HCPEA 201: Healthcare Policy Update

Prepared for the Healthcare Private Equity Association

July 20, 2023

BRG

Agenda

Key Regulatory Themes

Key Regulatory Theme: *Drug Pricing*

Rx manufacturers fight and adjust to the Inflation Reduction Act (and look to take advantage of the law's coverage provisions), while adjacent industries prepare for potential ripple effects.

Medicare Negotiation implementation

- First ten negotiated drugs named by September
- Merck, PhRMA, BMS, US Chamber first four to file lawsuits

Part D beneficiaries' OOP costs capped starting next year

- OOP cap ~ $3,500; will vary by patient's brand/generic mix
- OOP cap drops to $2,000 in 2025

CMS Coverage determinations

- Leqembi uptake in question due to CMS registry requirement
- Pressure mounting on Medicare to cover weight loss drugs

Drug pricing politics still hot

- President's Budget doubled down on negotiation
- Congress' PBM reform efforts active, unfocused so far

Other reform efforts remain

- Drug shortages stymie regulatory officials
- Launch prices will continue rising

Pharma services companies remain vigilant to IRA's potential downstream effects on their industry

- Considerable uncertainty around negotiation process
- Part D redesign means "new normal" will likely not arrive for some time

Brand Name	Part	2021 Spend	Years Since Approval	Expected Exclusivity Loss	Minimum Discount *
Eliquis	D	$12.6b	13.0	2028	35%
Xarelto	D	$5.2b	14.5	2027	35%
Trulicity	D	$4.7b	11.3	2027	25%
Januvia	D	$4.1b	13.3	2029	35%
Jardiance	D	$3.7b	11.4	2028	25%
Imbruvica	D	$3.2b	12.1	2033	35%
Ozempic	D	$2.6b	9.1	2031	25%
Xtandi	D	$2.4b	13.4	2027	35%
Trelegy Ellipta	D	$2.4b	9.3	2027	25%
Biktarvy	D	$2.2b	9.9	2036	25%

Source: BRG Analysis of CMS Part B and D Drug Spend, 2021; * Discount off Non-Federal Average Manufacturer Price.

Key Regulatory Theme: *Medicare Advantage*

Government actuaries predict $6-7T of spending on Medicare Advantage over the next ten years while regulators focus on program integrity (especially around risk adjustment) and beneficiary protections, trends we expect to continue in the remaining years of the Biden Administration.

2024 Rate Announcement near lowest all-time rate increase

- Lowest all-time before plan coding trends accounted for
- Risk Adjustment technical changes suggest future CMS approach

2024 MA final rule increased operational demands on MA plans

- New limitations on prior authorization, marketing
- New requirements for behavioral health networks, star ratings

Risk Adjustment Data Validation (RADV) audit rule finalized

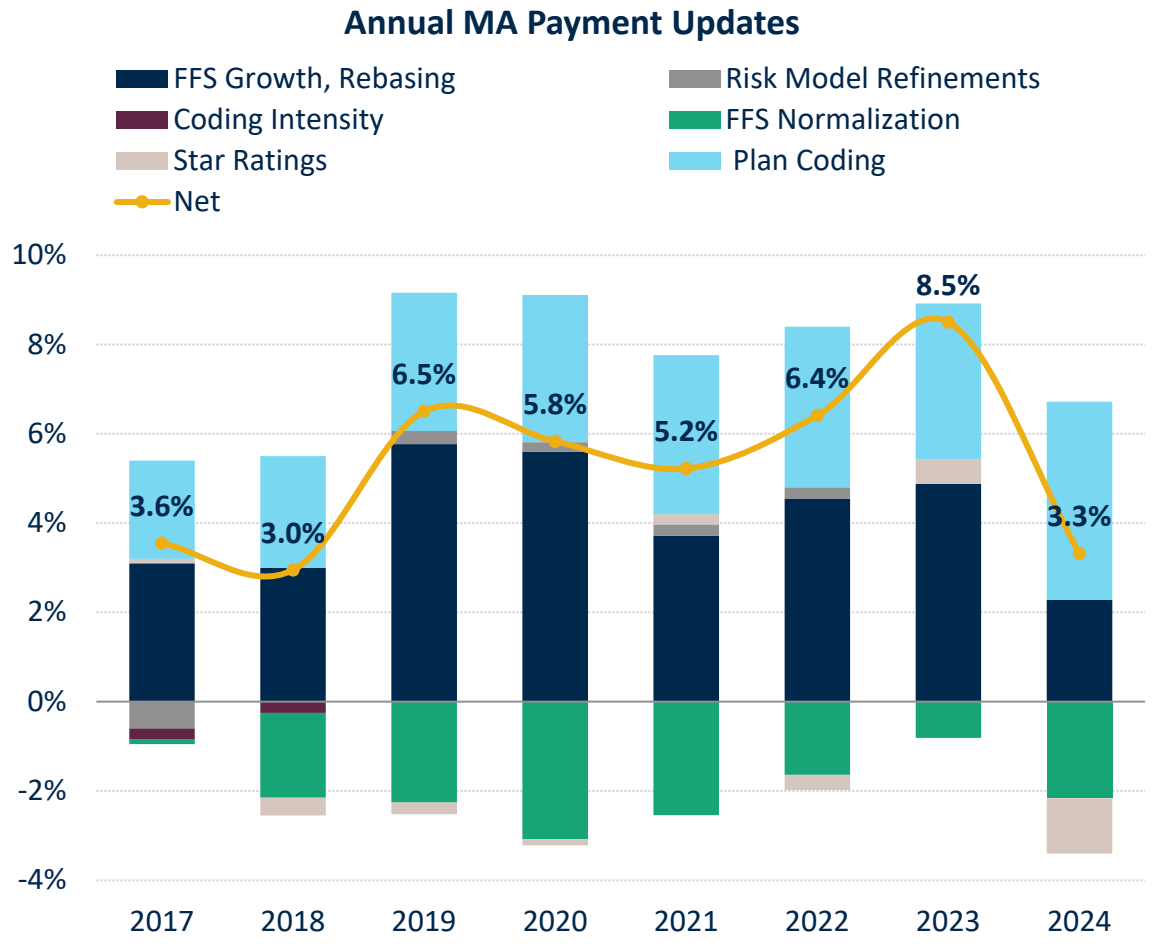
- CMS to extrapolate collections starting w/ 2018 RADV audits
- Focus on plans, diagnoses with highest improper payment risk

MA Growth will likely continue over next decade

- Single year of rule-making will not change MA trajectory
- No alternative to MA or Risk Adjustment on the horizon

Future regs will focus program integrity, Administration's priorities

- Better understanding supplemental benefits
- Ensuring MA and value-based care policies are complementary

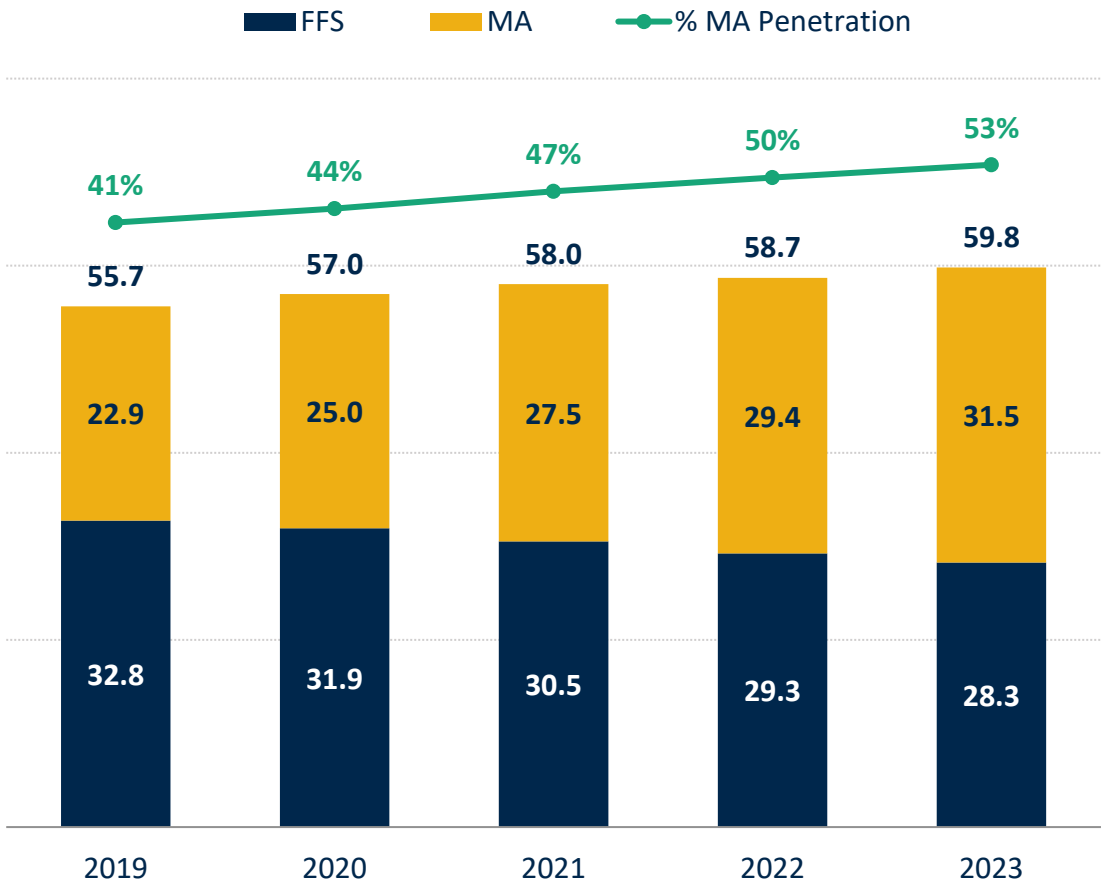


Source: BRG Analysis of CMS 2024 MA and Part D Rate Announcement

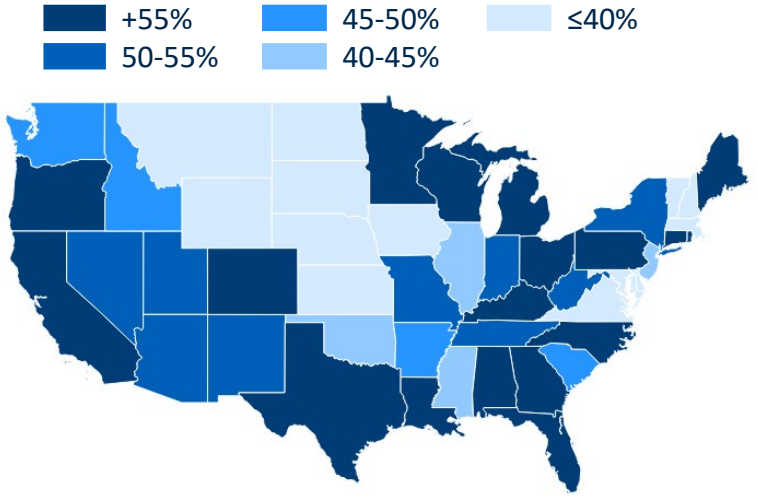
Key Regulatory Theme: *Medicare Advantage (continued)*

National MA penetration rate currently 53% of eligible beneficiaries but varies across states; penetration ranges from 14% in Wyoming to 63% in Rhode Island.

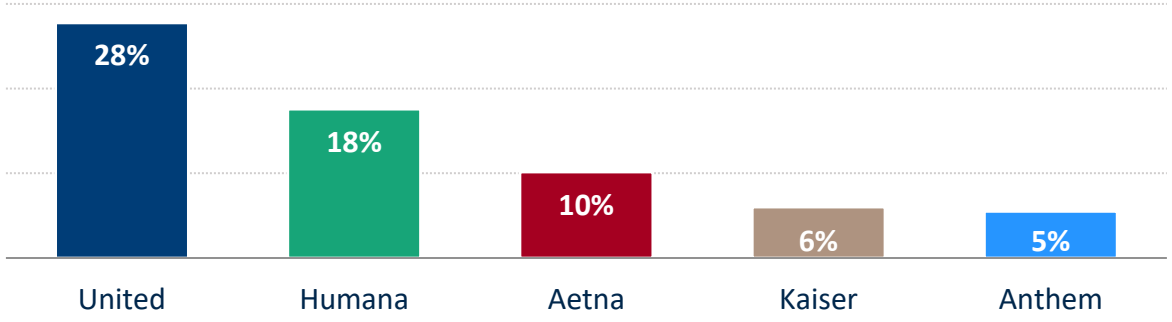
National Medicare Enrollment (M)



MA Penetration By State



National Market Share Top MA Plans



Source: BRG Analysis of CMS MA Enrollment Data January 2023, Plan Enrollment Data January 2023
Note: BRG calculated MA penetration as MA enrollees as a percent of those eligible to enroll in the program defined by an individual enrolled in Medicare Part A and Part B

Key Regulatory Theme: *Value-Based Care*

The Biden Administration has made clear their commitment to promoting value-based care while it confronts the operational and political realities of the movement's first decade.

Administration's "Strategy Refresh" backs value-based care

- Goal: All original Medicare, most Medicaid in VBC by 2030
- Widen scope to include left out beneficiaries, providers

New models mostly extend investments in same buckets

- TCC, Specialty, Primary Care models continue/evolve past work
- Drug models will try different approach than previous failed efforts

Thoughtful approach to achieving "success"

- Some new models tweak old model designs to "get it right this time"
- Some old models' design features added to incumbent programs

Political realities, opportunities must be navigated

- No mandatory models tried so far by Biden Administration
- Some Democratic allies skeptical of risk-based models (REACH)
- Specialty providers still have sway (Radiation Oncology)
- Admin leveraging CMMI for its drug pricing and health equity goals

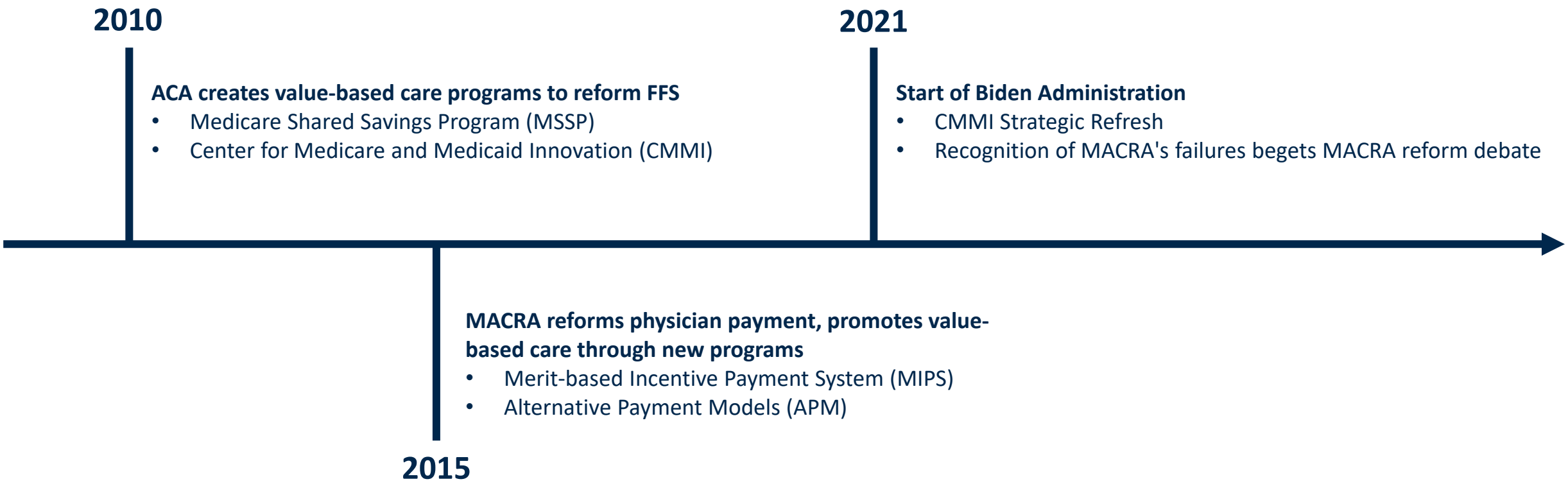
CMMI Models Announced Since Start of Biden Administration
ACO REACH Model (ACO)
MSSP - AIM Model Expansion (ACO)
Making Care Primary Model (Primary Care)
Radiation Oncology Model (Specialty)*
BPCIA Extension (Specialty)
ESRD Treatment Choices Model (Specialty)
Enhancing Oncology Model (Specialty)
High-Value Drug List (Rx)
Cell & Gene Therapy (Rx)
Clinical Evidence (Rx)

Source: BRG Analysis of CMS Innovation Models ; * RO Model was permanently delayed

Value-Based Care

Value-Based Care: *Overview*

We've entered the third stage of value-based care's evolution, with policymakers' assessments of what worked informing new policy development.



Value-Based Care: *The Center for Medicare And Medicaid Innovation (CMMI)*

CMMI develops and tests healthcare payment delivery models aiming to improve patient care, lower costs, and better align payment systems to promote patient-centered practices.

- CMMI through its models, initiatives, and Congressionally-mandated demonstrations, has gradually caused a shift from payments based on volume to those based on value
- Models are APMs which reward providers for delivering high-quality, cost-efficient care
- Models can apply to health conditions, care episodes, specific provider types, communities, and health plans
- CMMI tests whether alternatives to FFS payment improve quality and lower costs
  - Model outcomes mixed on savings and quality of care
- Some models have been announced, withdrawn, expanded, or indefinitely delayed

CMMI Model Category	Number of Models			
	Active	Ended	Other	Total
Statutory	3	15	1	**19**
Accountable Care Models	5	12	1	**18**
State & Community Based	6	11	--	**17**
Prescription Drug Models	1	3	1	**5**
Disease Specific, Episode Based	9	8	3	**20**
Health Plan Models	1	2	1	**4**
Total	25	51	7	**83**

Source: BRG Analysis of CMS Innovation Models

Value-Based Care: *Accountable Care Organizations (ACOs)/Total Cost Of Care Models*

Medicare ACOs offer additional care coordination and preventative services to beneficiaries aimed at reducing total cost of care.

ACOs will provide care to ~13.2m Medicare beneficiaries in 2023

- ACOs and aligned beneficiaries decreased slightly in 2023
- 700k+ providers and organizations will participate in ACOs

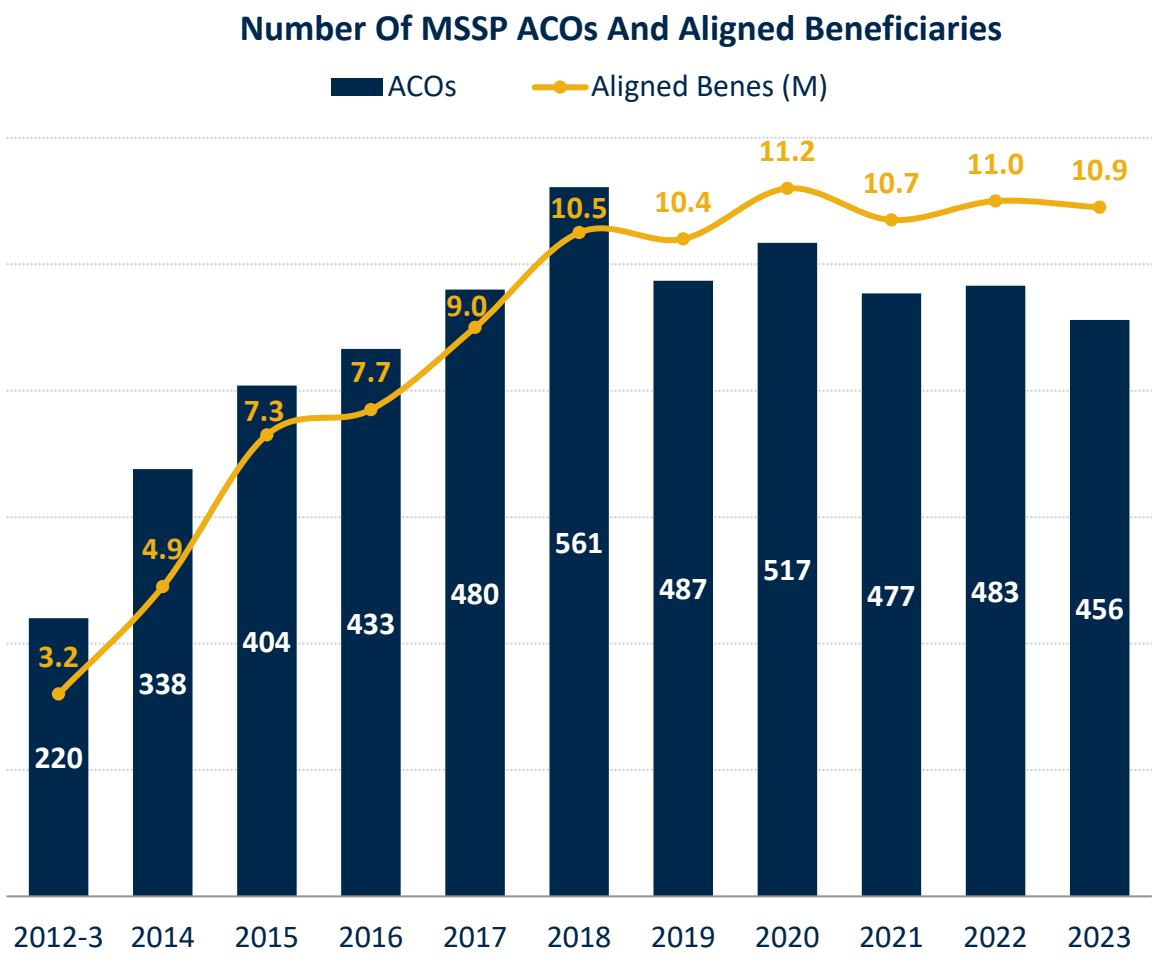
ACOs have reduced spending and improved quality

- MSSP saved $1.66B in 2021 compared to spending targets
- Pioneer ACO reduced net spending while improving care experience

CMS expects finalized policies will encourage MSSP participation 2024+

- 2024P PFS estimates changes will increase enrollment by 10-20%

ACO	Beneficiaries	Status
MSSP	~10.9m	2012 - Current (Permanent)
Pioneer ACO	~1.2m	2012 - 2016
Next Generation ACO	~1.0m	2016 - 2021
Direct Contracting	~1.7m	2021 - 2022
ACO REACH	~2.0m	2023 – Current (2026)



Source: BRG Analysis of CMS Innovation Models and Medicare Shared Savings Program Number of ACOs

Value-Based Care: *Primary Care Models*

Outside of its ACO programs, CMMI has tested primary care-focused models to promote value-based care in primary care settings without requiring practices to take on full risk.

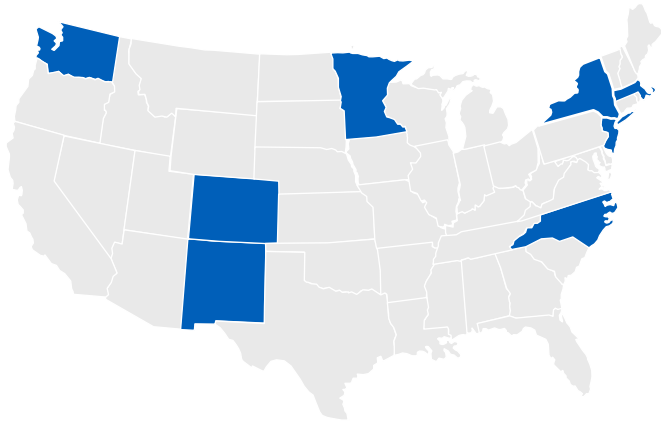
Category	Primary Care Models			
Model	Comprehensive Primary Care	Comprehensive Primary Care Plus	Primary Care First	Making Care Primary
Performance Years	2013-2017	2017-2022	2021-2026	2024-2035
States	7	18	26	8
Participants	442	2,610	2,515	--
Payment Structure	Blend of monthly non-visit care management fee and shared savings with Medicare program	Blend of care management fee, performance-based payments, and FFS payments	Blend of flat, population-based, and two-way risk- based payments	Blend of prospective, population-based, and FFS payments

Source: BRG Analysis of CMS Innovation Models

MCP is voluntary, tested in eight states starting July 2024— last 10.5 years

- CMS and state agencies will implement the model using different public payers, likely integrate private plans in future

States Selected for MCP Model Participation



Track	Description	Payment
Building Infrastructure (Track 1)	• Risk stratification, data review, disease management, social needs screening	• FFS and rewards for outcomes
Advanced Primary Care (Track 2)	• Track 1 plus collaboration with social service providers, care management, behavioral health screening	• Blend of prospective, population-based and FFS
Optimizing Care (Track 3)	• Track 2 plus improved care integration, partnerships with social services, connections to community resources	• Prospective, population-based payment

Value-Based Care: *Specialty Care Models*

CMMI's specialty care models have focused on episodes of care for certain conditions.

	Model	Timeline	Episodes	Description
Bundled Payments	**Bundled Payments for Care Improvement**	2013 - 2018	Model 1: Inpatient (IP) stay Model 2: IP stay + 90 days post discharge Model 3: IP stay, began at PAC facility Model 4: IP stay	• BPCI Model 1: Acute Care Hospital Stay Only • Models 2, 3 and 4 – Two Phased Implementation
	Comprehensive Care for Joint Replacement	2016 - 2024	IP and OP Knee and Hip Replacements (Mandatory Model)	• Holds hospitals financially accountable for quality and cost of CJR episode • Incentivizes increased coordination among hospitals, physicians, and PAC providers • ~324 hospitals in 34 MSAs participating
	Bundled Payments for Care Improvement Advanced	2018 - 2025	90-days	• Single retrospective bundled payment and one risk track • 8 Clinical Episode Service Lines Groups- 29 IP, 3 OP and 2 multi-setting categories • Qualifies as AAPM, payment tied to performance on quality measures
Kidney	**Comprehensive ESRD**	2015-2021	--	• Large Dialysis Orgs (LDOs) eligible to receive shared savings payments • Non-LDOs had option of participating in one-sided track
	Kidney Care Choices	2020-2026	3 years	• Remain participant for three years following successful kidney transplant or until kidney transplant fails
	ESRD Treatment Choices	2021-2027	Monthly	• Encourage greater use of home dialysis and kidney transplants for Medicare benes with ESRD, while reducing Medicare expenditures
Oncology	**Oncology Care Model**	2016 - 2022	6-months	• Participating practices take on financial and performance accountability for episodes of care around systemic chemo admin • 122 practices and 5 commercial payers participating
	Enhancing Oncology Model	2023 - 2028	6-months	• Similar to OCM, limited to 7 common cancer types • Health equity focus

Source: BRG Analysis of CMS Innovation Models

Value-based Care: *What's worked (and what hasn't)*

While few CMMI models have met the requirements for expansion, the first decade of value-based care efforts has had successes that will guide future policy development.

Six of 50+ completed models launched had statistically significant savings to Medicare and taxpayers

- The Maryland All-Payer Model (MDAPM)
- Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization Model
- Home Health Value-Based Purchasing (HHVBP) Model
- ACO Investment Model (AIM)
- Pioneer ACO Model
- Medicare Care Choices Model (MCCM)

Four models met requirements to be expanded in duration and scope

- RSNAT Prior Authorization Model
- HHVBP Model
- Pioneer ACO Model
- Medicare Diabetes Prevention Program (MDPP) Model

Flagship ACO, Primary Care, and Specialty Models have had mixed results

Unfavorable | No Change | Improvement

Model	Spending		Utilization				Quality	
	Gross	Net	IP Adm	ED Visits	PAC	Readmit	Care Experience	Mortality
BPCI Model 2			--					
BPCI Model 3			--					
BPCI-A Medical			--	--				
BPCI-A Surgical			--	--				
Comp ESRD								
CJR			--					
OCM								
CPC								--
CPC+								
Next Gen ACO							--	--
Pioneer ACO								--

Source: BRG Analysis of CMS Synthesis of Evaluation Results across 21 Medicare Models, 2012-2020

Value-Based Care: *Lessons From The First 10 Years*

CMS can't reach its goal of having 100% of traditional Medicare beneficiaries in a value-based care arrangement by 2030 without learning lessons from the last decade.

Model design requires balancing carrots and sticks to attract providers into sustainable models

- New models better calibrated, benchmark design reform, revising role of conveners

Overlapping risk models lead to confusion, dilute savings

- CMS published RFI on requesting stakeholder input on this question

Extra work required to encourage hard-to-reach providers to participate in value-based care

- CMMI designing models with FQHC, rural providers in mind (e.g. recent changes to MSSP and the Making Care Primary model)

Ease of performing under MIPS makes participating in value-based care less attractive

- Congress beginning MACRA reform policy development

Despite independent demonstration authority, politics will constrain attempts to expand value-based care

- Stakeholders forming new coalition to support value-based care movement

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