Health Capital Topics
Volume 19
Issue 1
January 2026
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CMS Innovation Center Announces Six New Payment Models

Between December 2025 and January 2026, the Centers for Medicare & Medicaid Services (CMS) Innovation Center unveiled six new alternative payment models spanning drug pricing, chronic disease management, lifestyle medicine, and accountable care. The models represent a significant expansion of both voluntary and mandatory payment reform initiatives. This Health Capital Topics article discusses the key provisions, reimbursement mechanisms, and participation requirements of each model.

ACCESS Establishes Outcome-Aligned Payments for Technology-Enabled Care

The Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model, announced in December 2025, seeks to create a novel payment approach for digital health-supported chronic disease management.[1] This voluntary model operates over a 10-year performance period beginning July 1, 2026.[2] Eligible participants include any entity enrolled in Medicare Part B as a provider or supplier, including physician practices, health systems, federally qualified health centers (FQHCs), and digital health companies that meet enrollment requirements.[3] Each participating organization must designate a physician medical director responsible for clinical oversight.[4]

Rather than fee-for-service reimbursement tied to specific activities, ACCESS introduces outcome-aligned payments (OAPs), providing recurring payments to participating care organizations for managing patients' qualifying conditions, with full payment contingent upon achieving measurable health outcomes.[5] The model will initially encompass four clinical tracks to address the most common chronic conditions:

- Early cardio-kidney-metabolic conditions (hypertension, dyslipidemia, obesity, prediabetes);
- Cardio-kidney-metabolic conditions (diabetes, chronic kidney disease stages 3a/3b, atherosclerotic cardiovascular disease);
- Musculoskeletal conditions (chronic pain); and
- Behavioral health conditions (depression and anxiety).[6]

The model will provide recurring payments to providers, with the amount determined based on the overall share of patients meeting condition-specific outcome targets.[7] A rural adjustment enhances payments for underserved geographic areas.[8] Applications must be submitted by April 1, 2026 to participate in the first performance period, starting July 5, 2026.[9]

MAHA ELEVATE Funds Lifestyle Medicine Through Cooperative Agreements

The Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence (MAHA ELEVATE) Model represents the Innovation Center's first model focused on functional and lifestyle medicine approaches.[10] Also announced in December 2025, with a first cohort launch of September 1, 2026, this voluntary model utilizes cooperative agreement grant funding rather than traditional shared savings or claims-based reimbursement.[11] The financial structure differs fundamentally from typical Innovation Center models. CMS will award approximately $100 million across up to 30 cooperative agreements over a three-year performance period.[12] Notably, this model involves no downside financial risk and no shared savings or losses arrangement. Funding supports whole-person care services not currently covered by Traditional Medicare, including interventions addressing stress management, physical activity, nutrition, sleep, and social connection.[13]

Eligible applicants include private medical practices, health systems, accountable care organizations (ACOs), academic organizations, federally qualified health centers, rural health clinics, and community-based organizations.[14] Three awards are reserved specifically for interventions addressing dementia, and all proposals must incorporate nutrition or physical activity components. The Notice of Funding Opportunity is expected in early 2026.[15]

BALANCE Creates GLP-1 Access Pathway with Negotiated Pricing

The Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model, announced December 23, 2025, addresses obesity medication access through CMS-negotiated drug pricing with glucagon-like peptide-1 (GLP-1) manufacturers.[16] This voluntary model involves state Medicaid agencies beginning May 2026 and Part D plans beginning January 2027.[17] The model will run through December 2031.[18]

Additionally, CMS will launch a short-term demonstration component in July 2026 as a "short-term bridge" to the BALANCE model, under which program

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beneficiaries will pay $50 per month for eligible medications.[19] This arrangement operates outside the standard Part D benefit structure, with CMS administering the entirety of the payment demonstration directly rather than through Part D plan sponsors.[20]

GLOBE and GUARD Implement Mandatory International Reference Pricing

Two proposed rules published by CMS in the Federal Register on December 23, 2025 would establish mandatory Most Favored Nation drug pricing models for Medicare Parts B and D, representing the Innovation Center's most significant mandatory drug pricing initiatives to date.[21] Unlike the voluntary models described above, the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model require mandatory participation from pharmaceutical manufacturers whose drugs meet specified spending thresholds.

The Global Benchmark for Efficient Drug Pricing (GLOBE) Model targets certain Medicare Part B physician-administered drugs with annual spending exceeding $100 million.[22] Commencing October 1, 2026 for a five-year performance period, GLOBE would calculate manufacturer rebates using a complex rebate formula utilization international benchmarks, with adjustments for drugs in a shortage or during "severe supply chain disruption[s]."[23] CMS estimates $11.9 billion in Medicare Part B net savings over the seven-year model period, with approximately $1 billion in Medicaid savings.[24] Beneficiaries of these reduced prices will include a cohort (approximately 25%) of Traditional Medicare Part B enrollees, selected based on certain geographic and coverage conditions.[25]

The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model applies similar international benchmark pricing to certain Medicare Part D outpatient prescription drugs with annual spending exceeding $69 million (for the first performance year).[26]

As noted above, both GLOBE and GUARD models require mandatory manufacturer participation. CMS justifies mandatory status as necessary to ensure sufficient market participation, prevent selection bias, and enable meaningful evaluation.[27] The proposed rules seek comment on whether voluntary participation would suffice and on potential exemptions. The comment period closes February 23, 2026, with final rules anticipated thereafter.[28]

LEAD Offers 10-Year ACO Framework with Enhanced Risk Options

Unlike the episodic or condition-specific payment models described above, the Long-term Enhanced ACO Design (LEAD) Model focuses on ACO total cost of care arrangements. Announced December 18, 2025, LEAD is the successor to the ACO REACH model and will have a 10-year voluntary performance period starting January 1, 2027, the longest period ever tested by the Innovation Center.[29] LEAD specifically targets expanded ACO participation among smaller, rural, and independent healthcare providers historically excluded from accountable care arrangements.[30]

The model offers two voluntary risk-sharing tracks. Under Global Risk, participants may earn up to 100% of savings while bearing up to 100% of losses relative to established benchmarks. Under Professional Risk, participants may earn up to 50% of savings while bearing up to 50% of losses.[31] Critically, LEAD benchmarks will not undergo rebasing (i.e., recalculation of financial benchmarks) during the 10-year model period, providing long-term financial predictability to participants.[32]

Payment mechanisms include flexible, capitated population-based payments designed to improve cash flow for participants, with an infrastructure add-on payment for rural providers building ACO capacity.[33] As part of LEAD, the CMS Administered Risk Arrangements (CARA) initiative will administer optional episode-based risk arrangements between ACOs and specialist providers through standardized contracting frameworks and data sharing mechanisms.[34]

Stakeholder Commentary

The models have generated a mixed response from healthcare industry stakeholders. Provider organizations have generally embraced the voluntary models. The American Medical Association (AMA) expressed support for the ACCESS Model, stating that ACCESS "is an important step toward bringing new, effective digital health tools into everyday care for Medicare patients" and that "for too long, outdated payment barriers have made it difficult for physicians to use new tools that can improve care for common chronic conditions."[35] The National Association of ACOs (NAACOS) supported the LEAD Model's 10-year timeline, noting it "will allow participants to move past implementation to develop long-term investments and meaningfully innovate strategies that help move the transition to accountable care forward."[36]

However, the pharmaceutical industry is firmly against the proposed mandatory GLOBE and GUARD models. The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a statement opposing both models, arguing that they would "increase costs for America's seniors" and "siphon billions from U.S. medicine [research and development]."[37] With comment periods still open for GLOBE and GUARD (which are still in the rulemaking process), additional formal industry positions are expected in the coming weeks.

Conclusion

These six announced models reflect the Innovation Center's strategic emphasis on prevention, technology-enabled care delivery, international drug pricing benchmarks, and long-term value-based arrangements. The ACCESS and MAHA ELEVATE models establish novel payment pathways for digital health and lifestyle medicine interventions, while BALANCE addresses GLP-1 medication access through direct CMS-manufacturer negotiations. GLOBE and GUARD represent the most significant mandatory drug pricing initiatives in Innovation Center history, implementing

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international reference pricing across both Medicare Part B and Part D. Further, the 10-year LEAD model provides unprecedented benchmark stability for ACOs. How these models will ultimately impact healthcare delivery, drug pricing, and provider participation remains to be seen as implementation unfolds throughout 2026 and 2027.

1 "ACCESS Model" Centers for Medicare & Medicaid Services, Innovation Center, December 2025, https://www.cms.gov/priorities/innovation/innovation-models/access (Accessed 1/21/26).
2 "CMS Innovation Center Unveils ACCESS Model to Expand Technology-Supported Care for Chronic Disease" ArentFox Schiff, Health Care Counsel Blog, December 2025, https://www.afslaw.com/perspectives/health-care-counsel-blog/cms-innovation-center-unveils-access-model-expand-technology (Accessed 1/21/26).
3 "CMS Innovation Center's ACCESS Model: What Medicare Organizations Need to Know" Health Management Associates, December 2025, https://www.healthmanagement.com/blog/cms-innovation-centers-access-model-what-medicare-organizations-need-to-know/ (Accessed 1/21/26).
4 *Ibid.*
5 "ACCESS Model" Centers for Medicare & Medicaid Services, Innovation Center, December 2025, https://www.cms.gov/priorities/innovation/innovation-models/access (Accessed 1/21/26).
6 ArentFox Schiff, Health Care Counsel Blog, December 2025.
7 "ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model" Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/access (Accessed 1/21/26).
8 ArentFox Schiff, Health Care Counsel Blog, December 2025.
9 "ACCESS Model" Centers for Medicare & Medicaid Services, Innovation Center, December 2025, https://www.cms.gov/priorities/innovation/innovation-models/access (Accessed 1/21/26).
10 "MAHA ELEVATE (Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence) Model" Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/maha-elevate (Accessed 1/21/26).
11 *Ibid.*
12 "CMS Announces New Model to Pilot Lifestyle Medicine Interventions" AAMC, December 12, 2025, https://www.aamc.org/advocacy-policy/washington-highlights/cms-announces-new-model-pilot-lifestyle-medicine-interventions (Accessed 1/21/26).
13 Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/maha-elevate (Accessed 1/21/26).
14 *Ibid.*
15 *Ibid.*
16 "Trump Administration Announces New CMMI Models: GLOBE, GUARD, and BALANCE" Covington & Burling LLP, December 2025, https://www.cov.com/en/news-and-insights/insights/2025/12/trump-administration-announces-new-cmmi-models-globe-guard-and-balance (Accessed 1/21/26).
17 *Ibid.*
18 "BALANCE (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth) Model" Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/balance (Accessed 1/23/26).
19 Covington & Burling LLP, December 2025.
20 Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/balance (Accessed 1/23/26).
21 "CMS issues mandatory Medicare models implementing Most Favored Nation drug pricing: GLOBE (Part B) and GUARD (Part D)" Hogan Lovells, December 2025, https://www.hoganlovells.com/en/publications/cms-issues-mandatory-medicare-models-implementing-most-favored-nation-drug-pricing (Accessed 1/21/26).
22 "GLOBE (Global Benchmark for Efficient Drug Pricing) Model" Centers for Medicare & Medicaid Services, Innovation Center, December 2025, https://www.cms.gov/priorities/innovation/innovation-models/globe (Accessed 1/21/26).
23 Hogan Lovells, December 2025.
24 Centers for Medicare & Medicaid Services, Innovation Center, December 2025.
25 Hogan Lovells, December 2025.
26 "CMS Proposes New Mandatory GUARD Model" Centers for Medicare & Medicaid Services, Press Release, December 23, 2025, https://www.cms.gov/newsroom/press-releases/cms-proposes-new-mandatory-guard-model (Accessed 1/21/26).
27 *See, e.g.,* "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model Federal Register, Vol. 90, No. 244 (December 23, 2025), p. 60358-60359.
28 "CMS issues mandatory Medicare models implementing Most Favored Nation drug pricing: GLOBE (Part B) and GUARD (Part D)" Hogan Lovells, December 2025, https://www.hoganlovells.com/en/publications/cms-issues-mandatory-medicare-models-implementing-most-favored-nation-drug-pricing (Accessed 1/21/26).
29 "LEAD (Long-term Enhanced ACO Design) Model" Centers for Medicare & Medicaid Services, Innovation Center, December 2025, https://www.cms.gov/priorities/innovation/innovation-models/lead (Accessed 1/21/26).
30 "CMS Announces the LEAD Model: A New Long-Term ACO Option Beginning in 2027" ATI Advisory, December 2025, https://atiadvisory.com/resources/cms-announces-the-lead-model/ (Accessed 1/21/26).
31 *Ibid.*
32 Centers for Medicare & Medicaid Services, Innovation Center, December 2025.
33 *Ibid.*
34 *Ibid.*
35 "AMA welcomes CMS model targeting chronic conditions with tech tools" American Medical Association, Press Release, December 3, 2025, https://www.ama-assn.org/press-center/ama-press-releases/ama-welcomes-cms-model-targeting-chronic-conditions-tech-tools (Accessed 1/21/26).
36 "Statement: NAACOS Supports New CMS Innovation Center Total Cost of Care Model" National Association of ACOs, Press Release, December 18, 2025, https://www.naacos.com/press-releases-letters-2025/statement-naacos-supports-new-cms-innovation-center-total-cost-of-care-model/ (Accessed 1/21/26).
37 "CMS Proposes New Medicare Payment Models Aimed at Lowering Drug Prices" Arkansas Center for Health Improvement, December 2025, https://achi.net/newsroom/cms-proposes-new-medicare-payment-models-aimed-at-lowering-drug-prices/ (Accessed 1/21/26).

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