

CMS Innovation Center Model Updates

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Today's Agenda:


CMMI in 2025

Overview of Models

- Mandatory Provider Models
- Voluntary Provider Models
- Drug Pricing Models
- Other Models

Questions & Discussion

CMMI's 2025 in a Nutshell



4 Early Terminations

- MD Total Cost of Care
- Making Care Primary
- Primary Care First
- ESRD Treatment Choices



9 New Models

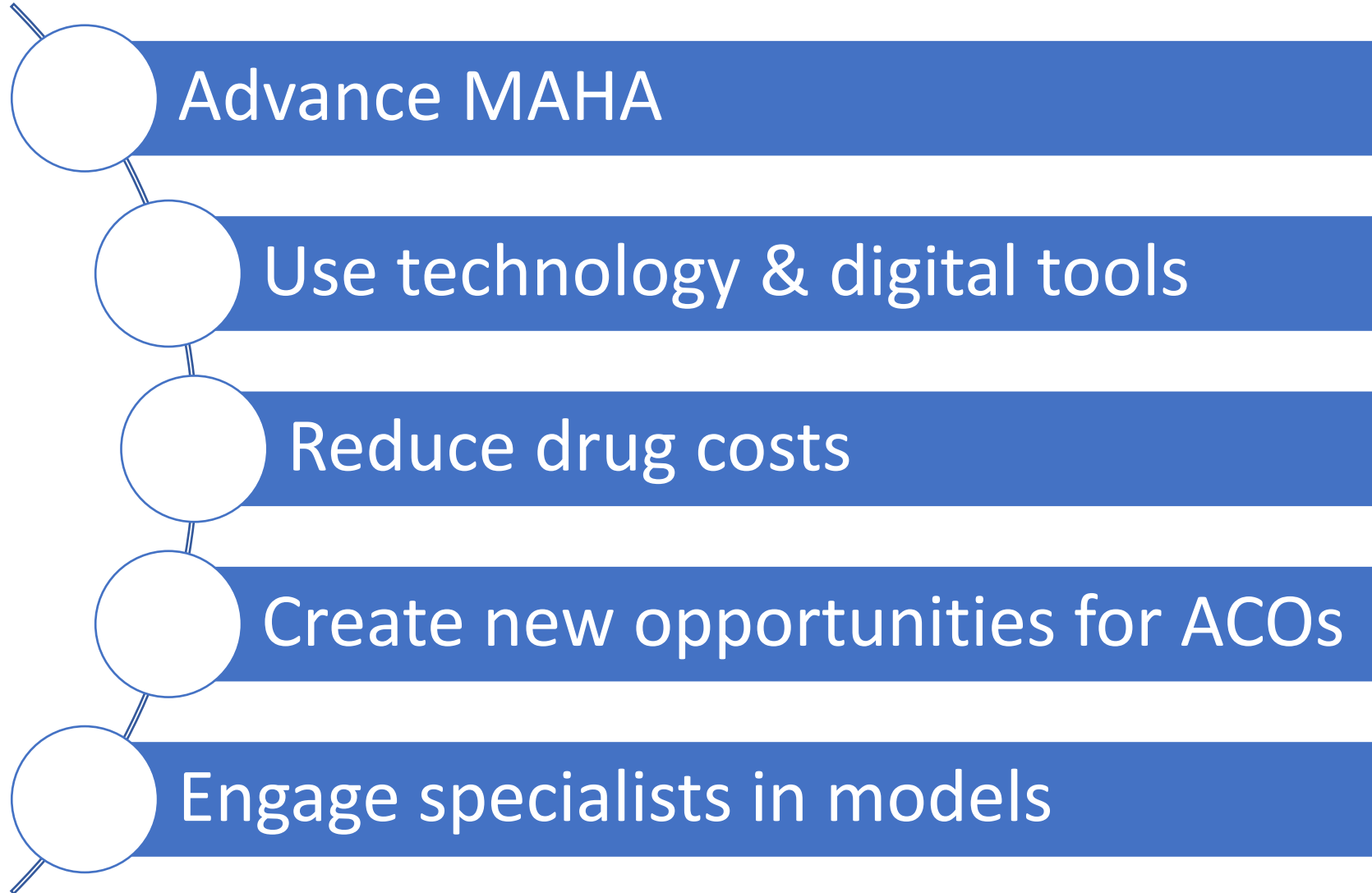
- GENEROUS
- GLOBE
- GUARD
- ASM
- BALANCE
- ACCESS
- LEAD
- MAHA ELEVATE
- WISeR



5 Modifications to Models

- TEAM
- AHEAD
- IOTA
- Cell & Gene Therapy Access

Key Themes for CMMI Actions in 2025



Mandatory Models for Providers

- **TEAM** (Transforming Episode Accountability Model)
- **ASM** (Ambulatory Specialty Model)
- **IOTA** (Increasing Organ Transplant Access) Model

TEAM Key Elements



Model Design	<ul style="list-style-type: none">• Mandatory episode payment model• 30-Day episodes:<ul style="list-style-type: none">• Coronary artery bypass graft (CABG)• Lower extremity joint replacement (LEJR)• Major bowel procedure• Surgical hip/femur fracture treatment (SHFFT)• Spinal fusion
Duration	<ul style="list-style-type: none">• January 1, 2026 to December 31, 2030
Eligibility	<ul style="list-style-type: none">• Acute Care Hospitals (ACHs) located in 188 selected core-based statistical areas, and ACHs who participate in BPCIA currently and opted-in in January 2025 https://www.cms.gov/team-model-participant-list <i>**limited deferment period for new hospitals</i>
Model Tracks	<ul style="list-style-type: none">• Track 1: No downside risk & lower levels of reward for PY1; safety net hospitals may remain in Track 1 for PY 2-3.• Track 2: Lower levels of risk & reward for certain hospitals (safety net, rural, MDHs, etc.) PY 2-5• Track 3: Higher levels of risk & reward for entire model duration
Quality Measurement	<ul style="list-style-type: none">• PY 1 : 3 metrics• PY 2: 3 additional metrics, drop PSI-90 (5 total measures)• PY 3-5: 1 additional metric (6 total measures)

ASM Key Elements



Model Design	<ul style="list-style-type: none">• Mandatory payment model (first for physicians)• Increase financial & quality accountability for certain specialists, through more effective chronic care management
Duration	<ul style="list-style-type: none">• January 1, 2027 – December 31, 2031 (performance)• January 1, 2029 – December 31, 2033 (payment)
Eligibility	<ul style="list-style-type: none">• Individual specialists who treat low back pain and heart failure in select geographic areas (mandatory CBSAs announced in Dec 2025; available here)
Performance Metrics	<ul style="list-style-type: none">• Quality: Specific quality metrics (predominantly eCQMs) – 50% of performance• Cost: MIPS Episode-Based Cost Measures (low back pain & heart failure) – 50% of performance• Improvement Activities: Specific activities• Promoting Interoperability: Consistent across MIPS/MVPs
Risk & Payment	<ul style="list-style-type: none">• Risk Level: Begins up to 9%, increases to 12% in PY5• Payment distribution within ASM condition (minus 15% for CMMI as savings)

IOTA Key Elements



Model Design	<ul style="list-style-type: none"> • Mandatory payment model • Goal to increase kidney transplants from both deceased and living donors
Duration	<ul style="list-style-type: none"> • July 1, 2025 to June 30, 2031 (no downside in PY1 [7/2025-6/2025])
Eligibility	<ul style="list-style-type: none"> • 103 transplant hospitals located in a subset of Donation Service Areas unless low volume (11 kidney transplants/annually in each of 3 baseline years) <i>proposal to increase low volume threshold to 15 transplants/year during baseline</i>
Scoring	<ul style="list-style-type: none"> • Achievement: Number of transplants (60 points) • Efficiency: Organ acceptance rate (20 points) • Quality: Post-transplant composite graft survival (20 points) <i>proposals to risk adjust for transplant recipient and donor characteristics, exclude multi-organ transplants (except kidney/pancreas) from measurement, and changing points allocation (currently min. 10 pts if below 10th percentile nationally; now must be ≥ 40th percentile nationally to achieve 10 pts)</i>
Payments	<ul style="list-style-type: none"> • Upside: ≥60 points – Maximum Upside Reward: \$15,000 (per FFS kidney transplant) • Neutral: 41 – 59 points • Downside: ≤40 points – Maximum Downside Penalty: \$2,000 (per FFS kidney transplant)

First adopted through rulemaking in 2024; *proposed updates* Dec 2025 – comments open until Feb. 9, 2026

Voluntary Models for Providers

- **ACCESS** (Advancing Chronic Care with Effective, Scalable Solutions) Model
- **LEAD** (Long-term Enhanced ACO Design) Model

ACCESS Key Elements

<https://www.cms.gov/priorities/innovation/innovation-models/access>

CMMI accepting applications to participate



Model Design	<ul style="list-style-type: none">• Tests Outcome-Aligned Payments (OAPs) for using digital technology to manage certain conditions instead of visit-based FFS• Compliments FDA Technology-Enabled Meaningful Patient Outcomes (TEMPO) Pilot
Duration	<ul style="list-style-type: none">• July 1, 2026 to June 30, 2036
Eligibility	<ul style="list-style-type: none">• Part B-enrolled Providers & Suppliers; participation at TIN level• Participants precluded from billing Medicare PFS for patients in the model
Patient Alignment	<ul style="list-style-type: none">• Medicare FFS patients may self-refer (CMS will publish directory of participants and outcomes)• Patients may also be referred to a participant by PCP (\$10 onboarding co-management PFS payment)
Tracks (by conditions)	<ul style="list-style-type: none">• Early cardio-kidney-metabolic eCKM (Dyslipidemia, hypertension, obesity, prediabetes)• Cardio-kidney-metabolic CKM (Atherosclerotic cardiovascular disease, chronic kidney disease, diabetes)• Musculoskeletal MSK (Chronic musculoskeletal pain)• Behavioral Health BH (Anxiety, Depression)
Scoring (by population)	<ul style="list-style-type: none">• Clinical Outcomes: must attain of target for 50% of patients to receive full OAP (can reduce OAP up to 50%)• Substitute Spend Adjustment (FFS): 90% of population must not have FFS claims for treating their condition during 12-month period to receive full OAP (can reduce OAP up to 25%)
Payments	<ul style="list-style-type: none">• Quarterly per-patient payments: Q1 and Q2 – 50% OAP; then no payment Q3 and Q4, additional 50% of OAP at reconciliation of 12-month care period within previous 6 months.• Tiered payment: initial 12-month period higher rate than follow-on periods• Co-management Payment: G-code for PCPs coordinating care w/ model participants (\$30, max. \$100/year)

Awaiting Request for Applications for greater detail

LEAD Key Elements



Model Design	<ul style="list-style-type: none">• Test new policies for highest risk ACO option in FFS Medicare
Duration	<ul style="list-style-type: none">• January 1, 2027 to December 31, 2036
Eligibility	<ul style="list-style-type: none">• ACOs, with focus on attracting new ACOs (especially rural ACOs)
Risk Arrangements	<ul style="list-style-type: none">• Professional: up to 50% total savings/losses to financial benchmark• Global: up to 100% total savings/losses to financial benchmark
Payments	<ul style="list-style-type: none">• Capitated, population-based payments to support team-based care• Rural add-on payments not reconciled to benchmarks to build up APM infrastructure
New Policy Concepts	<ul style="list-style-type: none">• Medicaid integration: Incentives for coordinating care & improving outcomes for dually eligible patients (pilot with 2 state Medicaid programs to start)• CMS Administered Risk Arrangements (CARA): Enable episode-based risk arrangements between ACOs and specialists/provider organizations; includes an episode-based falls prevention program (CARA is limited to Global Risk track)• Medical Nutrition Therapy: Expanded coverage for Medical Nutrition• Part D premium buy down: Allow ACOs to partially or fully offset, by 2029

Drug Pricing Models

- **GLOBE** (Global Benchmark for Efficient Drug Pricing) Model
- **GUARD** (Guarding U.S. Medicare Against Rising Drug Costs) Model
- **GENEROUS** (GENErating cost Reductions fOr U.S. Medicaid) Model

GLOBE Key Elements

<https://www.cms.gov/priorities/innovation/innovation-models/globe>

Model Design	<ul style="list-style-type: none">• Part B Rebates from Manufacturers to CMS• Mandatory: Manufacturers would be required to pay a rebate to Medicare if the Medicare net price for their drug subject to the model is greater than the international benchmark
Duration	<ul style="list-style-type: none">• Performance: October 1, 2026 – September 30, 2031• Payment: October 1, 2026 – September 30, 2033
Eligibility	<ul style="list-style-type: none">• Drug manufacturers participating in Medicare Part B with drugs subject the model• In selected geographic areas representing 25% of the country’s Medicare Part B beneficiaries.
Eligible Drugs	<ul style="list-style-type: none">• Part B rebatable drugs• Minimum Drug Spend Threshold: \$100 Million in Part B FFS spending over a 12-month period
Mechanism to effectuate lower price	<ul style="list-style-type: none">• Would use existing framework for providing Inflation Reduction Act inflationary rebates, going directly to Medicare• Beneficiary coinsurance adjusted based on lower price• Part B allowable amount to providers increased to offset lower coinsurance
International Reference Pricing	<ul style="list-style-type: none">• International benchmark based on pricing information from countries with GDP that is at least 60% of US’ and minimum economy size of \$400 billion

GUARD Key Elements

Model Design	<ul style="list-style-type: none">• Part D Rebates from Manufacturers to CMS: Use existing IRA Rebate Program for Part D drugs raising prices faster than inflation• Mandatory: Manufacturers would be required to pay a rebate back to Medicare if the Medicare net price for their drug subject to the model is greater than the international benchmark
Duration	<ul style="list-style-type: none">• Performance: January 1, 2027 to December 31, 2031• Payment: January 1, 2027 to December 31, 2033
Eligibility	<ul style="list-style-type: none">• Mandatory for drug manufacturers participating in Medicare Part D with drugs subject to the model
Eligible Drugs	<ul style="list-style-type: none">• Part D single source drugs and biologicals are subject, broader class of therapeutics subject than the GLOBE Model• Excluded: Generics, Biosimilars, Drugs subject to MFP, 340B Drugs• Minimum Drug Spend Threshold: \$69 million for GUARD.
Beneficiaries	<ul style="list-style-type: none">• Will apply to approximately 25 percent of Medicare beneficiaries (FFS and MA)• Based on pre-selection of ZIP Code Tabulation Areas (ZCTA)• No Policy Changes to Cost Sharing
International Reference Pricing	Benchmark Calculations for Part D Drugs Based On: Public pricing information or Manufacturer reported, volume weighted net pricing information

GENEROUS Key Elements

Model Design	<ul style="list-style-type: none">• Voluntary Medicaid drug model
Duration	<ul style="list-style-type: none">• January 1, 2026 – December 31, 2030 (ability to opt in on annual basis)
Eligibility	<ul style="list-style-type: none">• Drug manufacturers participating in the Medicaid Drug Rebate Program (MDRP)• States and US territories participating in the MDRP and have supplemental rebate agreements with CMS
Eligible Drugs	<ul style="list-style-type: none">• Drugs covered by MDRP• Single source, non-innovator drugs (non-generic drugs)• Excludes: drugs in CMMI’s cell and gene therapy model
Mechanism for providing reduced price	<ul style="list-style-type: none">• Manufacturers pay a supplemental rebate to state Medicaid agency on a quarterly basis, based on international pricing
International Reference Pricing	<ul style="list-style-type: none">• Second lowest country-specific manufacturer-reported net price, adjusted by GDP per capita (UK, France, Germany, Italy, Canada, Japan, Denmark, and Switzerland)

Impact of Drug Pricing Models

GLOBE Impacts	GUARD Impacts
Confusion, Uncertainty Around Interaction of Multiple Drug Pricing Initiatives and Changes at One Time	
Impact 340B Drug Ceiling Price, if Manufacturers respond by lowering the drug list price	
May not Address Access and Affordability Issues Related to Drug Pricing	
Increase in the Practice of <u>White</u> Bagging	Increase in the Practice of <u>Brown</u> Bagging
Uncertainty Around How Beneficiaries in the Model Will be Identified and Billed for Differing Rates of Co-Insurance	Part D beneficiary costs may rise due to changed behaviors in MFP drug price negotiations as a responses to this model. CMS estimates an increase in beneficiary costs of \$3.6 billion.

Other Models

- **WISeR** (Wasteful and Inappropriate Service Reduction) Model
- **MAHA ELEVATE** (Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence)

WISeR Key Elements

Model Design	<ul style="list-style-type: none">• Leverage AI and machine learning to test prior authorization in FFS Medicare for specified services considered vulnerable to fraud, waste and abuse (e.g., skin & tissue substitutes, knee arthroscopy for knee osteoarthritis, etc.) in certain states.• Model does not include inpatient-only services,* emergency services, or “services that would post a substantial risk to patients if delayed.”
Duration	<ul style="list-style-type: none">• January 1, 2026 to December 31, 2031
Participants	<ul style="list-style-type: none">• Technology companies able to streamline the review of medical necessity for the model’s select items and services earlier in the claims process.
Geographic Impact	<ul style="list-style-type: none">• Part B Providers in six states: AZ, NJ, OH, OK, TX, WA
Payment Implications	<ul style="list-style-type: none">• Participants receive a percentage of savings associated with averted spending• Providers in impacted states have “choice” when furnishing impacted items/ services to Medicare FFS patients:<ul style="list-style-type: none">• Submit a prior authorization request for the item/service, or• Go through post-service/pre-payment review

*CY2026 OPPS finalized the removal of the Inpatient Only List over three years (2026-28)

MAHA ELEVATE Key Elements

Model Design	<ul style="list-style-type: none">• Fund up to 30 proposals that promote health and prevention for Medicare FFS patients that utilize evidence-based, whole-person care approaches – including functional or lifestyle medicine interventions – currently not covered by Medicare to transform health care system to one that proactively addresses root causes of chronic disease.• Proposals must incorporate nutrition or physical activity as part of the design. Three awards reserved for interventions to address dementia.
Duration	<ul style="list-style-type: none">• September 1, 2026 to August 31, 2029
Eligibility	<ul style="list-style-type: none">• Organizations that either provide whole-person functional or lifestyle medicine services directly to patients or partner with other organizations to deliver services. Must select a chronic condition (or conditions) & identify the interventions to be offered to their Medicare FFS patients.
How to Apply	<ul style="list-style-type: none">• Forthcoming Notice of Funding Opportunity (NOFO) will be released in early 2026 for the first cohort of the model.
Payment	<ul style="list-style-type: none">• Total budget for all cooperative agreements is \$100M over a 3-year period

Questions & Open Discussion

Want to Reach Out?

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