interoperability, care coordination, and alignment with national data exchange and interoperability initiatives, participants will be expected to utilize, where applicable, health information technology that meets standards and implementation specifications adopted under 45 C.F.R. Part 170, Subpart B, and certain certification criteria adopted under 45 CFR Part 170, Subpart C, by the Office of the National Coordinator for Health Information Technology (IT) (ONC) consistent with the ONC Health IT Certification Program, and to meet the following minimum Health Information Technology (HIT) requirements:

1. **Standardized APIs for Patient and Population Services**: Participants must implement Application Programming Interfaces (APIs) in a manner that meets the Standardized API for patient and population services certification criteria, adopted by the Assistant Secretary for Technology Policy (ASTP) and ONC for use in the ONC Health IT Certification Program at 45 CFR § 170.315(g)(10) and at a minimum the most recent version of the USCDI adopted in 45 CFR 170.213. This requirement ensures patients and authorized health care providers can access and exchange electronic health information using FHIR®-based standards.

2. **Health Information Exchange**. Within 12 months of the model start date, participants must establish or maintain connectivity to a health information exchange (HIE) that enables bidirectional electronic exchange of health information across the geographic areas where the participant is able to deliver care. Connectivity must support timely, reciprocal exchange of clinical information with other health care providers involved in a beneficiary's care to ensure care coordination and continuity.
3. **Data Submission to CMS:** Participants must be able to transmit required clinical and patient-reported outcomes through the CMS Innovation Center's FHIR®-based reporting FHIR® server, consistent with CMS Innovation Center data collection processes, with technical specifications to be provided by CMS.

Participant Monitoring and Payment Validation

CMS will monitor ACCESS Participants on a regular, ongoing basis to ensure program integrity and support patient safety. CMS will use ACCESS Participant data reporting in its monitoring strategy, including but not limited to claims, cost, and quality data.

Regular program monitoring may result in audits of select ACCESS Participants. Data that ACCESS Participants submit to CMS, performance on quality measures, referral and billing patterns, and other practice information may trigger an audit of ACCESS Participants with anomalous findings. CMS may also randomly select ACCESS Participants for audit.

ACCESS Participants will be required to maintain copies of all documentation related to their implementation of the ACCESS Model in case of an audit. More information related to the ACCESS Model's record retention policy will be provided in the Participation Agreement.

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

Payment Validation and Monitoring

The ACCESS Model incorporates comprehensive financial safeguards to ensure payment accuracy and program integrity. Monthly monitoring processes track outcome achievement and payment calculations, with reconciliation processes identifying any overpayments or discrepancies. Participants may receive 30-day notice periods for overpayment recovery, with standard Medicare interest rates applying to amounts exceeding the notice period, in

alignment with standard Medicare overpayment recovery procedures under 45 CFR § 30.11(b)(1)(ii).

Financial Audit and Oversight

Annual financial audits are required for participants exceeding specified payment thresholds, ensuring appropriate use of Medicare funds and compliance with model requirements. Real-time monitoring systems integrate with existing CMS fraud detection capabilities to identify unusual billing patterns or potential program integrity concerns.

Evaluation

All ACCESS Participants will be required to cooperate with CMS efforts to conduct an independent, federally-funded evaluation of the ACCESS Model, which may include completion of surveys and participation in interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive evaluation. The ACCESS Model will be evaluated using a randomized design with beneficiary-level randomization. CMS will conduct the randomization and communicate assignment results to Participants through the CMS Eligibility and Alignment APIs. Before querying the APIs to verify a beneficiary's eligibility or enroll a beneficiary, Participants must inform the beneficiary that the service is offered as part of a new CMS payment model test and that, as part of model evaluation, their data may be shared with CMS subject to federal privacy and security protections; that they may be randomly assigned to a comparison group and therefore ineligible to participate in the clinical track while continuing to have access to all usual Medicare benefits and services; and that such assignment will not affect their Medicare benefits, rights, or coverage. If a beneficiary is assigned to the control group, they will not be eligible to participate in the model for the following 12-month period. To preserve the integrity of the evaluation, Participants will be required to use standardized language provided by CMS when informing beneficiaries of assignment to the control group.

The randomization rate will start at 90:10 intervention-to-control ratio in the first year and may be adjusted or eliminated in future years depending on the number of beneficiaries enrolled in the model and the evaluation's ability to detect impact of the model on improved quality and reduced Medicare spending. The evaluation will assess cost, utilization patterns, quality measures, and beneficiary outcomes using Medicare claims data, surveys, and other data sources.

Authority to Test the Model

The ACCESS Model will be tested under the authority granted in Section 1115A of the Social Security Act, which established the Innovation Center for testing innovative payment

and service delivery models to reduce expenditures while preserving or enhancing quality of care.

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

- Waive requirements of 42 U.S.C. 1395w–4(q) (e.g., MIPS eligibility, reporting, and payment adjustments) and § 1395l(a)(1) (e.g., the portion of reasonable charges that Medicare pays for services).
- Provide alternative payments outside the FFS structure.
- Allow CMS to pay 100 percent of the reasonable charge of certain services for Co-Management Payments.
- Withhold payment based on outcome performance.
- Apply payment adjustments without complex reconciliation.
- Support access and integration through specific waivers and safe harbors, including benefit enhancements, and program waivers as needed to provide for alternate payment mechanisms, allow for services to be provided via telehealth, asynchronously, and/or directly through the applicable technology.

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

These flexibilities are necessary to test a new payment approach aligned with the Center's mandate.

Merit-Based Incentive Payment System (MIPS) Alternative Payment Model (APM) and Advanced APM Status

The ACCESS Model will not qualify as an Advanced Alternative Payment Model (A-APM). CMS anticipates that ACCESS services would not contribute to MIPS-eligibility and reporting and will not receive MIPS payment adjustments (see *Authority to Test the Model*).

Program Overlaps

The ACCESS Model is designed to complement other CMS models, expanding access to technology-enabled care while maintaining alignment with broader efforts to manage quality and total cost of care.

Beneficiary Overlap

Aligned beneficiaries may be attributed to other CMS models, except where explicitly restricted, supporting risk-bearing organizations such as ACOs in managing total cost of care. For example, a beneficiary may be concurrently aligned to both an MSK participant and to an ACO, including both ACO REACH and the Medicare Shared Savings Program (MSSP). Costs associated with ACCESS G-codes would be treated like other FFS claims for purposes of ACO financial reconciliation. CMS is evaluating a temporary exclusion of ACCESS spending from ACO financial benchmarks and reconciliation during the first 18 months of the ACCESS Model, before incorporating related spending into total cost of care calculations in later years.

Certain beneficiary exclusions apply to avoid overlapping participation with programs addressing the same conditions or due to clinical exclusions:

- CKM and eCKM beneficiaries may not be receiving dialysis for End-Stage Renal Disease (ESRD).
- BH beneficiaries may not be enrolled in a Certified Community Behavioral Health Clinic (CCBHC) program.

Participant Overlap

Organizations (identified at the TIN-level) and individual practitioners (identified at the NPI level) may participate in the ACCESS Model and other current Innovation Center models, as well as MSSP. This flexibility is particularly relevant for organizations that participate in multiple care models, including those not covered by ACCESS. However, participants are not expected to align the *same beneficiary* to ACCESS and another model in which they are participating due to the *FFS Exclusion* policy described above.

Multi-Payer Alignment

The ACCESS Model is designed to support potential adoption by other payers, including Medicare Advantage, Medicaid, commercial plans, enabling alignment across payers, reducing health care provider burden, and scaling impact.

ACCESS Participants will use CMS-defined, track-specific codes that could also be used by other payers, facilitating consistency in billing, data exchange, and cross-payer performance analytics in the future. To further support uptake, support cross-payer standardization, and reduce administrative waste, CMS may publish optional payer

implementation resources, such as illustrative health care provider sample agreements and accompanying documentation, with appropriate CMS disclaimers.[33]

[33] Providing sample contracts aligns with proposals to reduce administrative waste by facilitating voluntary cross-payer contract standardization. See "Applying Precedents Thinking to the Intractable Problem of Transaction Costs in Healthcare." Istvan et al. Health Management, Policy and Innovation (HMPI). Nov 2024.

Appendix

Appendix A: Participant Application Guidance and Questions

Thank you for your interest in the CMS Innovation Center's Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model. This application must be submitted through the ACCESS online application portal. Submission of this PDF or paper versions will not be accepted. The application must be certified as true, accurate, and completed by an individual authorized to represent the organization (i.e., the legal entity submitting the application).

CMS review:

- CMS will review applications for completion and compliance with model eligibility criteria.
- CMS may request additional information from applicants after submission.
- CMS may deny participation based on program integrity concerns, including adverse legal history, failure to meet enrollment requirements, or other compliance risks.
- Not all applicants will be accepted into the ACCESS Model.

Participation agreement:

- If selected, applicants will be required to execute a Participation Agreement with CMS.
- All commitments in this application (including certifications and attestations) will be incorporated into that agreement and must be met as a condition of participation.

Program integrity:

- Applicants and their financially affiliated entities must be in good standing with Medicare and Medicaid.
- CMS will review ownership, affiliations, and historical billing data as part of the program integrity review.

Section 1: Applicant Information

1. **Legal Business Name:** _____
2. **Doing Business As (DBA), if applicable:** _____
3. **Primary Address:** Street, City, State, ZIP

4. **Website:** _____
5. **Primary Contact:** Name, Title, Email, Phone
6. **Secondary Contact :** Name, Title, Email, Phone
7. **Taxpayer Identification Number (TIN/EIN):** _____
8. **Year Incorporated (YYYY):** _____
9. **Workforce (as of application date):**
    - Full-time employees (W-2): _____
    - Licensed clinicians affiliated with this TIN[34]
        - Total _____
        - of which W-2: _____
        - of which 1099/contracted: _____
10. **Organizational NPIs**
    List all organizational NPIs that bill under your TIN: _____
11. **Medicare Enrollment**
    Is the applicant TIN enrolled as a Medicare Part B supplier eligible to bill under the Physician Fee Schedule?
    - ☐ Yes, currently enrolled
    - ☐ Not yet enrolled; we certify enrollment will be completed prior to execution of the Participation Agreement
12. **Medical Director**
    Each participant must designate a physician as Medical Director. The Medical Director must be individually enrolled in Medicare and in good standing by the time of execution of the Participation Agreement.
    - Name: _____
    - NPI: _____
    - Status (select one):

[34] Any physician and non-physician practitioner delivering or overseeing ACCESS services under the applicant's TIN who holds an active professional license in their practicing state.

- ☐ Currently enrolled in Medicare
- ☐ Not yet enrolled; will be enrolled prior to execution of the Participation Agreement

13. Associated Clinicians

Provide NPIs for all clinicians who will deliver or oversee ACCESS services under your TIN.

- ☐ If not final, we certify we will submit a complete roster prior to execution of the Participation Agreement

14. State Licensure

- States where your organization and clinicians are currently licensed: [Multi-select]
- States where you intend to be licensed by your start date: [Multi-select]
- ☐ I certify all clinicians delivering ACCESS services will be licensed and in good standing in each state where they practice

15. Restructuring / TIN Changes

Has your organization restructured, merged, changed ownership/TINs, or used a different TIN in the past 5 years?

- ☐ No
- ☐ Yes → Please describe (≤1,000 characters): _____

16. Historical TINs

List all TINs under which your organization has billed Medicare in the past 5 years, including effective start and end dates.
List TIN, Start Date, End Date

17. Prior CMS Initiative Participation

Has your organization participated in any other CMS Innovation Center models or Medicare programs (such as the Shared Savings Program)?

- ☐ No
- ☐ Yes → Please list: _____

18. Program Integrity (past 5 years)

In the past 5 years, has the applicant organization, any owner, or any affiliated entity, as defined in 42 CFR § 424.502, been subject to a final adverse legal action,

sanction, or ongoing investigation related to Medicare or Medicaid billing, fraud, abuse, or licensure?

- ☐ No
- ☐ Yes → Provide dates, agencies involved, and resolution (≤1,000 characters): _____

Section 2: Care Model and Clinical Scope

19. Track Selection (check all that apply):

- ☐ eCKM (Early Cardio-Kidney-Metabolic: hypertension, dyslipidemia, obesity, prediabetes)
- ☐ CKM (Cardio-Kidney-Metabolic: diabetes, chronic kidney disease, atherosclerotic cardiovascular disease)
- ☐ MSK (Musculoskeletal: chronic musculoskeletal pain)
- ☐ BH (Behavioral Health: depression, anxiety)

20. Conditions Coverage

- ☐ I certify we will deliver care for all conditions in each selected track

21. Patient Clinical Exclusions

- **If using additional criteria, beyond the CMS-required clinical exclusions, to exclude patients who would not be suitable for model services due to patient safety standards, please list (if any):**
  - ☐ None
  - ☐ Yes → List exclusions and provide rationale as to why this exclusion is necessary (≤500 characters): _____

22. Services Readiness Matrix

Which of the following services does your organization provide, or will provide at launch, under ACCESS? (Select all that apply)

- ☐ Medication management
- ☐ Prescribing medication
- ☐ Clinician consultations (real-time)
- ☐ Clinician consultations (asynchronous)

- ☐ Lifestyle support (nutrition, exercise, smoking cessation)
- ☐ Remote monitoring via connected devices
- ☐ Physical or occupational therapy
- ☐ Behavioral health and mental health therapy
- ☐ Patient education
- ☐ Connection to social support services (food, housing, transportation)
- ☐ Other (specify): _____

23. Scale and Patient Population Experience

Provide approximate number of patients treated in the past 12 months across all payers and Medicare-eligible patients (65+ or with Medicare entitlement); write "N/A" if none treated.

Condition	**Total patients (all payers)**	**Medicare-eligible patients**[35]
Hypertension	_____	_____
Dyslipidemia	_____	_____
Obesity and overweight	_____	_____
Prediabetes	_____	_____
Diabetes mellitus	_____	_____
Chronic kidney disease (non-ESRD)	_____	_____
Atherosclerotic cardiovascular disease	_____	_____
Chronic musculoskeletal pain	_____	_____
Depression	_____	_____
Anxiety	_____	_____
Other condition(s) (specify): _____	_____	_____

[35] A patient who is age 65 or older, or under 65 and entitled to Medicare due to disability or other qualifying criteria, regardless of whether services were paid through Original Medicare (Fee-for-Service) or another source.

24. Use of Technology in Care Delivery

Briefly describe how your organization uses or plans to use technology to deliver patient care. Please also identify any FDA-regulated digital health devices that your organization has integrated or plans to integrate into its care delivery model, which may include device software functions (including mobile medical applications), artificial intelligence/machine learning (AI/ML)-enabled medical devices, or connected medical devices that your organization furnishes, deploys, or manages as part of clinical care. See "FDA: Digital Health Terms" for more information. If you do not currently use and/or do not plan to use technology to deliver patient care, please enter N/A.[Short text, ≤1,000 characters]

25. Care Delivery Setting

Select all that apply:

- ☐ Virtual-only (no physical clinics)
- ☐ Virtual-first, with brick-and-mortar clinics operated directly
- ☐ Virtual-first, with brick-and-mortar clinics operated through contracted partners
- ☐ Brick-and-mortar only (no virtual care)
- ☐ Other (please describe): _____

26. Electronic Data Exchange

- ☐ Currently integrated with a Health Information Exchange (HIE) or equivalent system
- ☐ Not currently integrated; we certify we will establish this prior to delivering ACCESS services

27. Certification of Care Coordination

- ☐ I certify we will provide electronic Care Updates to referring and primary care practitioner(s), as described in the Request for Application's *Care Coordination Requirements* Direct Secure Messaging (DSM) Address, if applicable: _____

28. Geographic Service Area

List the states where you intend to deliver ACCESS services at launch: [Multi-select state]

29. Beneficiary Cost-Sharing Policy

ACCESS Participants must establish a uniform policy regarding the beneficiary cost-

sharing component for ACCESS Outcome-Aligned Payments (OAPs) and apply it consistently across all aligned beneficiaries within each clinical track. Participants may revise their cost-sharing policy after model launch with CMS approval, provided the updated policy is applied uniformly on a go-forward basis for new and renewing beneficiary alignments within the affected clinical track.
Select the cost-sharing policy your organization intends to adopt for ACCESS services:
• ☐ Collect standard Medicare Part B cost-sharing amounts
• ☐ Forego collection of beneficiary cost-sharing as a beneficiary engagement incentive subject to 42 CFR § 1001.952(ii)(2)

Section 4: Ownership Interest

29. Ownership and Financial Affiliations

- List all parties with **5 percent or greater ownership interest** in the applicant and in any parent entities.
- List all **affiliated TINs,** as defined in 42 CFR § 424.502

30. Common Ownership TINs

List all Taxpayer Identification Numbers (TINs) below that are entities separately enrolled, contracted, billing, and/or potentially could participate in ACCESS but share a common parent entity, majority common ownership, or controlling interest.

- List all Common Ownership TINs: _____
- ☐ This is the Primary TIN for our Common Ownership group
- ☐ This TIN is not part of a Common Ownership group

Section 5: Certifications

31. Beneficiary Alignment

- ☐ I certify our organization will obtain informed consent, apply CMS-defined eligibility rules (including exclusions), and preserve beneficiary choice to switch or disenroll.

32. Financial Affiliation

- ☐ I certify that neither our organization nor our financially affiliated entities will bill Medicare fee-for-service for aligned beneficiaries during an ACCESS care period.[36]

33. Performance Accountability

- ☐ I acknowledge that participation in ACCESS is contingent on meeting required outcome thresholds, and that failure to meet minimum clinical outcome performance may result in termination.

34. Regulatory Compliance

- ☐ I certify our organization is and will remain in compliance with all applicable federal and state laws and regulations governing the delivery of health care services.
- ☐ I certify our organization is and will remain in compliance with FDA requirements for regulated technologies.
- ☐ I certify our organization is a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that complies with and will remain in compliance with the HIPAA privacy, security, and breach notification rules.
- ☐ I certify all clinicians furnishing ACCESS services under our TIN are, and will remain, appropriately licensed and in good standing in the states where they practice.

35. Patient Escalation Protocols

- ☐ I acknowledge that ACCESS participants must establish and maintain predefined protocols for transitioning beneficiaries who require escalated care, consistent with clinical guidelines.

36. General

- I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief.
- I certify that I am authorized to make the assertions contained herein as an agent of the applicant.

[36] The period during which a Medicare beneficiary is prospectively aligned to an ACCESS participant for a clinical track. Includes the Initial Period (12 months) and any Follow-On Periods (12-month increments, where applicable.

- If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS immediately.
- Name: _____ | Title: _____ | Signature: _____ | Date: _____

Appendix B: Outcome Measures

This table presents the measures used for assessing participant performance as part of the Outcome-Aligned Payment methodology. Each measure is listed as required for specific programmatic tracks, and is categorized by measure type (clinical measure, PRO-PM, or PROM). The minimum necessary data for reporting each measure is included along with the minimum reporting frequency for these data.

Measure Name[37]	**Required for Track(s)**	**Description**[38]	**Measure Type**	**Data for Reporting**	**Data Reporting Frequency (minimum)**
Blood Pressure Reduction or Control	eCKM, CKM	The percentage of patients whose blood pressure decreased from baseline (systolic only) or was controlled (at or below a specific systolic and diastolic threshold) during the measurement period.	Clinical Measure	Blood pressure (systolic and diastolic)	Baseline, Quarterly,[39] End-of-period
Low-Density Lipoprotein Cholesterol (LDL-C) Reduction or Control	eCKM, CKM	The percentage of patients whose LDL-C decreased from baseline or was controlled during the measurement period.	Clinical Measure	LDL-C, Optional: triglycerides, total cholesterol, HDL	Baseline, End-of-period
Weight Reduction or Control	eCKM, CKM	The percentage of patients whose weight decreased from baseline or was maintained during the measurement period.	Clinical Measure	Weight, BMI Optional: waist circumference	Baseline, Quarterly, End-of-period
Hemoglobin A1c (HbA1c) Reduction or Control	eCKM, CKM	The percentage of patients whose HbA1c decreased from baseline or was controlled during the measurement period.	Clinical Measure	HbA1c	Baseline, End-of-period
Kidney Health Monitoring	CKM (Required only for patients with diabetes or CKD)	The percentage of patients with chronic kidney disease or diabetes (as of baseline measurement) who received a kidney health evaluation,	Clinical Measure	eGFR, uACR	Baseline

[37] All measures used for Outcome-Aligned Payment in the ACCESS model are stewarded by the CMS Innovation Center with specifications designed for use in the ACCESS model.
[38] The precise numerical target that defines "improvement" and "maintenance" for each measure, along with denominator exclusions, will be specified in a future guidance document.
[39] Quarterly is defined as the requirement to report four data points approximately every 3 months.

Measure Name[37]	Required for Track(s)	Description[38]	Measure Type	Data for Reporting	Data Reporting Frequency (minimum)
		defined by an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR), at least once during the measurement period.			
Musculoskeletal Pain: Improvement in Pain and Function	MSK	The percentage of patients whose chronic musculoskeletal pain and function improved from baseline.	PRO-PM	One PROM[40] selected according to site of pain: PROMIS PF short-form 6b[41] or Version 2.0 CAT AND PROMIS PI short-form 6a[42] or Version 2.0 CAT (any site or multiple sites of pain), QuickDASH[43] (shoulder, arm, hand),KOOS JR[44] (knee), HOOS JR[45] (hip), ODI[46] (lower back), NDI[47] (neck). AND NRS or PROMIS NRS v1.0 - Pain Intensity 1a	Baseline, Quarterly, End-of-period

[40] The PROMs or survey instruments required for the MSK track are pending final licensing approval with associated measure stewards.
[41] PROMIS Physical Function (PROMIS PF) Short-form 6b: https://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures
[42] PROMIS Pain Interference (PI) Short-form 6a: https://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures
[43] QuickDASH 11-item: https://dash.iwh.on.ca/about-quickdash
[44] Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS, JR): https://www.hss.edu/research/healthcare-research-institute/hoos-koos
[45] Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS JR): https://www.hss.edu/research/healthcare-research-institute/hoos-koos
[46] Modified Oswestry Disability Index (ODI) version 2.1a 10-item: https://eprovide.mapi-trust.org/instruments/oswestry-disability-index
[47] Neck Disability Index (NDI) version 2.0 10-item: https://eprovide.mapi-trust.org/instruments/neck-disability-index

Measure Name[37]	Required for Track(s)	Description[38]	Measure Type	Data for Reporting	Data Reporting Frequency (minimum)
Depression Reduction or Remission	BH	The percentage of patients with major depression or dysthymia who demonstrated a reduction in depressive symptoms or remission.	PRO-PM	PHQ-9	Baseline, Quarterly,[48] End-of-period
Anxiety Reduction or Remission	BH	The percentage of patients with an anxiety disorder who demonstrated a reduction in anxiety symptoms or remission.	PRO-PM	GAD-7	Baseline, Quarterly,[49] End-of-period
Overall Function: Improvement or Maintenance	BH	The percentage of patients with major depression, dysthymia, or an anxiety disorder who completed the WHODAS 2.0 12-item. In a future model year, the measure may assess the percentage of patients with major depression, dysthymia, or an anxiety disorder, who maintained or improved overall function.	PRO-PM	Optional: WHODAS 2.0 12-item[50]	Baseline, End-of-period
Patient Global Impression of Change	BH, MSK	The percentage of patients who completed the Patient Global Impression of Change (PGIC) assessment once during the measurement period.	PROM[51]	PGIC	End-of-period only

[48] Note: GAD-7 and PHQ-9 is required for all patients in the BH track, regardless of qualifying condition.
[49] Note: GAD-7 and PHQ-9 is required for all patients in the BH track, regardless of qualifying condition.
[50] World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) 12-item, self-administered. © World Health Organization, 2012. Measuring health and disability: manual for WHO Disability Assessment Schedule (WHODAS 2.0), World Health Organization, 2010, Geneva. For more information, see: https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health/who-disability-assessment-schedule
[51] The Patient Global Impression of Change (PGIC) questionnaire is adapted from Jaeschke et al., 1989, Controlled Clinical Trials 10(4):407–415. The PGIC is a single-item, patient-reported measure that captures a person's global assessment of improvement or worsening since the start of treatment. For ACCESS, the PGIC will be used as an anchor to refine the target for the BH and MSK PRO-PMs by linking patients' subjective ratings of improvement to observed score changes, thereby empirically calibrating the performance measure's threshold to reflect changes that patients perceive as meaningful. Therefore, the PGIC is listed as a PROM, rather than a PRO-PM as it will not be scored based on achievement of a specific performance target.

Appendix C: Data Collection Requirements

Clinical biomarker and patient-reported outcome data will be submitted to CMS via FHIR®-enabled APIs. Acceptable data collection, according to the required measures for each track, should follow the requirements outlined below:

- **Blood Pressure**: Blood pressure must be collected using a validated, upper arm cuff that supports timestamped, source-verifiable transmission. Manual entry of values is not permitted. Each submission to CMS must reflect an average of at least three readings. Data collection should follow the 2025 AHA/ACC Hypertension Guidelines for office blood pressure (OBP), ambulatory blood pressure monitoring (ABPM), or home blood pressure monitoring (HBPM), including appropriate cuff size, seated rest period, and multiple readings per occasion.[52]
- **Lipid panels, HbA1c:** CMS will accept lipid panels and HbA1c from accredited labs, CLIA-compliant Point-of-Care (POC) devices, HIEs, or lab networks.
  - **Lipids:** Use assays and labs that participate in CDC standardization programs (LSP/CRMLN) for accuracy.[53] Report total cholesterol, HDL-C, triglycerides, and calculated LDL-C. Nonfasting or fasting allowable.[54, 55]
  - **HbA1c:** If used for baseline eligibility (for qualifying condition of pre-diabetes or diabetes), a lab-validated HbA1c is required. Specifically, for diagnosis of diabetes, use NGSP-certified HbA1c assays. A POC A1c can be used for initial diagnosis of diabetes only if FDA cleared and performed in CLIA-certified moderate- or high-complexity lab setting. For ongoing monitoring of glycemic control for quality reporting, POC HbA1c devices that are FDA-cleared and CLIA-waived are acceptable.[56]

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[52] American Heart Association, & American College of Cardiology. (2025). *2025 AHA/ACC Guideline for the Management of Hypertension*. *Hypertension, 85*(1), e1–e132. https://www.ahajournals.org/doi/10.1161/HYP.0000000000000321

[53] American Association for Clinical Chemistry / Academy of Diagnostics & Laboratory Medicine. (n.d.). *Lipids and lipoproteins: Academy guidance*. https://www.myadlm.org/Science-and-Research/Academy-Guidance/Lipids-and-Lipoproteins

[54] Virani, S. S., Morris, P. B., Agarwala, A., Ballantyne, C. M., Birtcher, K. K., … & Grundy, S. M. (2024). 2024 AHA/ACC lipid guideline update: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation, 149*(12), e1–e120. https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000625

[55] Grundy, S. M., Stone, N. J., Bailey, A. L., Beam, C., Birtcher, K. K., Blumenthal, R. S., Braun, L. T., de Ferranti, S., Faiella-Tommasino, J., Forman, D. E., Goldberg, R., Heidenreich, P. A., Hlatky, M. A., Jones, D. W., Lloyd-Jones, D., Lopez-Pajares, N., Ndumele, C. E., Orringer, C. E., Peralta, C. A., Saseen, J. J., Smith, S. C. Jr, Sperling, L., Virani, S. S., Yeboah, J. (2018). *2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines*. *Journal of the American College of Cardiology.* https://www.jacc.org/doi/10.1016/j.jacc.2018.11.003

[56] American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S27–S49. https://doi.org/10.2337/dc25-S002

- **uACR:** For uACR, point-of-care semi-quantitative urine albumin tests, urine protein-to-creatine ratio (uPCR) tests, or total urine protein (UP) are not considered compliant for measure reporting. These tests may be used as an initial "rule-in" screen, but any positive protein result must be confirmed by quantitative uACR. For the purpose of the measure, the recorded result must come from either a direct quantitative uACR, or a quantitative urine albumin test and a quantitative urine creatinine test from the same specimen. UACR on a first-morning spot urine preferred; if unavailable, a random spot uACR is acceptable.[57]
- **eGFR:** eGFR should be estimated calculated using clinically validated methods appropriate to the patient population and clinical context. For adults, accepted methods include serum creatinine-based eGFR equations (e.g., 2021 Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI 2021]), cystatin C based eGFR when creatinine is unreliable and testing is unavailable, combined creatinine–cystatin C eGFR when greater precision is clinically indicated, or 24 hour urine eGFR (utilizing a creatinine clearance calculation) (e.g., 24-hour urine collection) when estimation equations are unreliable or impractical.[58]
- **Weight and BMI:** Weight may be reported by the patient using a home scale. BMI is calculated as weight (kg) divided by height (m^2). Participants must retain documentation of the date and method of reporting (clinic versus self-report).
- **Patient-Reported Outcome Measures (PROMs):** PROMs can be administered to patients using web portals, or web-first mixed-mode approaches using web followed by phone (voice-only), and/or paper/mail. Participants cannot make changes to the wording, response options, order, or layout conventions of any PROMs required in the model. PROMs must be collected by Participants in a format that preserves scoring fidelity and allows CMS audit. CMS will release additional, specific guidance for each PROM selected for the model and will

[57] uACR guidance: American Diabetes Association. (2025). Standards of Care in Diabetes — 2025. *Diabetes Care, 48*(Supplement 1), S239–S243. https://diabetesjournals.org/care/article/48/Supplement_1/S239/157554; National Institute of Diabetes and Digestive and Kidney Diseases. (n.d.). Assessing urine albumin (albumin-to-creatinine ratio). In *Identify and manage patients: Evaluate CKD*. https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/kidney-disease/identify-manage-patients/evaluate-ckd/assess-urine-albumin Orth, S. R., Peters, H., & Ritz, E. (1994). How to measure microalbuminuria in patients with chronic renal failure: 24-h versus spot urine collection. *Kidney International, 45*(2), 300–307. https://pmc.ncbi.nlm.nih.gov/articles/PMC12158546/ Lamb, E. J., Gill, J. S., & Testa, H. J. (2019). Variability of urinary albumin and albumin-to-creatinine ratio: inherent biological and analytical variation, and implications for monitoring progression or response to treatment. *Kidney International Reports, 4*(6), 849–861. https://pmc.ncbi.nlm.nih.gov/articles/PMC10725805/

[42] Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. (2024). *KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease.* Kidney International, 105(4S), S117–S314. https://www.kdigo.org/guidelines/ckd-evaluation-and-management/ KDIGO+1; American Diabetes Association. (2025). *Standards of Care in Diabetes — 2025* (especially section on Chronic Kidney Disease). Diabetes Care, 48(Supplement 1). https://diabetesjournals.org/care/article/48/Supplement_1/S239/157554

request screenshots and copies of the patient-facing version in use. For electronic administration, the following best practices are required:

- Test across browsers and devices to ensure readability and assistive-tech compatibility.
- Provide on-device instructions and training on system use.
- Do not present a default response selection.
- Capture a data point for all items, while preventing out-of-range or illogical responses.
- Provide the ability to go back to the previous screen and do not auto-advance to the next screen.
- Provide respondents with an indication of progress and include a final save and submit screen.

For all measures, participants must retain documentation of the data source, date, and method of collection; these data are required for submission via FHIR®-based profiles (see Person-Centered Outcomes (PCO) HL7® FHIR® Implementation Guide). CMS will monitor suspicious patterns and may require documentation and device logs. Participants may be subject to audit, corrective action, or payment recoupment if 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.

Appendix D: Required Clinical Exclusions by Track

eCKM and CKM

- Severe cardio-kidney-metabolic conditions:
  - Severe heart failure (NYHA Class III-IV)
  - Active unstable angina or acute coronary syndrome
  - Unstable or complex secondary hypertension (e.g., pheochromocytoma, Cushing's syndrome, unstable renal artery stenosis) that require specialist management
  - Patients with a diagnosis of CKD Stage 4 or Stage 5/End stage renal disease (ESRD)
  - Severe valvular disease
- Metabolic Disorders:
  - Active thyrotoxicosis
  - Severe electrolyte imbalances
  - Active eating disorders (e.g., untreated anorexia nervosa, bulimia nervosa, binge-eating disorder)
- Pregnancy
- Psychiatric/Psychological:
  - Moderate to severe dementia, or severe cognitive impairment.
  - Acute or unstable psychiatric conditions (e.g., active suicidal/homicidal ideation or psychosis) that may impede safe participation.
- Frailty & advanced illness:
  - Patients 81 and older by the end of the measurement period with an indication of frailty[59] for any part of the measurement period.
  - Patients who have an order for or are receiving hospice or palliative care
  - Patients 66 and older who enter into long term nursing home care during the intervention window

BH

- Psychiatric/Psychological:
  - Suicidal or homicidal ideation
  - Moderate to severe dementia, or severe cognitive impairment
  - Any psychiatric disorder with distinct psychotic features (Schizophrenia, Major Depression with psychotic features, Bipolar I Disorder)
  - Active and severe eating disorders (e.g., untreated anorexia nervosa, bulimia nervosa, binge-eating disorder)

[44] CMS to release additional guidance on frailty.

- Pregnancy
- Frailty & advanced illness:
    - Patients 81 and older by the end of the measurement period with an indication of frailty for any part of the measurement period
    - Patients who have an order for or are receiving hospice or palliative care
    - Patients 66 and older who enter into long term nursing home care during the intervention window

MSK

- MSK conditions:
    - Inability to bear weight on affected limb
    - Significant surgery or trauma to affected area within 3 months
    - Patients during the peri- and postsurgical period (e.g., post-knee or hip replacement)
    - Severe arthritis limiting mobility
    - Recent, unstable fractures
    - Severe osteoporosis with fracture risk
- High fall risk
- Pain from non-MSK cause, such as metastatic cancer or active cancer undergoing treatment, autoimmune disorders, or infections
- Patients with primary neurological disorders that have symptom severity that would make participating in the service unsafe (e.g., stroke, Parkinson's, Multiple Sclerosis)
- Severe heart failure (NYHA Class III-IV)
- Pregnancy
- Psychiatric/Psychological:
    - Suicidal or homicidal ideation
    - Moderate to severe dementia or severe cognitive impairment
- Frailty & advanced illness:
    - Patients 81 and older by the end of the measurement period with an indication of frailty for any part of the measurement period
    - Patients who have an order for or are receiving hospice or palliative care
    - Patients 66 and older who enter into long term nursing home care during the intervention window

Appendix E: Medicare Physician Fee Schedule Services Included in Substitute Spend Adjustment[60]

To be included in the Substitute Spend Adjustment calculation, these services must be furnished by another Medicare-enrolled provider or supplier during the beneficiary's ACCESS care period, and the principal diagnosis codes on the claim must match the condition for which the beneficiary is enrolled in ACCESS. The initial list of included services is limited to services that represent the initiation of new care for the same diagnosis which CMS believes could reasonably be considered substitutes. CMS may add or remove services over time to reflect changes in PFS billing codes as well as CMS' analyses of utilization patterns and billing trends.

Appendix Table 1: Services Included in Substitute Spend Adjustment for eCKM and CKM Tracks

Service Type	**HCPCS / CPT® Codes**
Ambulatory Blood Pressure Monitoring	93784, 93786, 93788, 93790
Ambulatory Continuous Glucose Monitoring	95249-95251
Remote Physiologic Monitoring (RPM) (includes Self-Measured Blood Pressure Monitoring (SMBP)): Device set-up	99453, 99473
Diabetes Self-Management Training (DSMT)	G0108
Intensive Behavioral Therapy (IBT) for Cardiovascular Disease	G0446
Intensive Behavioral Therapy (IBT) for Obesity	G0447
Medical Nutrition Therapy (MNT): Individual initial visit	97802
Remote Therapeutic Monitoring (RTM): Patient education and device set-up	98975
Medicare Diabetes Prevention Program (MDPP)	G9880, G9881, G9886, G9887

Appendix Table 2: Services Included in Substitute Spend Adjustment for MSK Track

Service Type	**CPT® Codes**
Physical Therapy (PT) Evaluation	97161-97163
Occupational Therapy (OT) Evaluation	97165-97167
Remote Therapeutic Monitoring (RTM): Patient education and device set-up	98975

Appendix Table 3: Services Included in Substitute Spend Adjustment for BH Track

Service Type	**HCPCS/CPT® Codes**
DHMT: Supply of digital device and monthly treatment	G0552-G0553
Psychiatric Diagnostic Evaluation	90791, 90792

[60] These HCPCS codes are current as of the CY 2026 Medicare Physician Fee Schedule Final Rule but are subject to change based on updates to the PFS. Source: CMS-1832-F. Available at: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f.

Remote Therapeutic Monitoring (RTM): Patient education and device set-up	98975
Initial Psychiatric Collaborative Care Management	99492

Appendix F: Chronic disease burden and costs

Chronic diseases such as hypertension, prediabetes, and obesity contribute significantly to healthcare costs and burden. Multiple studies demonstrate the high annual expenditures associated with these conditions and the potential for substantial savings through effective management.

eCKM: A 2013-2014 study of Medicare patients with hypertension found annual expenditures were $669 higher than for those without the condition.[61] A more recent study from 2015–2019 estimated the mean annual per capita healthcare cost associated with hypertension to be $2,500.[62] Obesity and prediabetes also have a significant financial impact, but interventions show promise for substantial cost reductions. A study on adults with employer-sponsored insurance found that a 5% weight loss could result in $670 in annual gross savings, while a 25% weight loss could lead to $2,849 in annual savings. For Medicare adults with comorbidities, these savings were even greater, with $1,262 for a 5% weight loss and $5,442 for a 25% weight loss.[63] For individuals with metabolic syndrome, a 10-year study of elderly adults found total Medicare costs were 20% higher compared to those without the syndrome, amounting to an extra $7,863 over the decade.[64]

CKM: Managing diabetes is also associated with significant costs, especially with poor control and complications. Research on Medicare beneficiaries with type 2 diabetes found that the median annual cost per person with diabetes complications was $5,876.[65] A study of Medicare beneficiaries found that individuals with both diabetes and hypertension had estimated annual total medical expenditures of $2,753 per year.[66] CKD presents a substantial financial burden, with costs varying depending on the disease stage. A 2023 review of global economic burden found that annual CKD management costs for Medicare

[61] Wang G, Zhou X, Zhuo X, Zhang P. Annual Total Medical Expenditures Associated with Hypertension by Diabetes Status in U.S. Adults. *Am J Prev Med*. 2017;53(6s2):S182-S189. doi:10.1016/J.Amepre.2017.07.018

[62] Kazi Ds, Elkind Msv, Deutsch A, Et Al. Forecasting the Economic Burden of Cardiovascular Disease and Stroke in The United States Through 2050: A Presidential Advisory from the American Heart Association. Vol 150–150.; 2024:E89-E101. Doi:10.1161/Cir.001258

[63] Thorpe Ke, Joski Pj. Estimated Reduction in Health Care Spending Associated with Weight Loss in Adults. Jama Netw Open. 2024;7(12):E2449200. Published 2024 Dec 2. Doi: 10.1001/Jamanetworkopen.2024.49200

[64] Curtis Lh, Hammill Bg, Bethel Ma, Anstrom Kj, Gottdiener Js, Schulman Ka. Costs Of the Metabolic Syndrome in Elderly Individuals. Diabetes Care. 2007;30(10). Doi: 10.2337/Dc07-0460

[65] Wang Y, Zhang P, Shao H, Et Al. Medical Costs Associated with Diabetes Complications in Medicare Beneficiaries Aged 65 Years or Older with Type 2 Diabetes. Diabetes Care. 2022;45(11):2570-2576. Doi:10.2337/Dc21-2151

[66] Wang G, Zhou X, Zhuo X, Zhang P. Annual Total Medical Expenditures Associated with Hypertension by Diabetes Status in U.S. Adults. Am J Prev Med. 2017;53(6s2):S182-S189. Doi:10.1016/J.Amepre.2017.07.018

beneficiaries in the U.S. were $11,908 for stage 3A and $13,102 for stage 3B patients (in 2022 dollars). The average for both stages was $25,010.[67]

MSK: Musculoskeletal pain, specifically chronic low back pain, is a significant healthcare expense. A retrospective analysis of Medicare claims data from 2009-2016 found that patients diagnosed with chronic, refractory low back pain incurred a median of $10,156 in total healthcare costs in the first year after diagnosis. This figure remained high in the second year, with costs around $9,000.[68]

BH: Lastly, depression significantly increases healthcare costs; A retrospective analysis of a 2019 survey found that individuals with major depressive disorder (MDD) had a mean annualized direct medical cost of $8,814, compared to $6,072 for those without MDD. This represents an annual difference of $2,742.[69]

[67] Jha V, Al-Ghamdi Smg, Li G, Et Al. Global Economic Burden Associated with Chronic Kidney Disease: A Pragmatic Review of Medical Costs for the Inside CKD Research Programme. Adv Ther. 2023;40(10):4405-4420. Doi:10.1007/S12325-023-02608-9

[68] Spears Ca, Hodges Se, Kiyani M, Et Al. Healthcare Resource Utilization and Management of Chronic, Refractory Low Back Pain in the United States. Spine (Phila Pa 1976). 2020;45(20):E1333–E1341. Doi: 10.1097/Brs.0000000000003572

[69] Culpepper L, Martin A, Nabulsi N, Parikh M. The Humanistic and Economic Burden Associated with Major Depressive Disorder: A Retrospective Cross-Sectional Analysis. Advances In Therapy. 2024;41(5):1860-1884. Doi: 10.1007/S12325-024-02817-W