BRG Healthcare

Always HEALTHCARE

US Healthcare Reimbursement & Regulatory Diligence 101

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Agenda	

I | *Introduction*

BRG

BRG Overview

BRG is a global consulting firm that helps leading organizations advance in three key areas: disputes and investigations, corporate finance, and performance improvement and advisory.

2010	1,400+	1,500	40+
ESTABLISHED BY EXPERTS	PROFESSIONALS	HEALTHCARE CLIENTS SERVED	OFFICES AROUND THE WORLD

CORPORATE FINANCE

Multidisciplinary solutions to realize value achievement throughout the business change continuum.

ECONOMICS & DAMAGES

Clear, compelling testimony and economic analysis in complex disputes.

HEALTHCARE

Multidisciplinary services to deliver innovative, independent, and data-driven solutions.

GLOBAL INVESTIGATIONS & STRATEGIC INTELLIGENCE

Relevant and timely information required to make fully informed business and legal decisions.

PERFORMANCE IMPROVEMENT & ADVISORY

Evidence-based, theory- informed, and insight- driven strategic advice with a dynamic capability framework.

Healthcare Transactions & Strategy

With decades of experience in both the public and private sectors, our professionals offer unmatched expertise for investors, companies and advocacy groups when navigating today's evolving regulatory and reimbursement environment. Our team includes former policy makers and regulatory professionals from the Executive branch, including CMS/HHS and the White House, as well as from Capitol Hill, trade associations and state governments. This wealth of experience enables us to provide valuable insight throughout the transaction process or to inform strategic initiatives.

Integrated Services and Solutions

Healthcare Transactions

- Regulatory and Reimbursement
  - Federal
  - State
  - Health plan
  - Other payers
- Data Analytics
- Market Survey and Sizing
- Revenue Cycle Management Assessments
- Billing/Coding Audits and Compliance Program Reviews
- Financial and Tax Diligence (Quality of Earnings)
- Merger Integration

Healthcare Strategy

- Corporate Strategy
- New Market Growth/Business Intelligence (BI) Tools
- Focused Commercial Diligence

Healthcare Operations

- Performance Improvement
  - Cost reduction
  - Revenue cycle improvement
  - Physician alignment solutions
  - Value-based transformation
  - Clinical variation
  - Integration solutions
  - Staffing optimization
- Finance
  - CFO Solutions
  - Turnaround and restructuring
  - Transition and interim management
- Compliance
  - Investigations and disputes
  - Mock audits
  - Program and process improvement

James Teisl
Managing Director
jteisl@thinkbrg.com

Jim Teisl, MPH, is a healthcare policy professional with 20+ years of Medicaid payment and financing experience. At BRG, Mr. Teisl has advised institutional investors on the buy-side of approximately 400 healthcare transactions. He joined BRG from the Medicaid and CHIP Payment and Access Commission (MACPAC), at which he authored and presented work related to Medicaid payment policies for institutional and non-institutional providers, primary care payment incentives, supplemental payments to hospitals and other providers, state approaches to Medicaid financing, state policies for dual eligibles, and Medicaid value-based purchasing initiatives (e.g., accountable care organizations, episodes).

He has a Master of Public Health and Certificate in Health Finance and Management from The Johns Hopkins Bloomberg School of Public Health, and a BA from The Johns Hopkins University.

Simon Morgan
Associate Director
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Simon Morgan has more than a decade of healthcare policy experience including participation in hundreds of M&A buy-side engagements with private equity firms and directly leading multiple strategic engagements for corporate clients. Simon has extensive experience in regulatory diligence and policy analysis, focused on the mechanics of reimbursement in both Medicare and Medicaid and the risks or opportunities presented through payment complexities.

Prior to his work in health policy, Simon was a project manager in Haiti for an NGO which focused on access for the disabled, and he completed cattle research for a feed manufacturer in Kentucky.

Simon has an MBA from Oxford University, Master of Public Health in Health Policy from Columbia University, and a BA in Music from Loyola University Chicago, where he also completed pre-med studies.

II | *Macro Context*

55% US Population Insured Through Private Plans, 37% Gov't Programs, 8% Uninsured

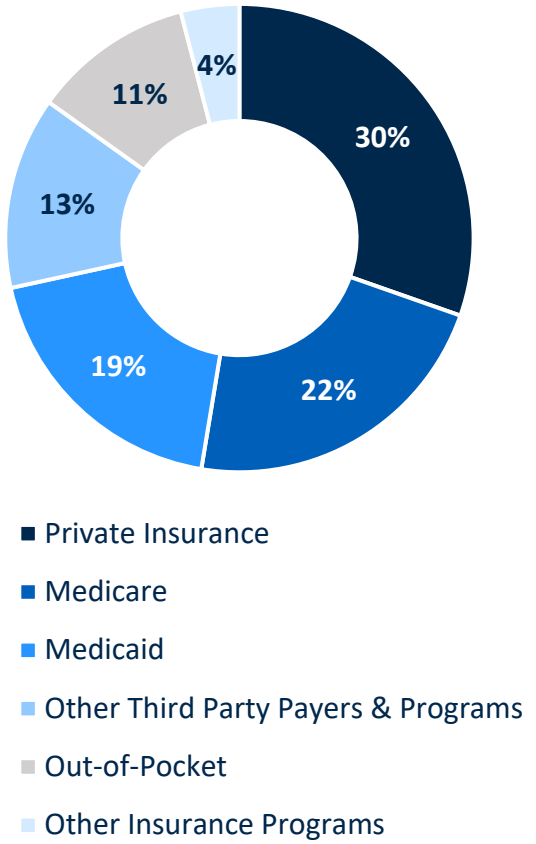
Most healthcare services in the US health system are paid for via health insurance – either commercial or government sponsored.

Private Plans
~55% 178M Lives
	• More than half of Americans have commercial coverage
	  • Most have large group or self-funded (ERISA) plans, others have individual market or small group (for employers with 2-50 employees)
	  • Individual Market/Exchanges
	  • Small Group
	  • Large Group/ERISA

Government Programs
~37% 120M Lives
	• Expansion of Medicaid and growth in Medicare population
	• Growing number of these plans are privately managed
	  • Medicaid/CHIP
	  • Medicare
	  • Duals (Medicaid/CHIP)
	  • Tri-Care, VA, IHS

Uninsured ~8% 26M Lives	• ~8% do not have health coverage as of 2022, all time low • Reduced from 15% prior to ACA • Declines in uninsured since 2019 correspond with increases in individual market and Medicaid/CHIP coverage

Healthcare Spending, 2022



Source: BRG analysis of HHS report, Commonwealth Fund, NHE data, KFF data

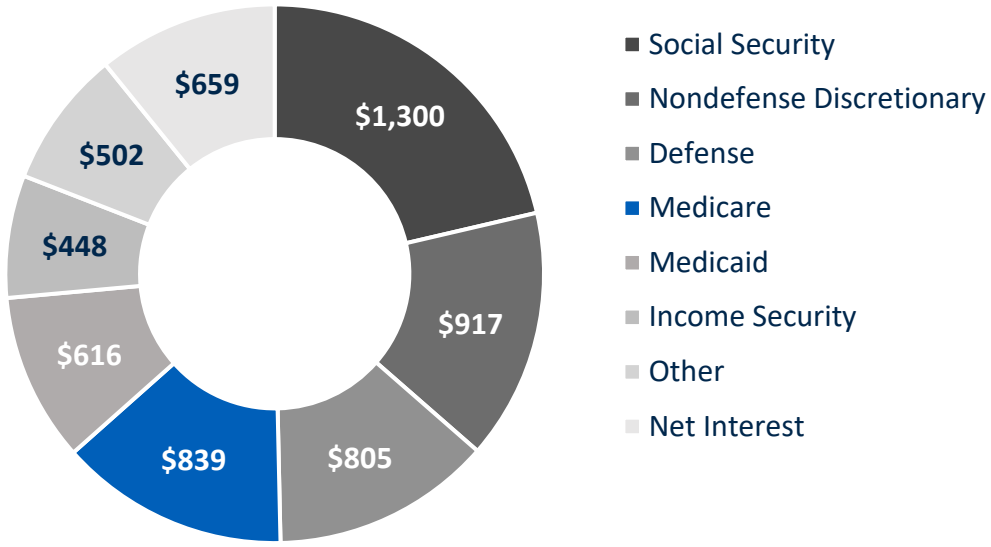
Medicare – Insurance For Older Americans, Those With Disabilities, And Those With ESRD

Medicare is administered by CMS and covers ~18% of the US population, accounting for ~14% of the federal budget.

Medicare	
Eligibility	• People 65 years of age and older • People under age 65 with certain disabilities • People with End-Stage Renal Disease (ESRD)
Lives Covered	• 61M lives, 18% of US Population
Dual Eligibles	• Eligible for Medicare due to age or disability and are also eligible for Medicaid • Primary healthcare services covered by Medicare, with beneficiary cost sharing and other medical benefits (e.g., long-term nursing) covered by Medicaid

Medicare As Share Of Federal Budget, 2023 ($B)

$6.1 Trillion Total

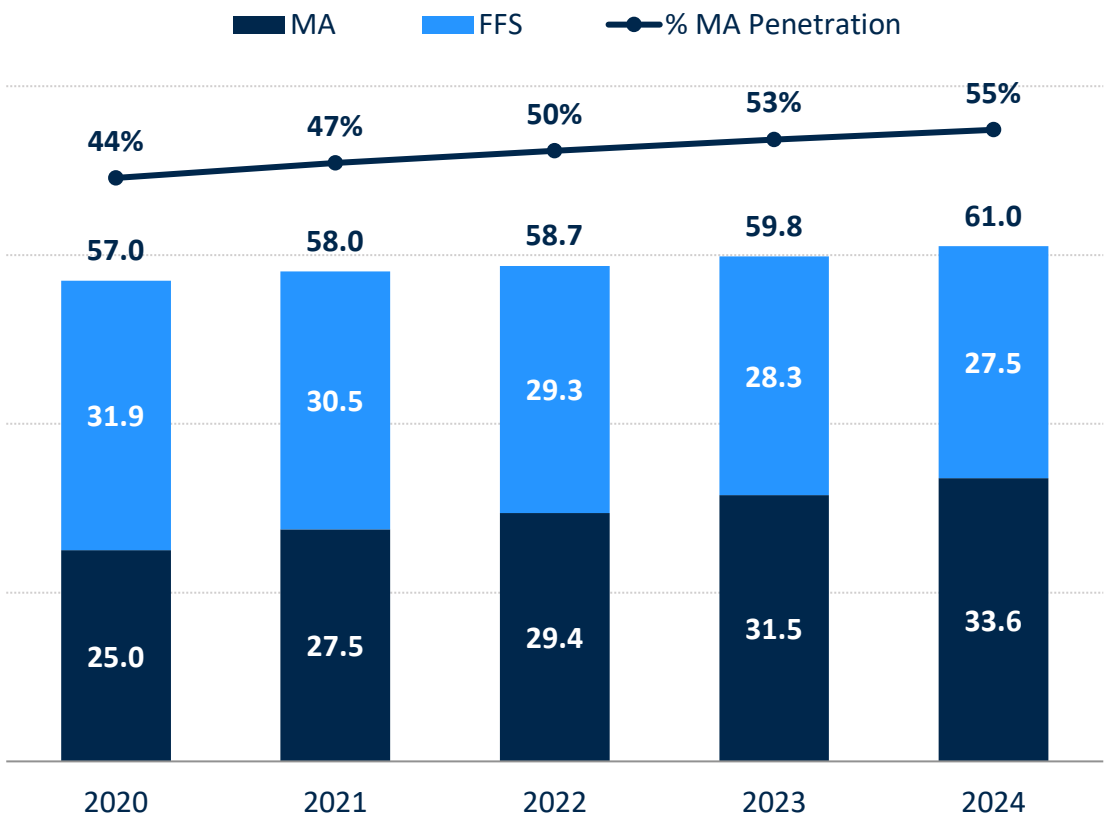


Source: BRG analysis of KFF 2022 data; CBO March 2024

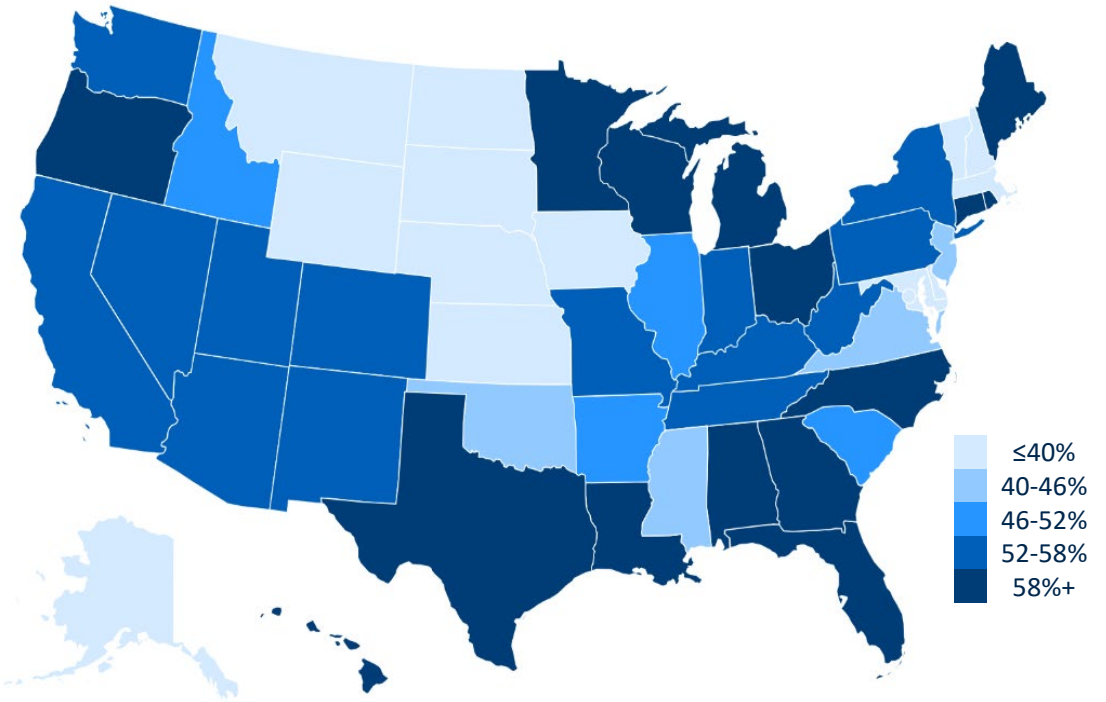
MA Penetration Continues To Grow, Currently At 55% Nationally

Majority of Medicare Part A and B beneficiaries were enrolled in FFS in 2021 but shifted to MA in 2022. In 2024, national MA penetration rate is ~55% of eligible beneficiaries but varies across states.

National Medicare Enrollment (M)



MA Penetration By State, 2024



Source: BRG analysis of CMS MA Enrollment Data January 2024, Plan Enrollment Data January 2024
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

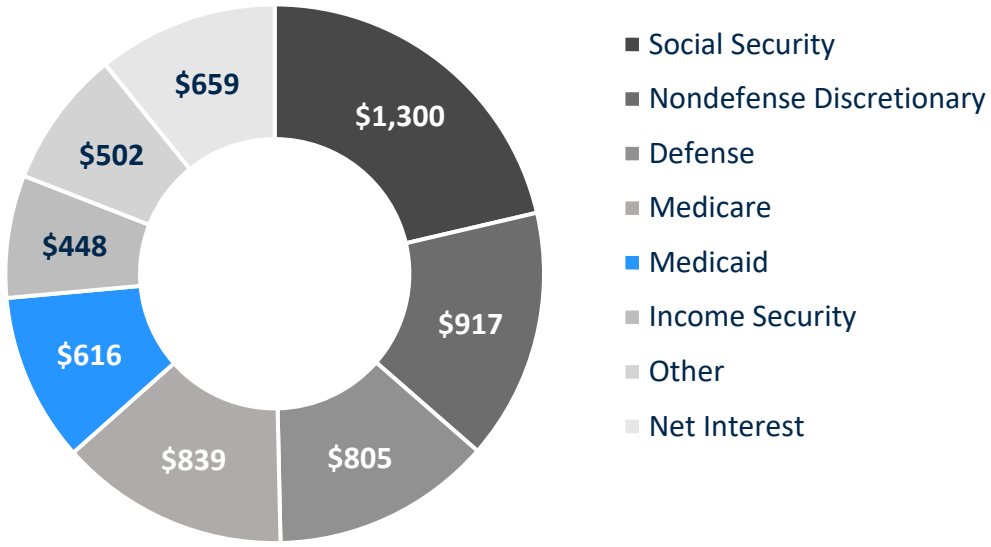
Medicaid – Joint Federal-State Program, Insurance For Diverse Low-Income Population

Medicaid covers ~21% of the US population, accounting for ~10% of the federal budget.

Medicaid/CHIP	
Program	• Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports
Lives Covered	• Medicaid is for low-income populations, including children, pregnant women, adults, individuals with disabilities, and people aged 65+
Funding	• Eligibility levels, the use of managed care, and payment methods and rates all vary • Federal government provides each state with funding called federal medical assistance percentage (FMAP) • Federal funding ranges from floor of 50% to nearly 83%
What it means for diligence work	• State-specific coverage and rates vary widely • Many services mandatory for kids • Medicaid MCOs often negotiate rates • State budgets and politics play roles

Medicaid As Share Of Federal Budget, 2023 ($B)

$6.1 Trillion Total



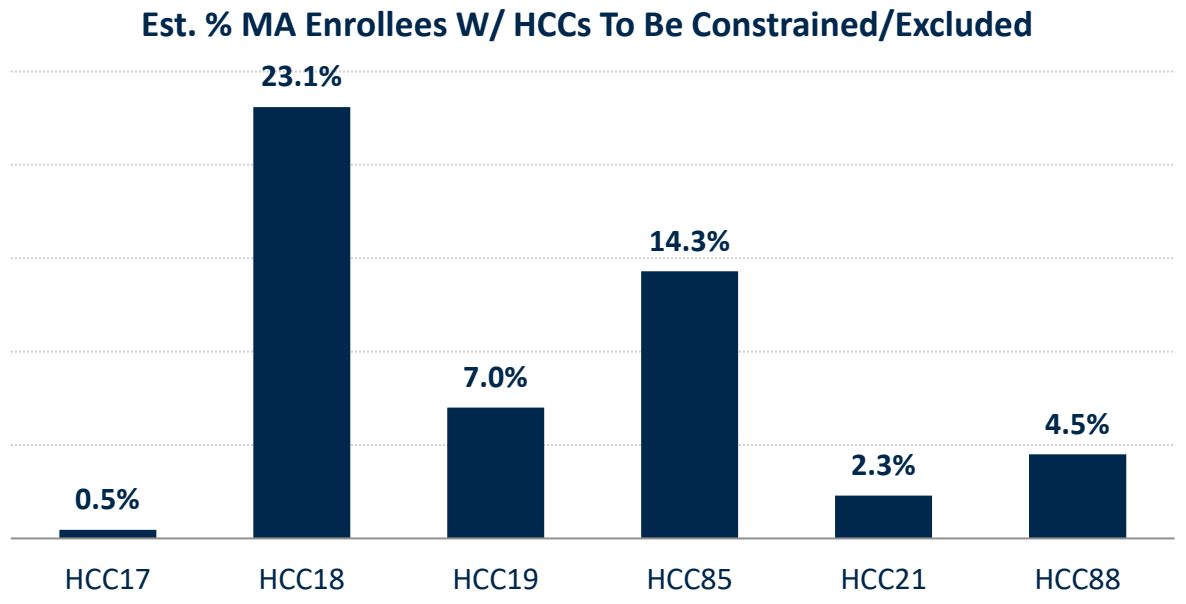
Source: BRG analysis of KFF 2022 data; CBO March 2024

III | *Hot Policy Topics*

Medicare Advantage Revised V28 Model Constrains Or Removes Several HCCs From Risk Adjustment Model, Policy Phased In Over 2024-2026

In the 2024 Rate Notice, CMS cites a principle of the risk adjustment model to identify several diagnosis codes with variation relative to coding in FFS and that are inconsistent across the industry.

- **CMS believes differential indicates conditions** where there may be discretionary coding variation which can lead to distortion of marginal costs estimated by the model
  - Revised V28 model, phased in 2024-2026 attempts to address discretionary coding
- **Diagnoses that map to some HCCs are excluded altogether,** i.e., protein malnutrition, angina pectoris
  - For others, diagnoses would map to new HCCs, i.e., CHF, vascular disease
- **New model constrains some HCC coefficients to single value across multiple payment HCCs**
  - All diabetes HCCs have same coefficient



HCC	Description
HCC17	Diabetes w/ Acute Complications
HCC18	Diabetes w/ Chronic Complications
HCC19	Diabetes w/o Complications
HCC85	Congestive Heart Failure
HCC21	Protein Calorie Malnutrition
HCC88	Angina Pectoris

Source: Proprietary BRG analysis of 100% Medicare Advantage encounter data for 2019, based on Data Use Agreement with CMS. BRG analysis does not constitute any advisory opinions on coding practices

Inflation Reduction Act Allows Medicare To Negotiate Drug Prices, Inflation Limits In 2023

CBO projects impact of changes within Medicare program to reduce total US drug spend by <5% over decade, estimated savings of $99B over 10 years.

- **Drug provisions in Inflation Reduction Act include:**
  - Medicare to negotiate price of certain prescription Part D drugs starting in 2026, Part B 2028
  - Effective 2023, manufacturers of single-source drugs and authorized generics pay rebate equivalent to difference between CPI & AMP (Part D drugs), or ASP (Part B drugs) multiplied by units sold to Medicare
  - Increases add-on payment for biosimilars from 6% of reference product ASP to 8% from 2022-2027
    - Return of sequestration in 2022 reduced add-on payment to +6.272%
- **Studies indicate in typical year ~50% of prescription drugs have price increases above inflation**
  - According to BLS, since 2000, overall prescription drug inflation has been 0.3ppt above CPI-U
  - Prescription drugs average inflation of 2.9% above CPI-U average rate of increase of 2.6%

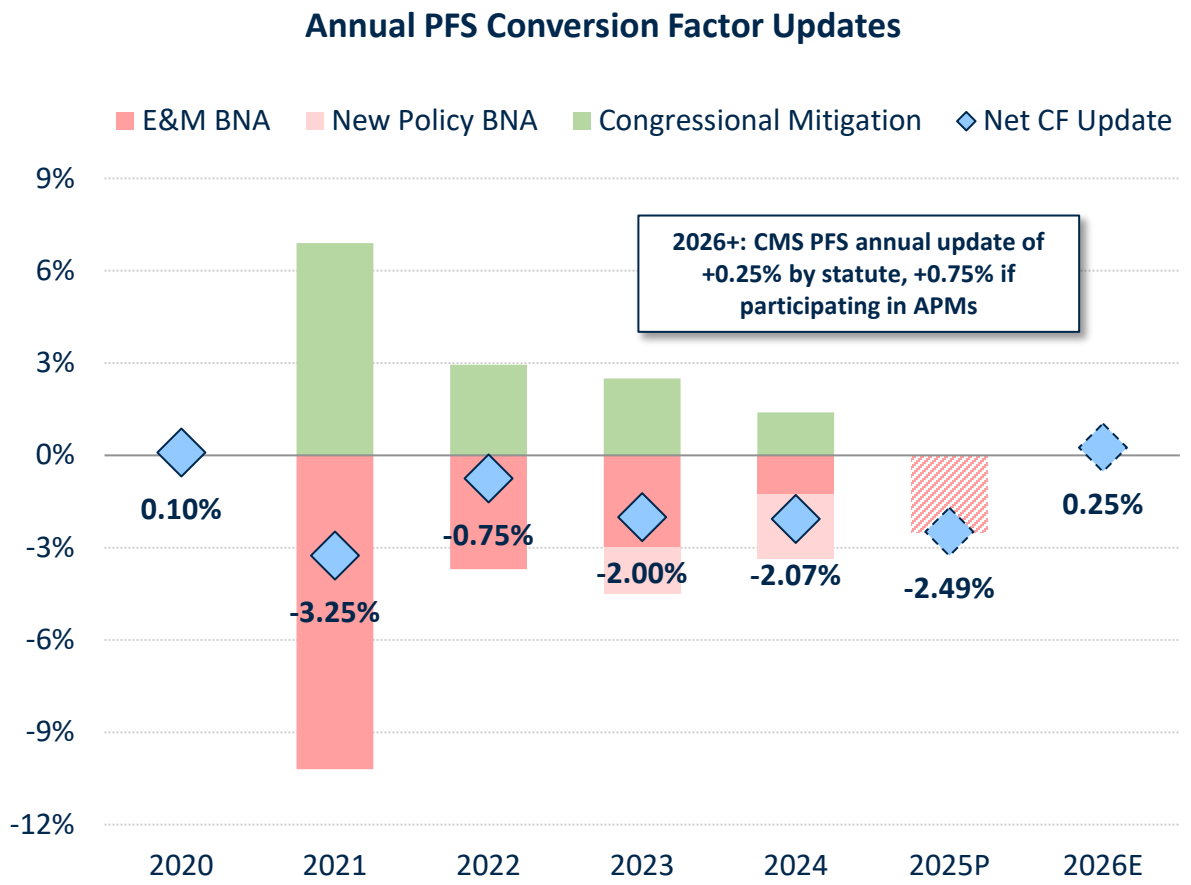
Category	Analysis
New Authority	• Drug pricing legislation requires the HHS Secretary to negotiate prices for certain single-source Part B & Part D drugs among the top 50 in Medicare spend
Drugs Excluded	• Low spend, orphan, and plasma-derived drugs are exempt
Drugs Included	• Small-molecule drugs on market for 9 years and biologics on market for 13 years • Minimum price reduction of 25% rising to 60% by time drug has been on market for 16 years
Timing Of Impact	• Part D drugs selected in 2023, updated pricing effective in 2026 • Part B drugs eligible for negotiations in 2026, updated pricing effective 2028

Source: BRG analysis of Inflation Reduction Act, 2022

Medicare Physician Fee Schedule: Budget Neutrality Achieved Through CF Changes, Congressional Relief Across Entire PFS Helps Mitigate Impact By Phasing-In Cuts

March 2024 healthcare package partially mitigated –3.4% reduction that went into effect January 1, annualized impact for 2024 was –2.1% reduction to CF. –2.5% reduction in 2025 is from the annualized impact of 2024 adjustments.

- **Mitigation simply delays reductions that were scheduled in 2021 to offset E&M increases**
  - Mechanically, Congress is not changing existing policy, just providing funding so reductions are not as low in a specific year
- **Rate increased +1.68% effective Mar 9, 2024**
  - No mitigation from Jan 1, 2024 to Mar 8, 2024
  - Annualized CF impact is approximately -2.1% for 2024 and -2.5% for 2025
- **-2.5% scheduled for 2025 from:**
  - Leftover -1.25% BNA from 2023 mitigation
  - 2022 end of year budget, Congress mitigated scheduled 2023 -4.5% PFS reduction
  - YoY result was -2% in 2023, -1.25% in 2024, and -1.25% in 2025
  - PFS 2024 final rule included additional -2.1% BNA for new policies

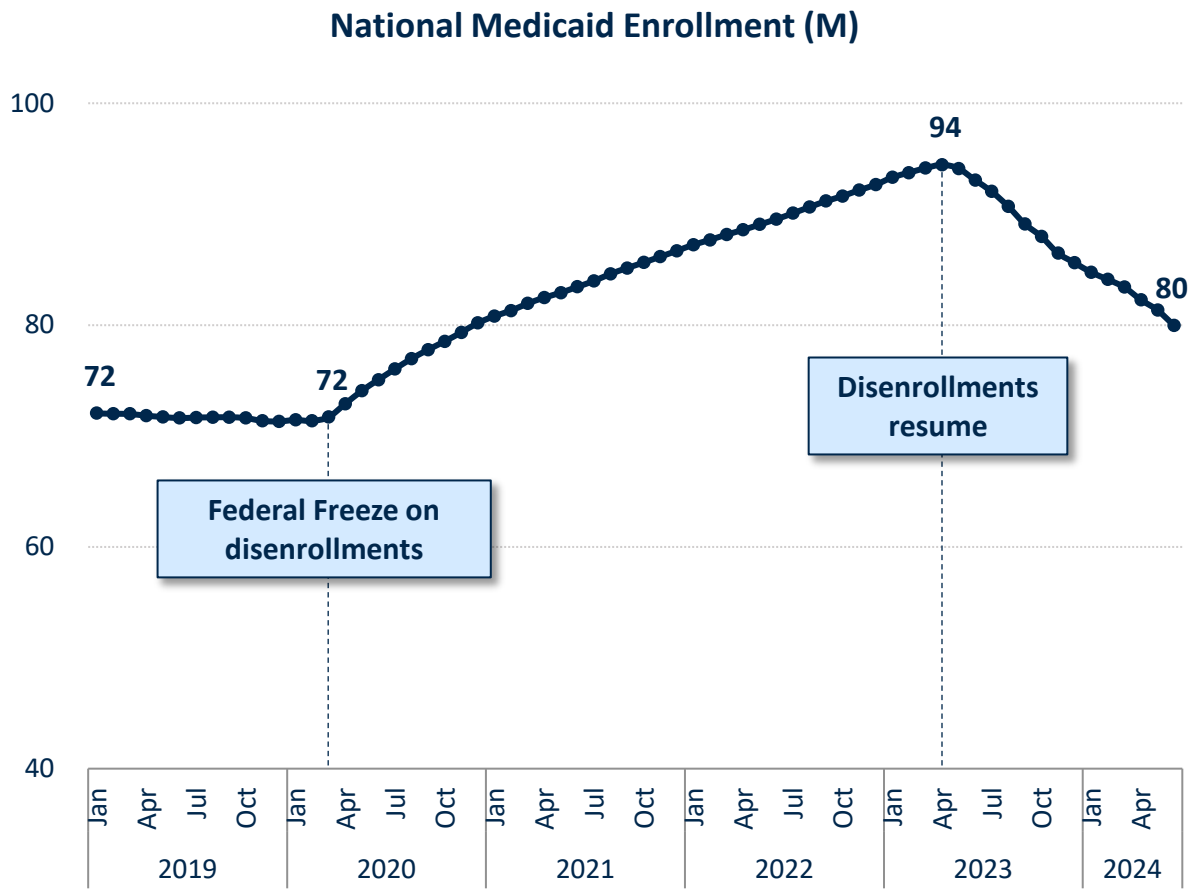


Source: BRG analysis of Medicare Physician Fee Schedules, 2020-25P

US Medicaid Enrollment Increased By 32% From March 2020 To April 2023; Declined By -15% Through June 2024 Data, Following Resumption Of Disenrollment Process

March 2020 to April 2023, Federal COVID-relief legislation prevented states from disenrolling Medicaid enrollees who lost eligibility; eligibility redeterminations and disenrollments resumed in April 2023 and led to -15% decline in enrollment as of most recent data through June 2024.

- **Dec 2022, Congress passed legislation requiring Medicaid eligibility redeterminations to resume starting April 2023**
  - 15% net decline in enrollment between April 2023 and June 2024
  - Many who lose Medicaid coverage are eligible for other sources (e.g., ESI, Marketplace); not all may enroll
- **Nationally, states had completed eligibility redeterminations for 90%+ of all Medicaid enrollees as of June 2024 data**
  - Varies by state—some have completed redeterminations, some still in progress
  - National enrollment expected to be largely stable moving forward
- **March 2020, FFCRA increased each state's federal share of Medicaid spending (FMAP) by 6.2 percentage points**
  - Tied to continuous coverage requirement that prohibited disenrollment, driving enrollment to historic peaks



Source: BRG analysis of KFF, Analysis of Recent National Trends in Medicaid and CHIP Enrollment, as of October 2024

40 States And DC Have Expanded Medicaid Coverage, 10 States Have Not; South Dakota And North Carolina Most Recent To Expand

ACA's Medicaid expansion expanded Medicaid coverage to nearly all adults with incomes up to 138% of the FPL, $20,783 for an individual in 2024, and provided states with an enhanced FMAP for their expansion populations.

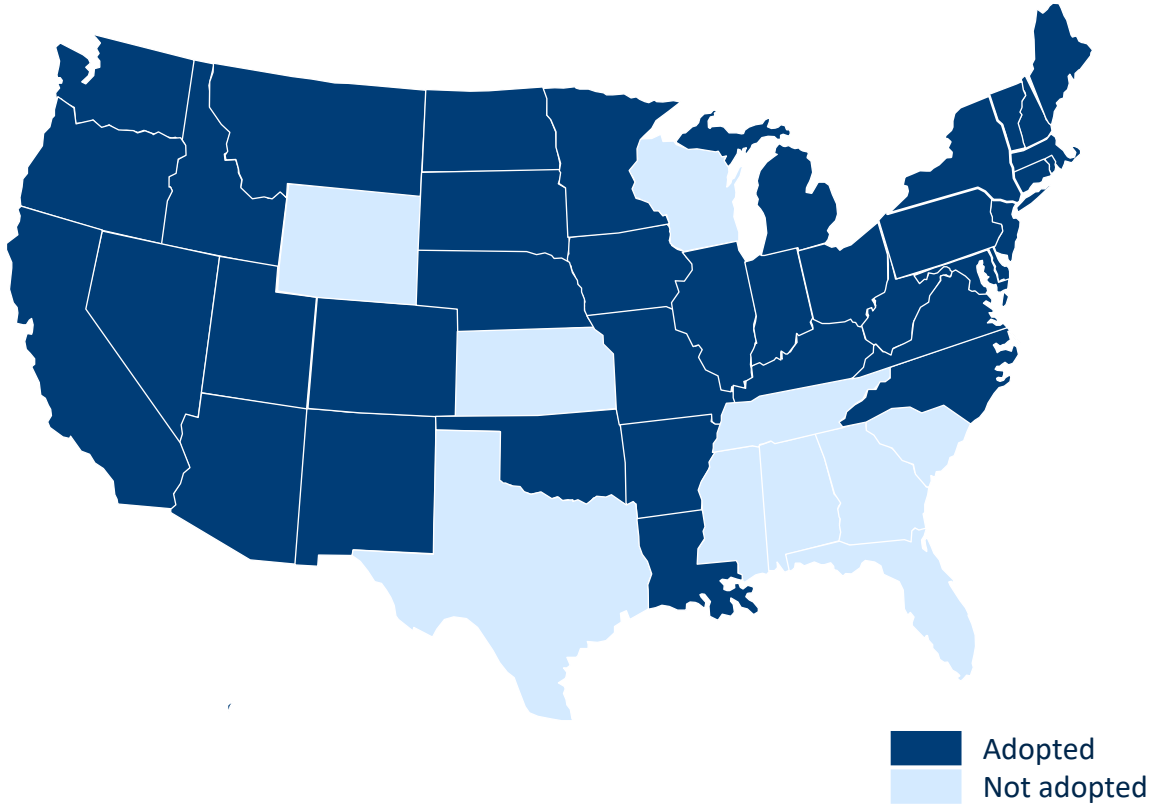
- **Coverage under Medicaid expansion became effective January 1, 2014** in all states that adopted Medicaid expansion under original expansion

- **40 states + DC have implemented full expansion**
  - Supreme Court made expansion optional
  - Federal gov't contributes 90% of funds for expansion population
  - NC most recent to expand, effective December 1, 2023

- **2 states implemented policies to partially expand**
  - WI covers adults up to 100% FPL but has not fully expanded
  - GA covers adults to 100% FPL if they meet work requirements

- **Some non-expansion states discussing possibility of expansion**
  - Recent efforts to expand in FL, KS, and MS have been unsuccessful

Medicaid Expansion States, October 2024



Source: BRG analysis of KFF, Status of State Medicaid Expansion Decisions

Starting In 2030, State Must Ensure ≥80% Of Certain Medicaid Payments Go To Compensation For Direct Care Workers

80/20 requirement applies to compensation for direct care workers that provide homemaker, home health aide, and personal care under certain specific Federal authorities.

- **CMS released final Medicaid Access Rule April 2024**
  - 2021 and 2022 Executive Orders directed agencies to improve quality and access
  - Proposed rule received 2k comments, including concerns about costs to providers

- **Payment Adequacy Provision (80/20) requires ≥80% of Medicaid payments for homemaker, home health aide, and personal care under certain authorities be spent on compensation for direct care workers**
  - Services chosen because most payment comprised of compensation for direct care, with low facility or other indirect costs
  - Payments include wages, benefits, education, workers compensation, taxes, non-admin costs related to clinical supervisory positions
  - Applies to FFS and managed care
  - Habilitation not included in 80/20 requirement

- **Numerous other provisions of Access Rule are generally good for Medicaid providers—states must:**
  - Publish fee schedules
  - Regularly compare their rates to Medicare
  - Demonstrate that proposed cuts will not diminish access

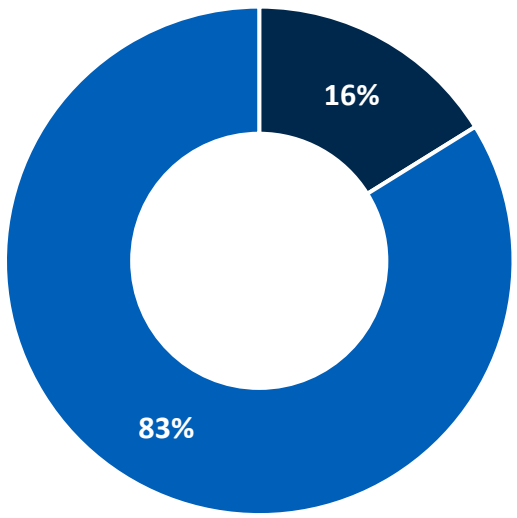
IV | *Diligence Focus Case Studies*

Case Study 1: Office-Based Substance Use Disorder Treatment

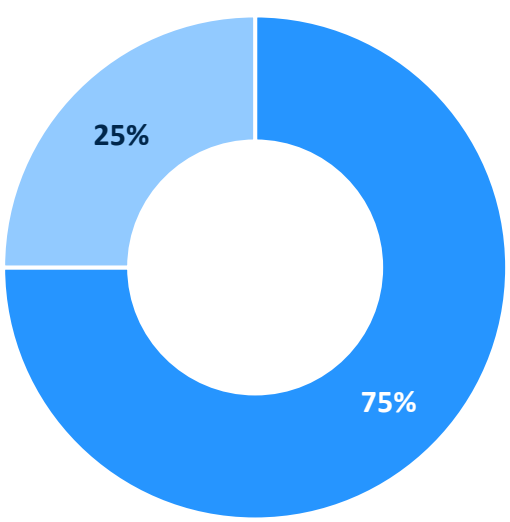
What potential diligence issues does the Company revenue profile present?

- Multi-state office-based substance use disorder treatment provider
- Patients generally prescribed buprenorphine to control opioid addiction
- Prominent use of telehealth for patient visits
- Attributes?
- Things to “dig into”?

Payer Breakdown



Revenue Mix



Case Study 2: Autism Therapy (Applied Behavior Analysis)

What potential diligence issues does the Company rate profile present?

- Multi-state autism service provider—rates in table are from the Company's single largest state
- Services are provided by both Masters-level Behavioral Analysts (BCBA) and paraprofessional technicians (RBTs)
- Autism service provider revenue is typically ~90% RBT
- Attributes?
- Things to "dig into"?

Payor Name	Payor Type	Clients	RBT	BCBA
Payor 1	Commercial	77	$49	$72
Payor 2	Medicaid	69	$100	$110
Payor 3	Managed Medicaid	54	$100	$110
Payor 4	Commercial	27	$60	$92
Payor 5	Commercial	4	$76	$92
Payor 6	Commercial	6	$200	$240
Payor 7	Commercial	15	$68	$68
Payor 8	Managed Medicaid	18	$50	$42

Case Study 3: Outsourced Benefit Manager

What potential diligence issues does the Company client profile present?

- Company contracts with states and MCOs to manage specific benefits
- Much of Company revenue is "at risk"
  - Company paid a contracted amount per member per month and pays providers for any services used
- 82% of members are Medicaid enrollees
- Attributes?
- Things to "dig into"?

Operational Scale	2018	2021	2018-2021
Total Members (M)	25	33	+36%
Medicaid Risk Members (M)	6	12	+94%
MA/Commercial Members (M)	4	6	+54%

Financial Performance	2018	2021	2018-2021
Revenue (M)	$1,791	$2,635	+47%
Adjusted EBITDA (M)	$97	$197	+102%
Margin	5.4%	7.5%	204bps

Case Study 4: Interoperative Neuromonitoring

How can pending but not yet enacted legislation affect a transaction? How should investors think about forward looking scenarios for the legislative process?

- **IONM has received media scrutiny for out OON billing practices**
  - Neuromonitoring provider association have issued position statement on ethical business practices
- **Several recent media articles have drawn attention to surprise billing for IONM services**
  - In 2019, Texas patient received $94,031 balance bill for IONM 1 year after undergoing a spinal procedure, patient's insurance only covered $816 of IONM services
  - Multiple Colorado patients were charged up to $169,000 for IONM after undergoing spine surgery from single provider in 2015
- **American Society of Neurophysiological Monitoring (ASNM) issued position statement on business practices in neuromonitoring in July 2019**
  - ASNM raised concern about certain financial arrangements, including kick-backs and self-referrals
    - Acknowledged that some groups have charged excessive fees for IONM in order to gain business by paying the money back to surgeons
  - While technically legal in a few states, the ASNM is clear in their view that the practice is unethical
- **ASNM has also raised concerns about timing for when patients sign the consent for neuromonitoring**
  - Because the majority of IONM is considered elective, surgeons and hospitals may fear that if they tell the patient IONM is OON, the patient will choose not to have their surgery at that location
  - Patients are often informed IONM is OON in the minutes just before surgery when they sign the consent for neuromonitoring

	Compromise Proposal
Scope of bill	• Regulates surprise OON billing for both emergency and non-emergency services • Applies to all commercial plans, including self-insured • Superseded by state legislation • Treat OON services as if in-network for purposes of cost-sharing, deductibles, and OOP limits
Payment Standard	• Requires health plans to pay OON emergency and facility-based providers the median contracted rate for the relevant service in geographic area
Dispute Resolution	• For services over $750 doctors will be allowed to appeal to an outside arbitrator for reconsideration

Case Study 4: PT Assistant Rate Reductions

Can an investor become comfortable with target company plans to mitigate the impact of a known regulatory or legislative that has a negative impact on the target company business model?

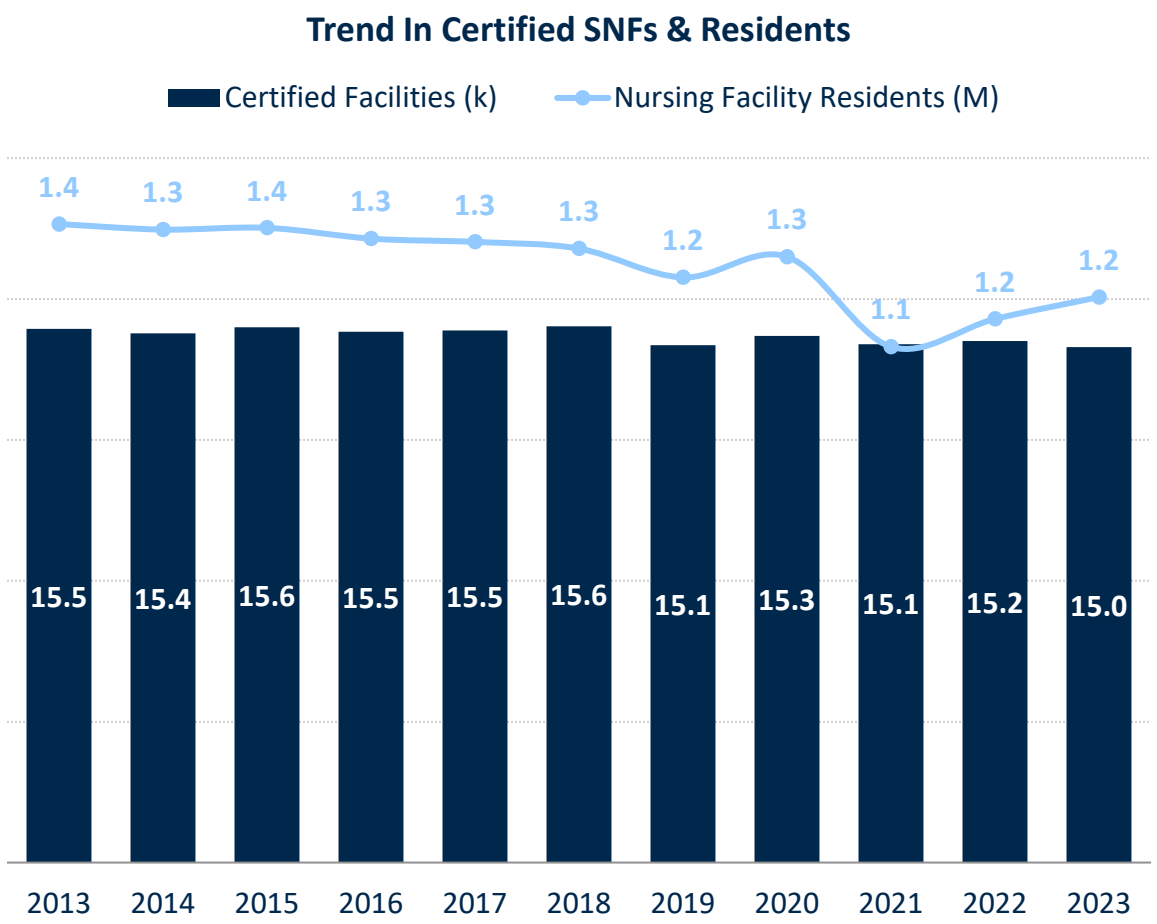
- PTAs will be reimbursed at 85% of full PFS rate beginning in 2022
  - Reduction from full PFS rate in past years
    - Independent PTA care specified by time threshold for services
- 2018 law repealed Medicare physical therapy caps, but implemented this reduced rate for PTAs
  - Therapy cap had limited total payments for PT services per year
- Process for E&M restructuring began in 2019 rulemaking and culminated in a substantial (-10.2%) budget neutrality adjustment
  - Congress mitigated by spreading impact from 2021 to 2024

Codes	2020	2021	20-21	2022	21-22	Total
Physical Therapist Reimbursement, 2020-2022						
97110	$31	$30	-3%	$29	-4%	-7%
97140	$29	$28	-3%	$27	-4%	-7%
97530	$40	$39	-2%	$38	-4%	-6%
97112	$36	$35	-2%	$34	-4%	-6%
97161	$88	$102	16%	$98	-4%	12%
97535	$35	$34	-3%	$33	-4%	-7%
97162	$88	$102	16%	$98	-4%	12%
PTA Reimbursement (85% of PT in 2022)						
97110	$31	$30	-3%	$25	-18%	-21%
97140	$29	$28	-3%	$23	-18%	-21%
97530	$40	$39	-2%	$32	-18%	-20%
97112	$36	$35	-2%	$29	-18%	-20%
97161	$88	$102	16%	$83	-18%	-5%
97535	$35	$34	-3%	$28	-18%	-21%
97162	$88	$102	16%	$83	-18%	-5%

Case Study 6: SNF End-Market

What can be a consideration for an investor other than the direct reimbursement or regulation of the target company model? How can investors become comfortable that the market into which a vendor or provider is selling is healthy?

- Facilities closures in recent years due to low Medicaid rates, lower rates and ALOS by MA enrollees, and oversaturation of SNF market
- Closures particularly in rural areas drive press coverage and may be only local SNF
- Newly-opened SNFs receive less press but siphon off more profitable Medicare patients from existing SNFs
- SNFs, even with poor financial outlooks, will often change management or restructure through bankruptcy
- Operator may have long-term lease that cannot be broken through closure – SNFs can borrow money based on property value
- 2020 reflects partial COVID impact due to report timing



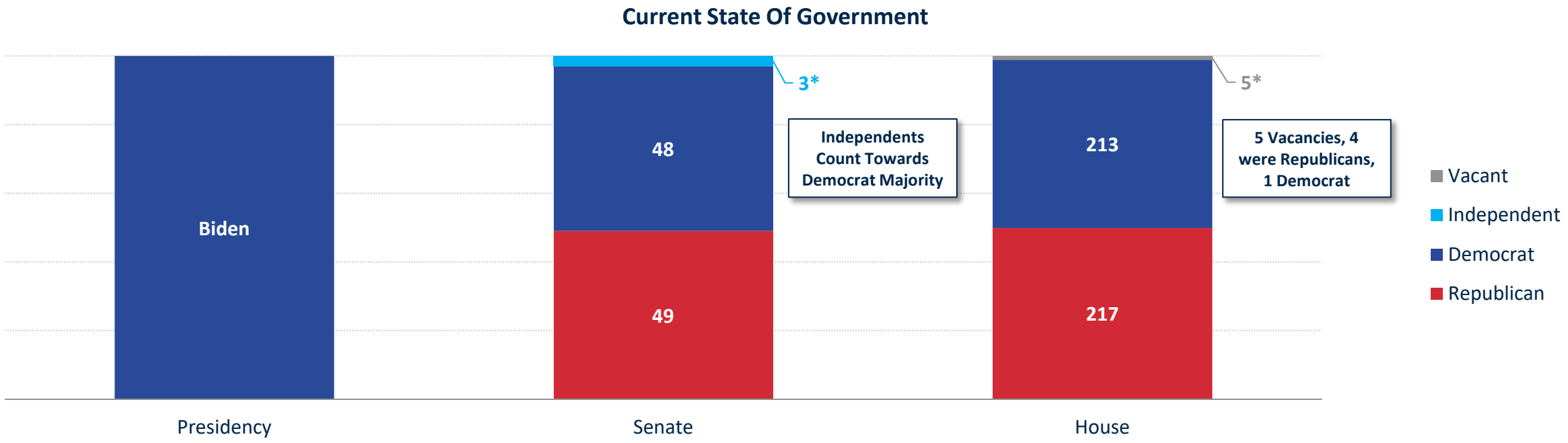
Source: BRG analysis of KFF, CASPER Data July of each noted year

V | *Election Politics*

Divided Gov't Creates Legislative Gridlock Leading Up To Election, Especially For Healthcare

Legislative gridlock as Republicans maintain slight majority in the House, while Democrats maintain slight majority in Senate – likely little healthcare action leading up to the election.

- Current Congress more focused on foreign aid than healthcare
- During lame duck session, potential end year package extending certain policies, such as:
  - Mitigation of Medicare PFS BNA
  - Further delay of scheduled DSH cuts
  - Modest PBM reforms (transparency)



Prior/Current: Biden/Harris vs Trump Administration Healthcare Accomplishments

Most notable healthcare policy of Biden/Harris Administration is the Inflation Reduction Act, little disruptive change across both Administrations in part due to divided Government and other priorities.

Policy		Biden/Harris	Trump
Medicare	FFS	• Expanded covered Medicare services – dental, BH & SDOH • Enrollment flexibilities	• Increase access to telehealth • Attempted to phase-out IPO list
	MA	• Continued MA scrutiny and administrative tightening	• Expand access to MA for patients with ESRD
Medicaid		• Minimum Staffing Standards for Nursing Homes Rule • Ensuring Access to Medicaid HCBS Rule • Medicaid and CHIP Managed Care Access, Finance and Quality Rule	• Attempted structural legislative change in 2017 • Medicaid work requirements
Drug Policy		• Inflation Reduction Act • Gene therapy initiatives	• Drug importation from Canada • Most Favored Nation • 340B reductions that were overturned by courts
Exchange Plans		• Restricted access to non-ACA compliant plans • ACA subsidies enhancement/extension	• Supported ACA repeal/replace legislation • Expanded access to non-ACA compliant plans
Value-Based Care/ CMMI		• DC became ACO REACH – focus on health equity • Additional models on specific conditions, treatments, and lowering drug costs	• Direct Contracting (DC) Model • No mandatory models, such as CJR • General support of ACOs and CMMI
Other		• Strengthened Mental Health Parity requirements	• No Surprises Act

2025+: Harris vs Trump Administration Healthcare Policies, Proposals & Agendas

Neither Presidential candidate has campaigned on strong healthcare proposals, focus will likely be on continued implementation of previous policies and addressing deficits and debt – unlikely radical change. While fundamental changes unlikely, smaller legislative and regulatory changes will happen.

- **After election, policy agenda likely shifts to address deficits and debt**

- **Sunset of Tax Cuts and Jobs Act (TCJA) at end of 2025**
  - Would lead to tax increases for almost all Americans
  - Permanent extension would lead to estimated $3T in spend
  - Likely extended for several years, with some spend offsets

- **Entitlement programs pressured, including Medicare and Medicaid**
  - Major healthcare programs are primary driver of deficits
  - Both Trump and Harris have yet to comment on how to address Medicare Trust Fund Insolvency

- **Policies with strong, bipartisan support include:**
  - "Doc fix" for Medicare PFS
  - Expanding access to rural health services
  - Expanding access to behavioral health services

- **Emerging issues for both parties:**
  - Scrutiny of MA, but delicate issue for both parties
  - Advent of AI and new technologies and therapies

Harris

- Continued implementation of IRA policies
- Expansion of IRA policies to commercial market
- Continued MA scrutiny and administrative tightening
- Continued focus on health equity and value-based models
- No major cuts to Medicare or Social Security

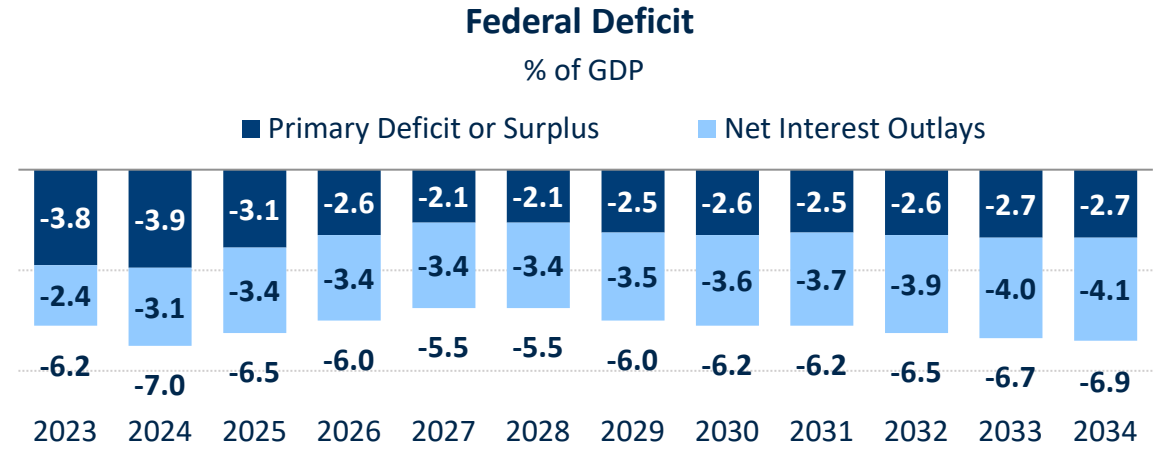
Trump

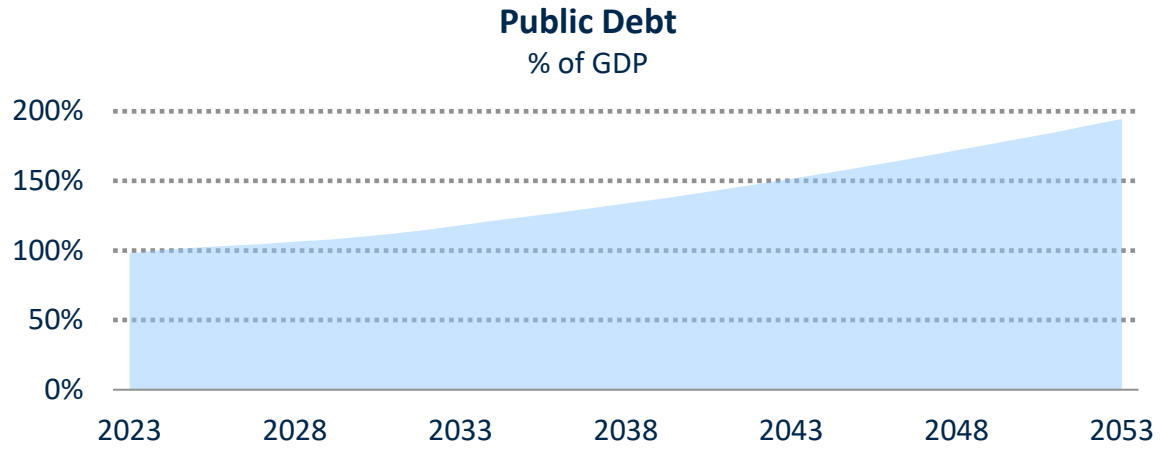
- Unlikely to retry "Repeal and Replace" from 2017
- Increase competition in health insurance market
- More support of MA but some scrutiny and administrative tightening
- Most Favored Nation Rule (pharma pricing legislation)
- No major cuts to Medicare or Social Security

CBO Projects Increasing Deficits & Debt Due To COVID Recession; Pressuring Late-2020s Spending – After 2024 Election

Deficits, debt, and entitlement program funding shortfalls could eventually bring pressure to reduce the rate of spending growth for healthcare programs in the late-2020s – all of Medicare would be impacted.

- **Deficit reduction involves reductions in the rate of increase** – not absolute declines
  - Medicare and Medicaid impacted
  - Deficit spiked 300% in 2020-2021 but has reverted to pre-COVID trajectory
    - Baseline steadily increases total debt
- **After 2024 election, policy agenda likely begins shift to addressing deficits and debt**
  - Entitlement program finances pressured
    - Major healthcare programs are primary driver of deficits
- **Debt projected to increase to over 100% of GDP** and then continue increasing throughout decade





Source: BRG analysis of CBO Budget & Economic Outlook: 2024-2033

2026 Fiscal Cliff Will Present Next President & Next Congress With Major Challenge

In January 2025 as Congress and President are sworn in, they would be 11 months away from a major fiscal policy "cliff". 2017 tax cuts and expanded ACA subsidies will both expire at the end of 2025. The baseline is expiration so any legislation extending current policy scores as making the deficit worse.

What Happened/Current Environment

- After 2024 election, at the end of 2025, major tax policies and healthcare policies will expire
  - Individual provisions of 2017 tax cut expire
    - Brackets, child credit, standard deduction, personal exemption, small-business pass through etc.
    - Tax provisions skew to middle income tax brackets
    - Expiration will be felt in January 2026 as IRS would adjust withholding tables
    - Approximately $3T to make permanent
  - Expanded ACA subsidies (400% of FPL)
    - Approximately $300B to make permanent
    - Expiration would impact 2026 plan year and likely reduce enrollment in ACA marketplace plans
- Neither party is focusing on longer-term fiscal problems

Outlook

Harris

- Only extended 2017 provisions for those making less than $400k
  - Bulk of provisions skew to middle incomes
- Extend the ACA subsidies
- Divided government would bring major political battle

Trump

- Extend all the tax provisions
  - All GOP government may be able to use reconciliation
- Allow the ACA subsides to expire

Federal Level Focus On Private Equity In Healthcare Includes Anti-Trust Scrutiny & Ownership Transparency Proposal

FTC under current progressive Chairwoman most active at Federal level with anti-trust litigation and developing investigatory effort – ultimate impact likely minimal.

Action	Provisions
FTC, DOJ, HHS RFI on PE ownership in Healthcare Industry	• RFI on deals conducted by health systems, private payers, PE funds, and other alternative asset managers that involve healthcare providers, facilities, or ancillary products/services • Understand how transactions may increase consolidation and generate profits for firms while threatening patients' health, workers' safety, quality of care, and affordability • Investigation will likely go on for years, unlikely to produce more than a report
FTC US Anesthesiology Partners Anti-Trust Lawsuit	• September 2023, FTC sued US Anesthesia Partners Inc., and its PE investor for series of acquisitions that allegedly enabled firm to gain market power • FTC alleged that in 2012, PE firm and USAP began scheme to consolidate anesthesia practices in Texas through series of roll-up acquisitions • May 2024, Federal judge dismissed the case

Healthcare Ownership Transparency Act	• Bill would require healthcare corporations participating in Medicare to disclose PE interests and related financial information
	  • Bill mandates transparency about debts, assets, and financial transactions
	  • Providers controlled by PE funds must disclose info relating to PE fund
	  • Sponsor: Rep. Jayapal (D-WA) very progressive; legislation unlikely to be enacted

Corporate Crimes Against Health Care Act	• Bill would create new criminal penalty of up to 6 years in prison for executives who loot health care entities like nursing homes and hospitals, if that looting results in patient's death • Sponsors: Senators Warren (D-MA) and Markey (D-MA); legislation unlikely to be enacted

Source: BRG analysis of FTC, DOJ, and HHS RFI, FTC Anti-Trust Lawsuit and Congress.gov Scan 118th Congress (2023-2024)

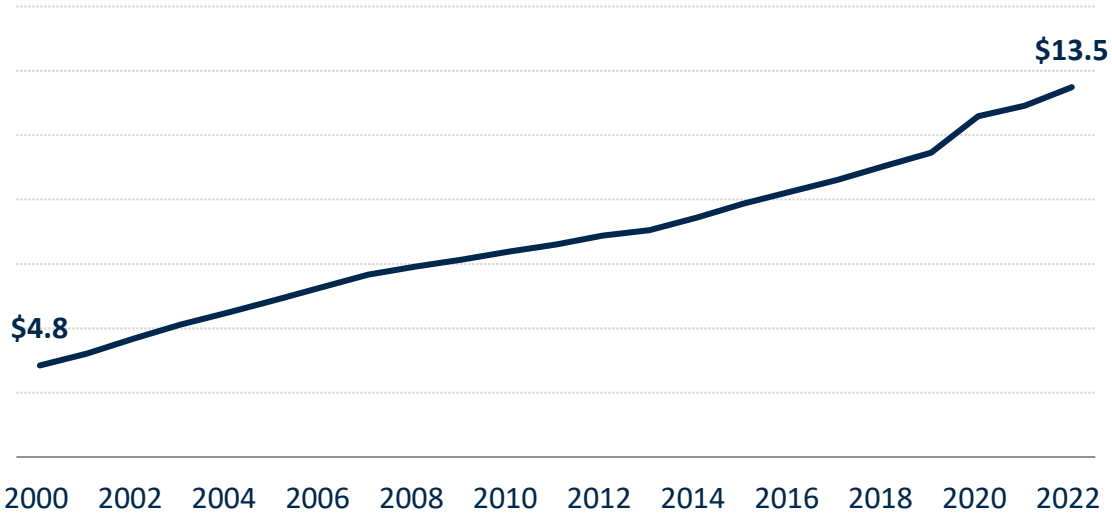
Q&A

Appendix

US Per Capita Healthcare Spending Increasing, Particularly For Aged Population

Aging U.S. population and rising prices drive increasing healthcare spending; Spending on U.S. health care has grown steadily, rising from $4.8k per person in 2000 to $13.5k per person in 2022, ~178% increase.

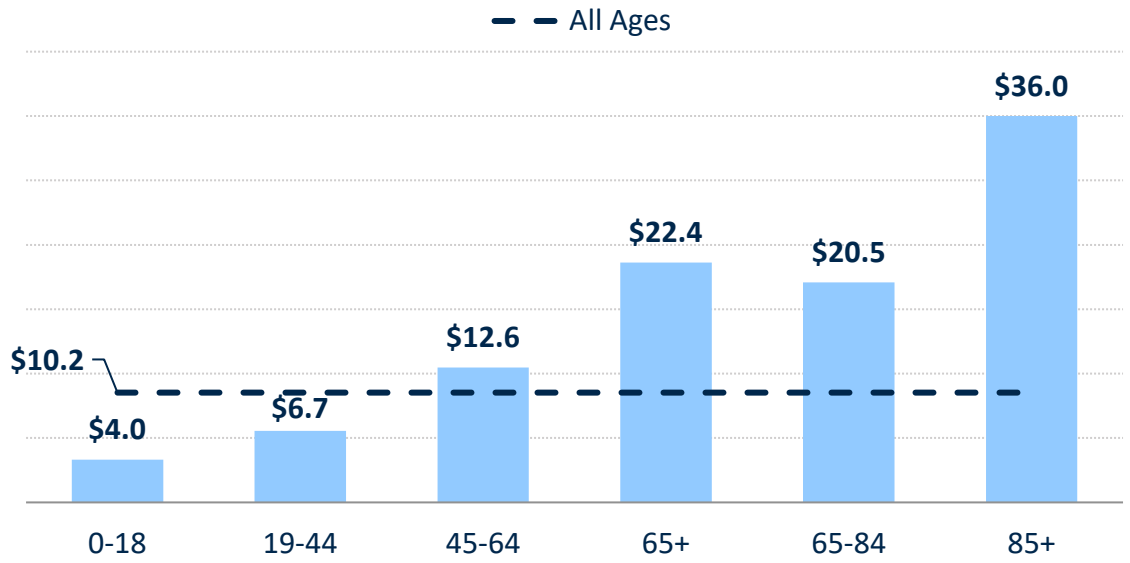
National Healthcare Spend Per Capita ($k)



Labor intensive industries, like healthcare, usually have constantly rising prices

- Phenomenon is known as Baumol's cost disease
  - Baumol, an economist, observed that labor intensive sectors with little technology driven productivity growth, like health care, must have constantly rising prices in order to preserve the purchasing power of individuals employed in the industry

Personal Healthcare Spend Per Capita, 2020 ($k)



Aging Of The U.S. Population Drives Increasing Spend

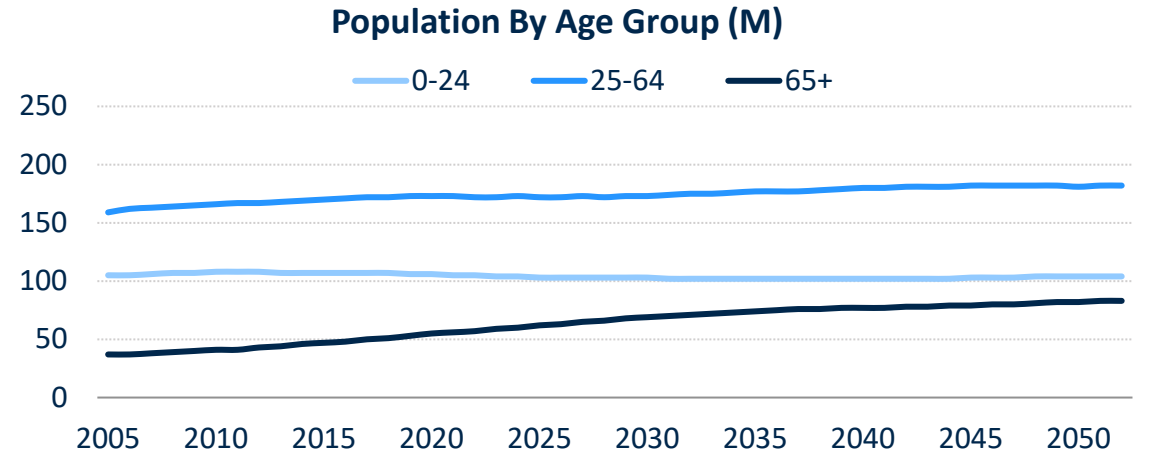
- $22,350 for an average person 65 to 84 years old
- $36,000 on an average person 85 or older
- $4,000 on an average person 18 or younger

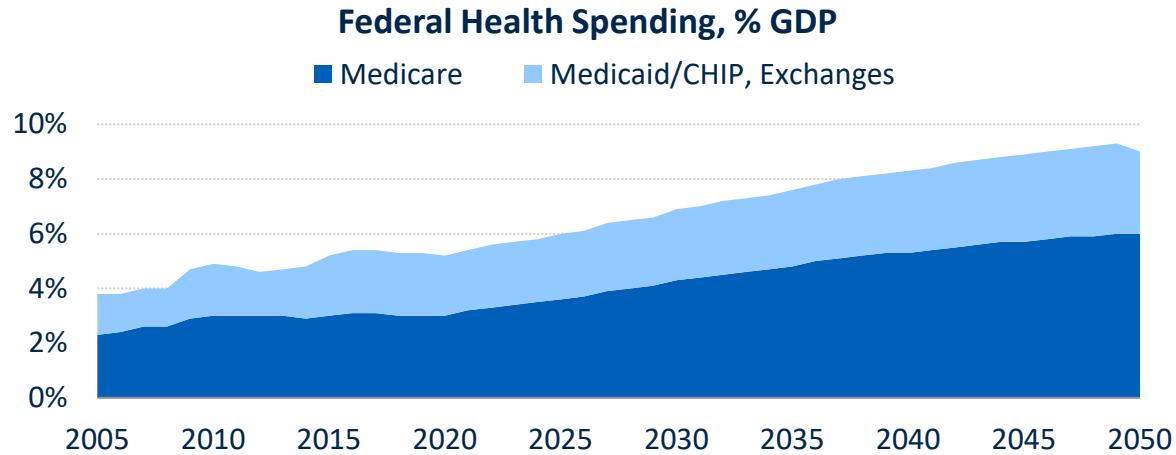
Source: BRG analysis of CMS 2022; BEA 1980-2018; Peterson-KFF 2022; Brookings 2020

Aging Demographics Increase Demand For Healthcare

The percentage of the population age 65+ is projected to rise in the coming decades, with the aging population likely to increase demand for healthcare services– 80+ cohort also growing.

- **CBO projects by 2052, 22% of population will be age 65 or older**
  - This age group currently accounts for 17% of population
- **Aging population is likely to increase demand for healthcare services** as higher percentage of the US population will be 65+
- **Government and private payor policy changes only slow the growth of spending,** not actually reduce it
- **Major Federal healthcare programs are projected to double** their share of GDP
- **Medicaid and related programs are larger** in total spending and serve more beneficiaries than Medicare



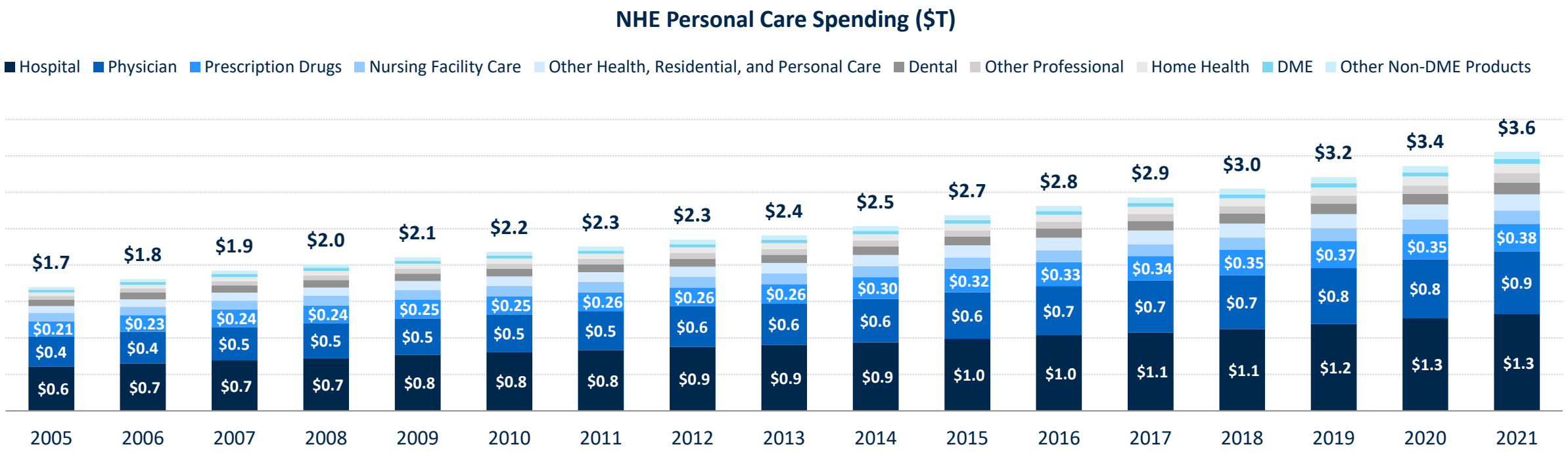


Source: BRG analysis of CBO Demographic Outlook 2022

Hospital Spending Is The Biggest Component Of PHC And Among Top 3 Fastest Growing

Hospital spending is the biggest component of PHC and has risen from $609B (36% of PHC) in 2005 to $1.3T (37%) in 2021. Physician spending has remained around 24% of PHC over this period but has grown 111% since 2005.

- Home health and residential care, historically smaller categories, have grown 6% annually since 2005 to combined $348B in 2021
  - Nursing home growth (3% CAGR) most impacted by home health growth and in recent years COVID, has still grown over that time period
- Fastest growing category is "Other Non-DME Products"
  - Grown 174% since 2005 – $97B in 2021 – largely OOP spending on products such as OTC drugs



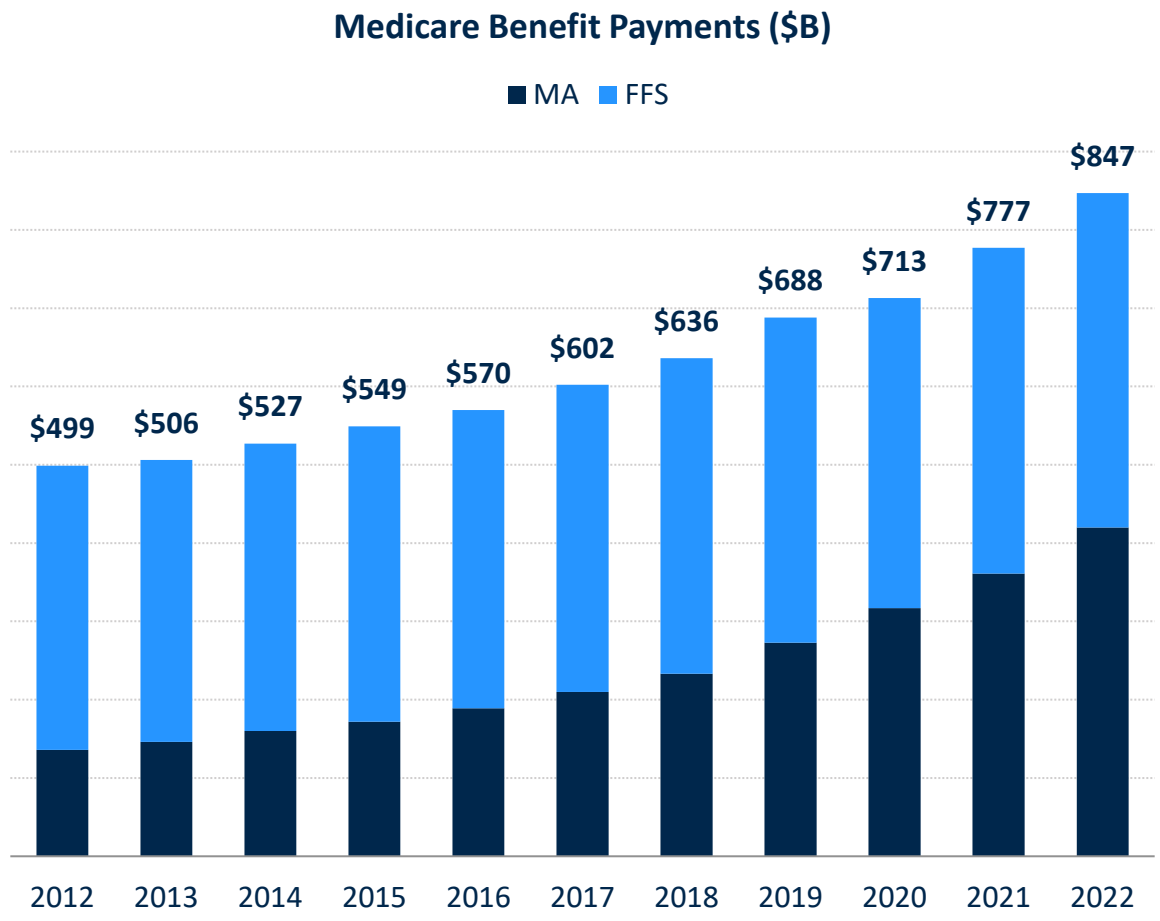
Source: BRG analysis of NHE 2023 data

Medicare

Medicare Program Has Four Components, With MA An Increasingly Large Share Of Spend

Medicare Part A and Part B are traditional FFS Medicare, Part C combines A, B and D in a single private plan, and Part D is retail prescription drug benefit.

Medicare Program Components	
Part A	Patients in facility settings: Hospital, skilled nursing home stays, home health services, and hospice care
Part B	Physician payment: Physician office and outpatient services such as PT
Medicare Advantage (Part C)	Covers beneficiaries via enrollment in private Medicare Advantage insurance plans which negotiate rates with providers and set their own cost sharing criteria Medicare Advantage plans cover all the services covered by Parts A and B; and some also cover Part D • May cover added benefits such as optometry not covered under Medicare FFS
Part D	Covers prescription drug costs through enrollment in private Part D or MA health plans



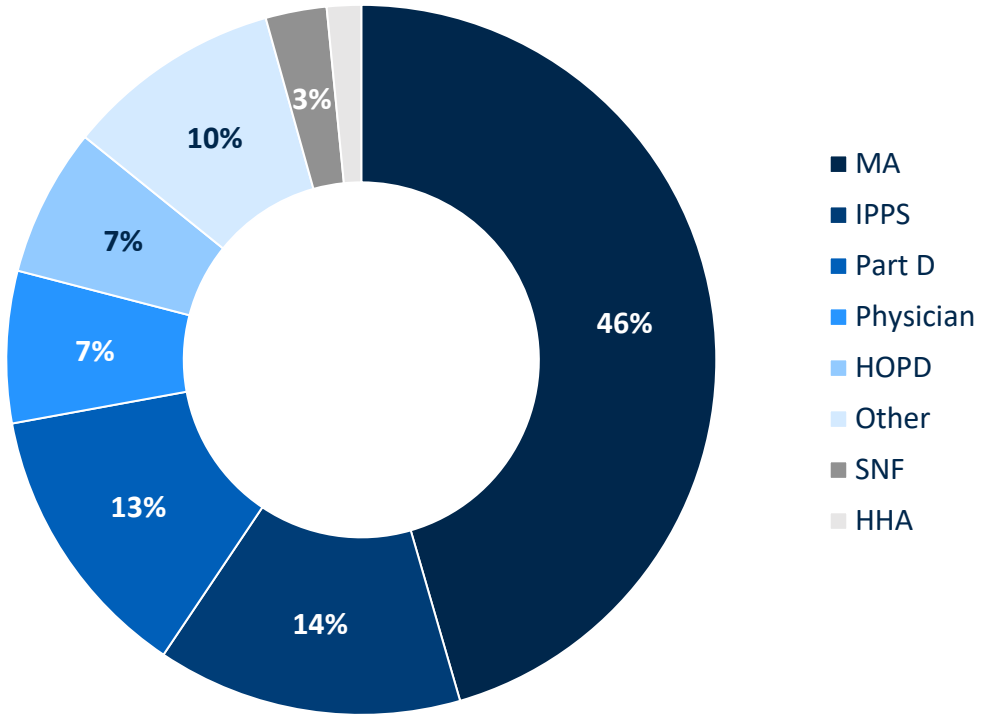
Source: BRG analysis of KFF 2023 data

Medicare Advantage Spend Growing As More Beneficiaries Elect MA Over FFS

MA spend has grown rapidly in recent years to 46% of program spend, FFS programs make up 41% and Medicare Part D 13%.

- **Hospitals including IP and OP** account for ~21% of FFS spend
- **PAC spending in aggregate is less than 10%** but is a focus of policymakers seeking more efficient care
- **MA is almost half of total spending and increasing** as more beneficiaries opt to enroll in MA
- **Part D drugs are 13%**
- **Part B drugs grouped within "Other" category**

Medicare Program Spend, 2023

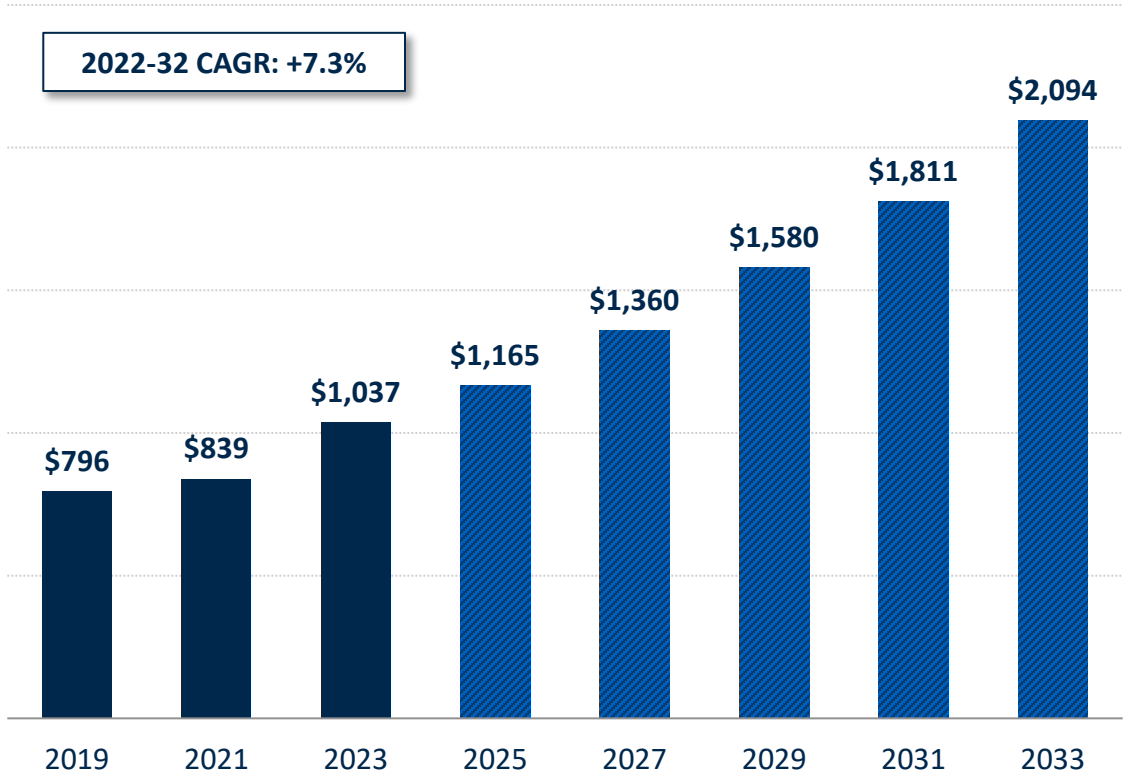


Source: BRG analysis of 2024 Medicare Trustees Report

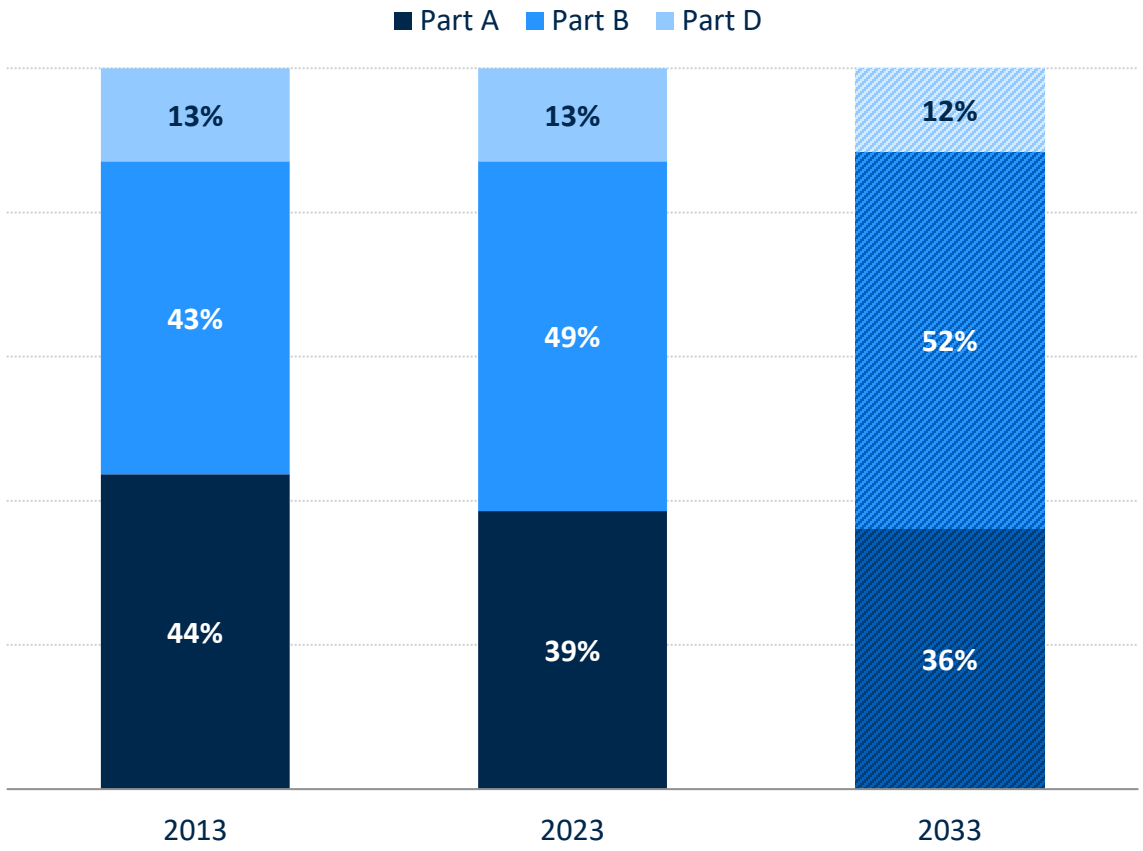
Medicare Spend Projected To Double From $1T In 2023 To $2.1T In 2033

Medicare spend projected to double from 2023 to 2033 due to growth in aging population and increased costs. Spending on physician services and other Medicare Part B services accounts for largest share of total Medicare benefits spending – trend likely to continue.

Total Medicare Expenditures ($B)



Medicare Spend By Service Type



Source: BRG analysis of 2024 Annual Report on the Boards of Trustees of the Federal Hospital Insurance and Federal Supp Medical Insurance Trust Funds

Fee Schedules, Prospective Payment Systems & Managed Care

Medicare has 20 different payment systems – each applying to a different program or type of service.

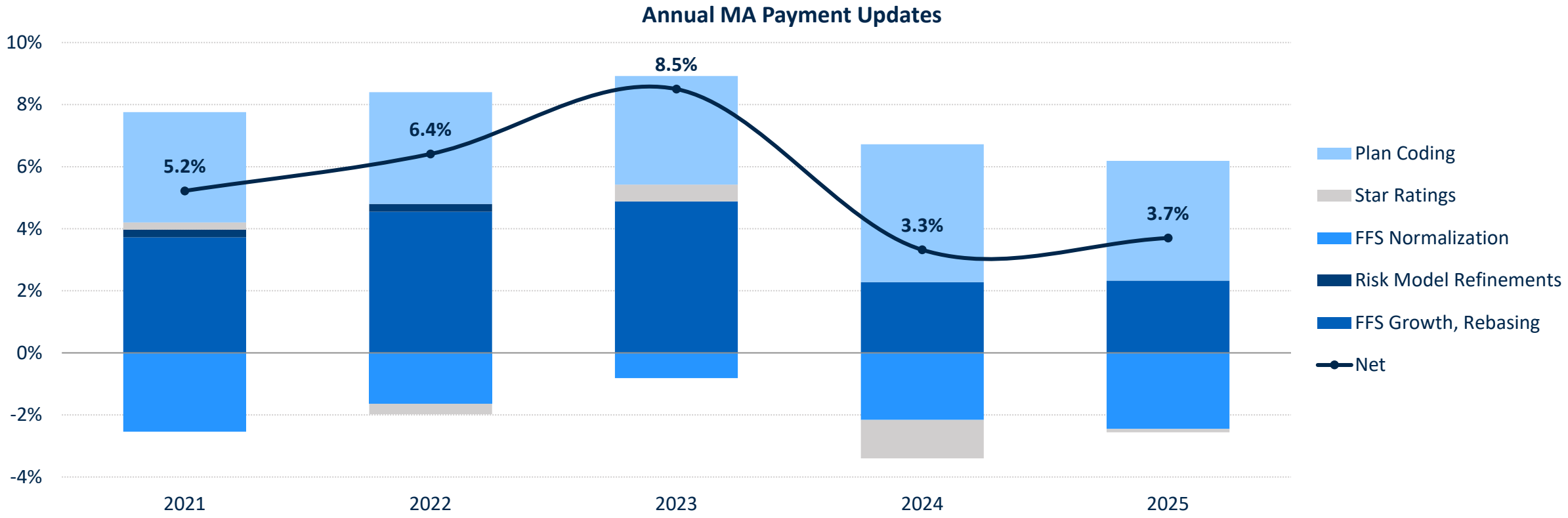
- **Prospective Payment System (PPS) is method of reimbursement** in which Medicare payment is made based on predetermined, fixed amount
  - Payment amount for a particular service is derived based on the classification system of that service or per day for that service
- **Capitation payments are agreed upon in a capitated contract** by a health insurance company and a medical provider
  - Fixed, pre-arranged monthly per patient enrolled in a health plan, or per capita
- **Fee schedule is complete listing of fees** used by Medicare to pay doctors or other providers/suppliers
  - List of fee maximums used to reimburse physician and/or other providers on FFS basis
- **Cost-plus reimbursement pays** the provider their reported costs plus a fixed percentage

Medicare Payment Systems					
Capitated			MA	Part D	ACOs
FFS	**PPS**	**Episode of Care**	Hospital IP	LTCH	IRF	Home Health
		Per Diem	Hospice	IPF	SNF	
	Hybrid PPS/ FS		ASC	Hospital OP	Dialysis	FQHC
	Fee Schedule		PFS	CLFS	Ambulance	DME
	Cost-Plus		CAH	Part B		

CMS Finalized Flat 2025 MA Payment Update, Estimates Growth From Risk Coding

Annual MA payment updates have been more than 5% in recent years, estimated to be ~3.7% in 2025. Changes to effective growth rate and risk model revision phased-in from 2024-2026.

- **CY 2025 Rate Announcement continues three-year phase-in of updated MA risk adjustment model (V28)**
  - Updates to calculation of growth rates related to medical education costs and other technical changes finalized in CY 2024 Rate Announcement



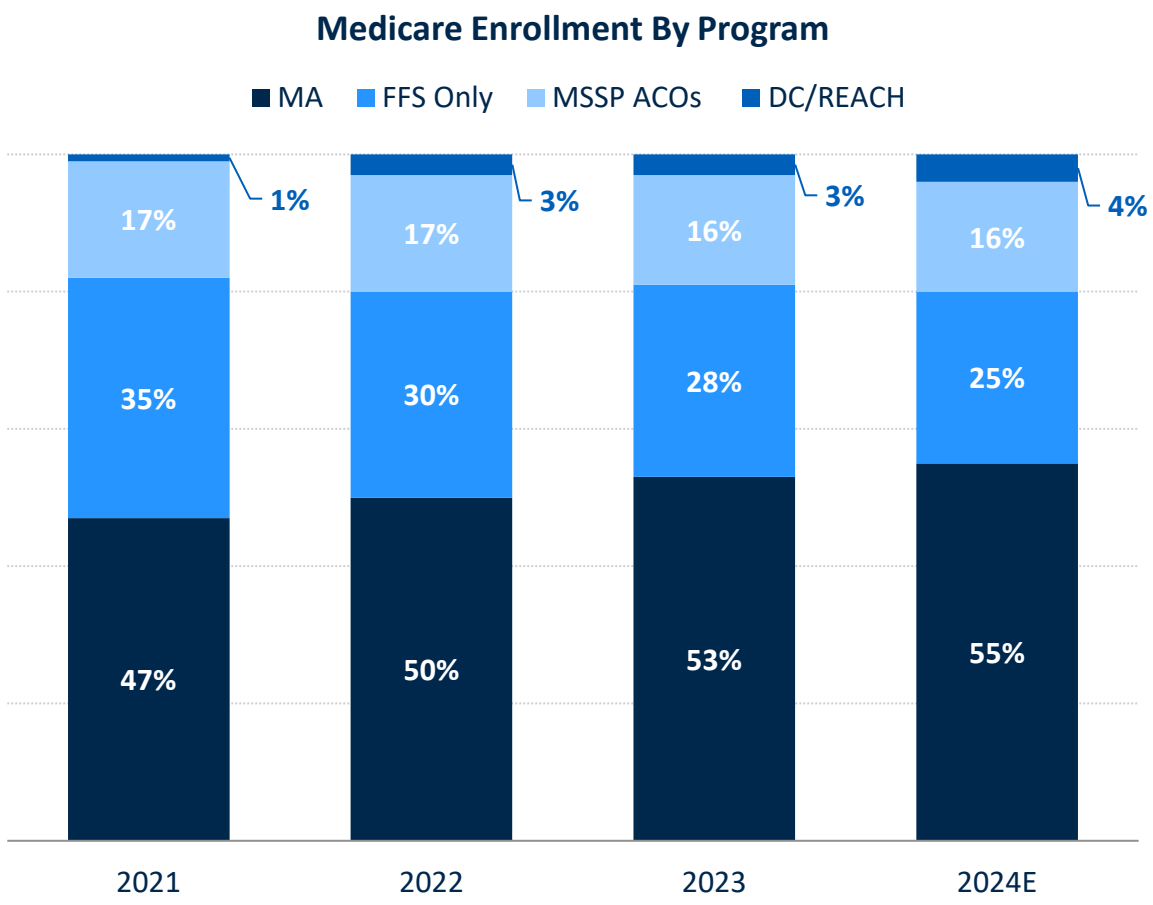
Source: BRG analysis of CMS 2025 MA and Part D Rate Announcement

Most Medicare Beneficiaries In Value-Based Or Capitated Arrangements

CMS has set a goal that 100% of Medicare FFS beneficiaries will be part of accountable care relationship by 2030.

- **ACOs provide care to ~13.7M Medicare FFS beneficiaries in 2024**
  - ~700k providers and organizations participating
- **CMS expects ACO participation to increase 10% to 20%** due to new policies for 2024 and 2025
- **CMS continues to add other ACO-like demonstrations,** such as "Making Care Primary" and "Primary Care First"
- **Over next 10 years, programs likely converge**

ACO	Beneficiaries	Status
MSSP	~10.8M	Permanent since 2012
ACO REACH	~2.6M	2023 - 2026
Direct Contracting	~1.7M	2021 - 2022
Next Generation ACO	~1.0M	2016 - 2021
Pioneer ACO	~1.2M	2012 - 2016



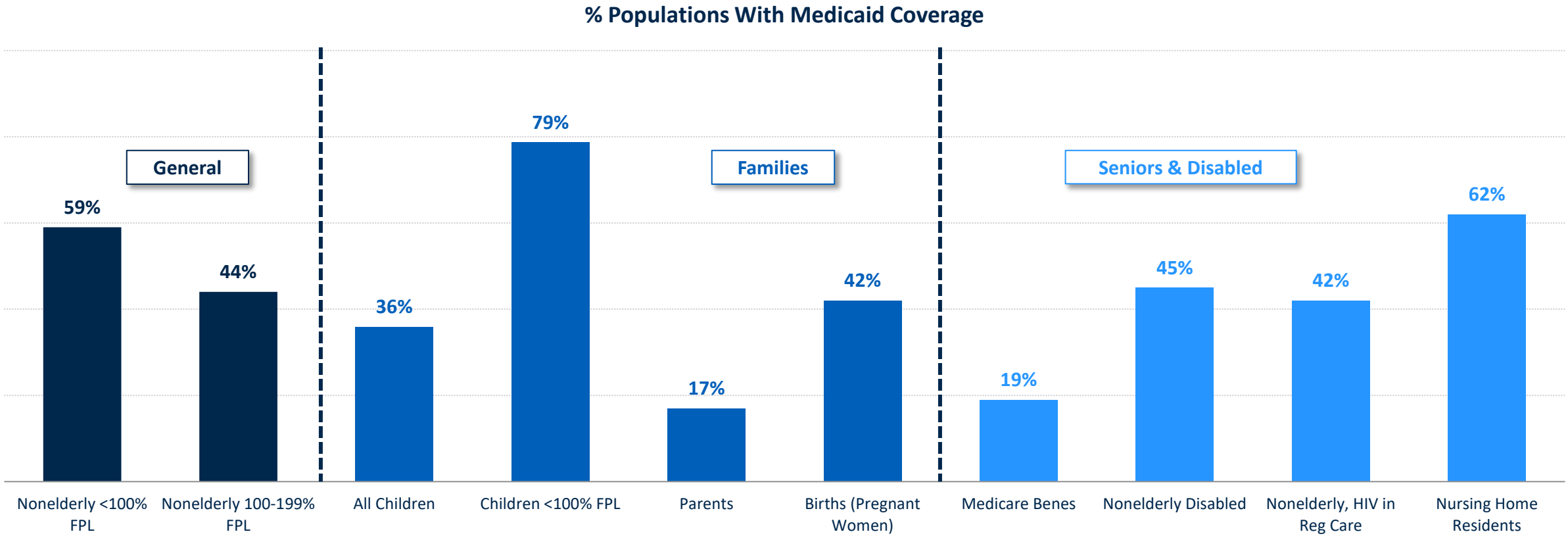
Source: BRG proprietary analysis of 100% of Medicare Part A & B Claims Data, 2021-23 and CMS Innovation Models and Medicare Shared Savings Program Number of ACOs

Medicaid

Medicaid Plays A Key Role In Covering Selected Populations

There is substantial variability in Medicaid eligibility across states. Individuals qualify for Medicaid coverage by meeting the requirements of a specific eligibility pathway offered by the state.

- Some eligibility pathways are mandatory, others are optional
- Medicaid provides health coverage for large portions of different populations



Source: BRG analysis of American Community Survey & KFF 50-State Budget Survey

Benefits Are Defined By States Within Federal Law Parameters

Medicaid coverage includes primary and acute care services as well as LTSS. States establish and administer their Medicaid programs and determine the type, amount, duration, and scope of services within Federal guidelines.

- **Enrollee's eligibility pathway determines the available services in a benefit package**
- **Federal law provides two primary benefit packages** for state Medicaid Programs
  - Traditional benefits
  - Alternative benefit plans (ABPs)
    - ABPs are tailored to meet needs of certain Medicaid population groups, target residents in certain areas of the state, or provide services through specific delivery systems
- **Early and Periodic Screening, Diagnosis and Treatment (EPSDT)** benefit requires Medicaid to cover all medically necessary services for children
- **Beneficiary cost sharing is limited under the Medicaid program**
  - Medicaid enrollees generally receive benefits through FFS or managed care delivery systems

Required Services

- Hospital
- EPSDT
- Nursing facilities
- Home health
- Physicians, CNPs
- Labs, X-Rays
- Pregnancy related
- Transportation
- FQHC/Rural Clinics

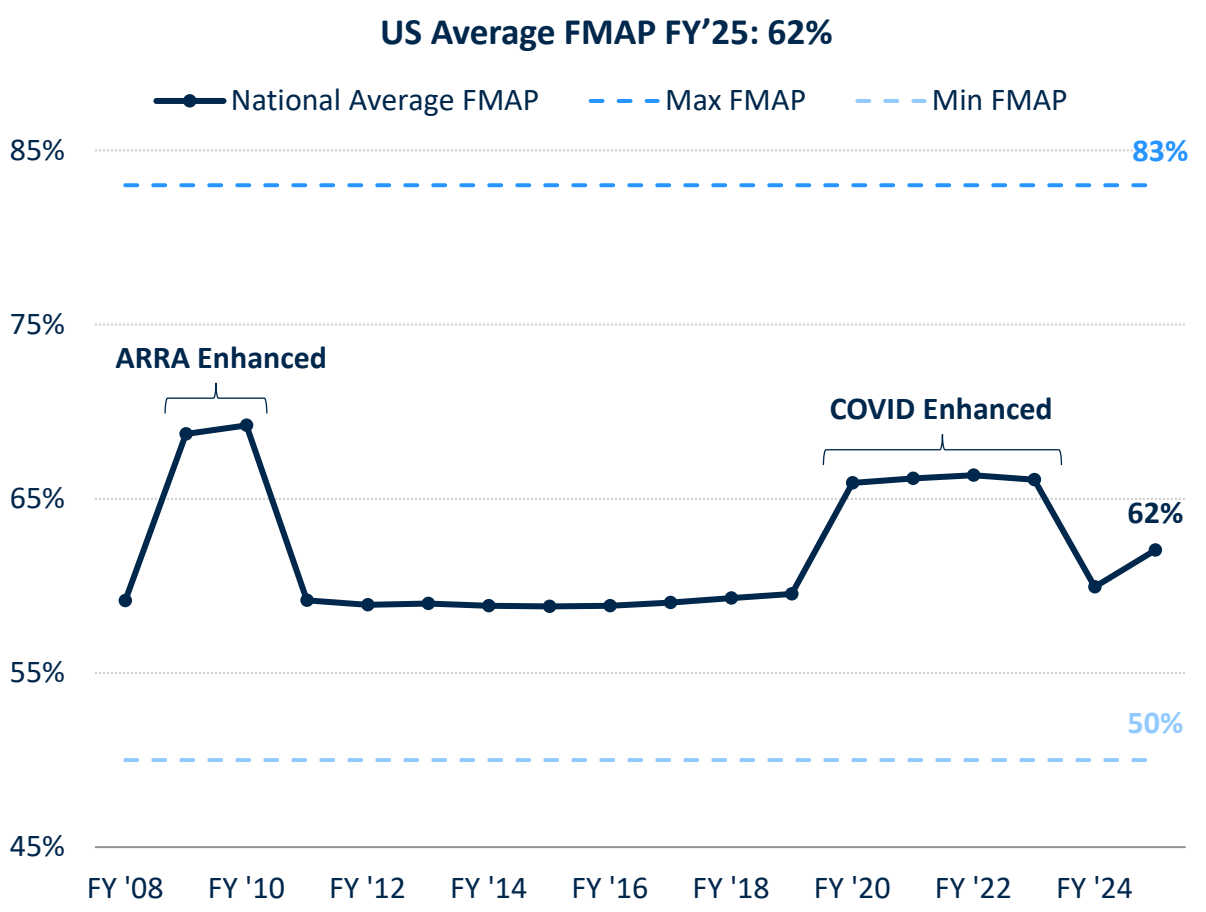
Optional Services

- Drugs
- Therapy (PT, OT, SP)
- Respiratory
- Podiatry
- Optometry/Eyeglasses
- Dental/dentures
- Chiropractic
- Prosthetics
- Personal care/ nurse
- Hospice
- Case Management
- Elderly IMD
- ICF for IDD
- HCBS
- Health homes
- IPFs for youth

Federal Government Reimburses States For ≥ 50% Of Medicaid Spending Based On FMAP

Federal Medical Assistance Percentage (FMAP) is recalculated for each fiscal year and fluctuates by state based on per capita income, with statutory matching limits ranging from 50% to 83%.

- **FMAP is inversely proportional to state's per capita income and is recalculated for each federal FY**
  - Recalculation is based on state and national income data over the most recent 3-year period
  - Statutory limits are minimum of 50% and maximum of 83%
- **For some populations, Federal matching rates are enhanced**
  - ACA included enhanced FMAP for newly eligible adults with incomes up to 138% of federal poverty level
    - For this population, Federal government reimburses states for 90% of Medicaid spending
- **Congress increased states' FMAP +6.2 percentage-points for duration of COVID-19 PHE**
  - Enhancement phased out between April and December 2023
- **FY09 and FY10,** FMAPs were temporarily increased to provide fiscal relief in response to the Great Recession



Source: BRG analysis of Kaiser Family Foundation, State Health Facts

States Administer Medicaid Either Through FFS Or Medicaid Managed Care (MCOs); Medicaid Programs Predominantly Rely On Managed Care

States release RFPs and typically allow for a minimal number of awardees. Plans hold multi-year contracts and may negotiate with providers directly.

- **Medicaid MCOs are typically limited in each state where they operate** – with states selecting only a handful of contract recipients
- Some MCOs are responsible for select populations (long term care, children, etc.), but structures vary by state

- **Most states use a combination of FFS and managed care,** using FFS for select populations, including children and parents
- About half of all benefit spending nationally is FFS – majority split between acute care services and LTSS

Medicaid MCOs

- Medicaid managed care provides benefits and services through contracts between Medicaid agencies and MCOs that accept a per member per month payment
- MCOs contract with providers at negotiated rates

Medicaid FFS

- Healthcare providers are paid by the state Medicaid agency for each service according to a fee schedule or other state-determined rate
- States describe payment methodologies for mandatory and optional Medicaid services in their State Plan

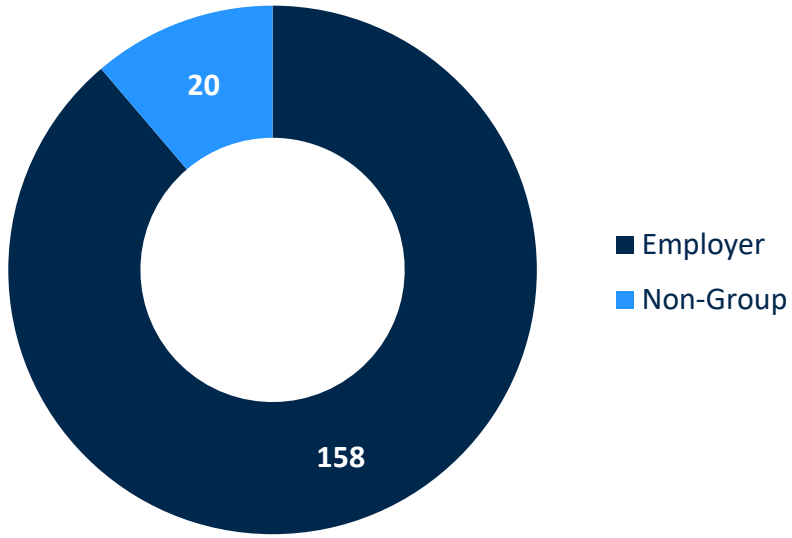
Commercial

Commercial Insurance Covers About 55% Of US Population

Most insurance is provided by employers (large group + small group), some of whom self-insure. Individual insurance (nongroup) market is predominantly individuals who are unlikely to have access to employer coverage.

- **Employers offer insurance coverage to employees,** both as a conventional norm, but also as a tax-incentivized benefit
  - Self-insured employers have more control over premiums and costs, and are regulated at the Federal level by ERISA
- **Some people use individual insurance market as a temporary source of coverage**
- **Individual health insurance is very different than group**
  - Individual market carriers are more limited in their ability to spread risk and benefit packages are less extensive
  - Deductibles and cost-sharing are generally higher in order to produce a lower premium
  - Healthcare Reform (ACA) sought to address challenges in the individual insurance market
  - Established guaranteed issue, ratings limits, minimum AVs, essential benefits etc.
  - Established credits to subsidize purchase of plans
- **Enhanced subsidies in the American Rescue Plan Act (ARPA),** boosted outreach and extended enrollment period – extended under IRA

Coverage Type By Lives, 2022 (M)



Commercial Insurance Type	
Employer	158M lives, 49% of US Population
Non-group	20M lives, 6% of US Population

Source: BRG analysis of KFF 2022 data

ACA Regulated And Subsidized Individual Insurance Market

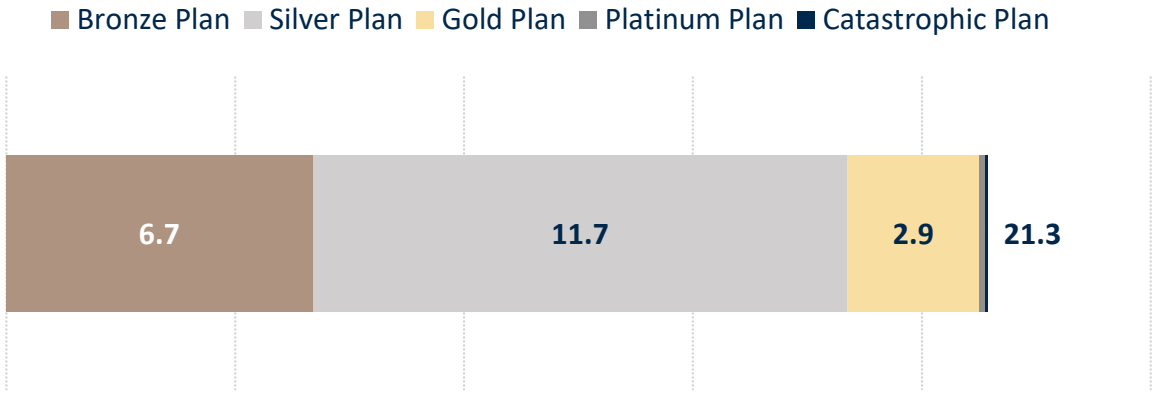
ACA provides refundable and advanceable premium credits to eligible individuals and families with incomes between 100-400% FPL to purchase insurance through the Exchanges.

- **Premium credits tied to the second lowest cost silver plan** in the area
- **Set on a sliding scale** such that the premium contributions by beneficiary are limited to the following percentages of income for specified income levels:

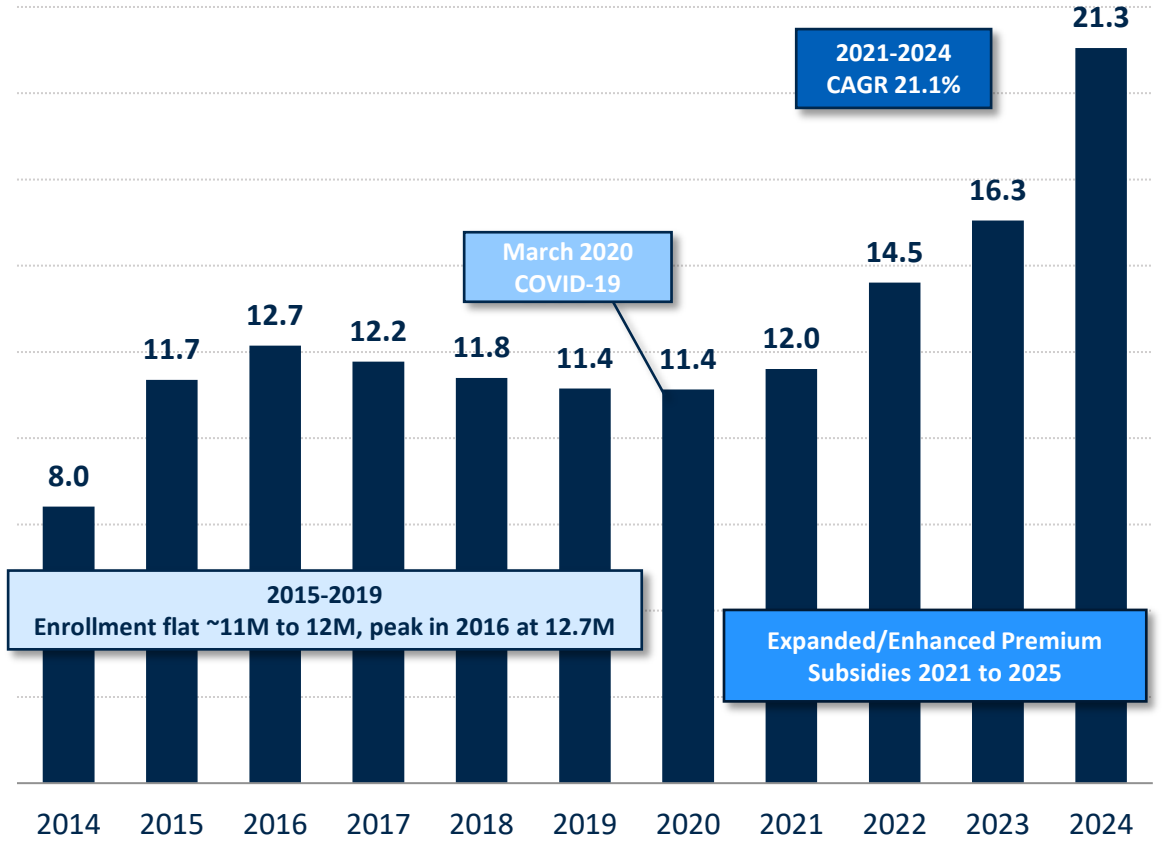
  Up to 150% FPL: 0% of income
  150% FPL: 0 – 2% of income
  200% FPL: 2 – 4% of income
  250% FPL: 4 – 6% of income
  300% FPL: 6 – 8.5% of income
  400% FPL: 8.5% of income

- **Increase premium contributions for those receiving subsidies annually** to reflect the excess of the premium growth over the rate of income growth
  - Total subsidies capped at 0.5% of GDP

Marketplace Plan Selection By Metal Level, 2024 (M)



National Marketplace Enrollment (M)



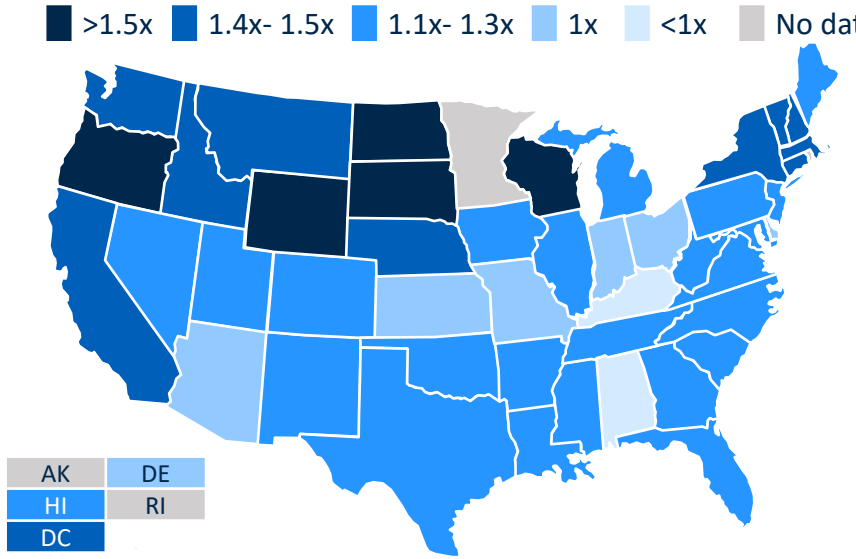
Source: BRG analysis of KFF 2014-2024 Marketplace Enrollment Trend; CMS Open Enrollment Report, 2024

Wide Variation In Commercial Rates As Percent Of Medicare Across States

24 states are 1.1x to 1.3x of National Medicare, 30 states are 1.1x to 1.3x of their own state Medicare geographically adjusted rates.

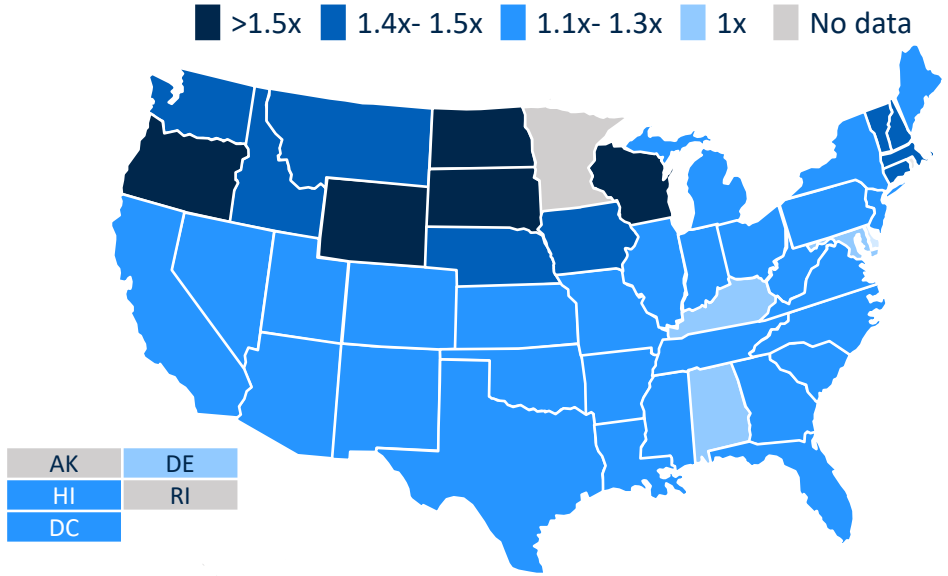
- Average, weighted average, and median rates are ~1.2X Medicare
- 15 states have premium rates >1.4X Medicare, across northern US
- KY and AL are only states below 100% national Medicare average

Commercial Prices Percent Of National Medicare, 2017



- IA, MO, OH, KS, IN, AZ, KY, AL, MD commercial rates are larger percentage relative to state Medicare than national Medicare
  - OH, IN, MO, NE, AZ are 1.1X to 1.3X
- CA, NY, DC commercial rates are smaller percentage relative to Medicare
  - 1.1-1.3X their own state Medicare

Commercial Prices Percent Of State Medicare, 2017



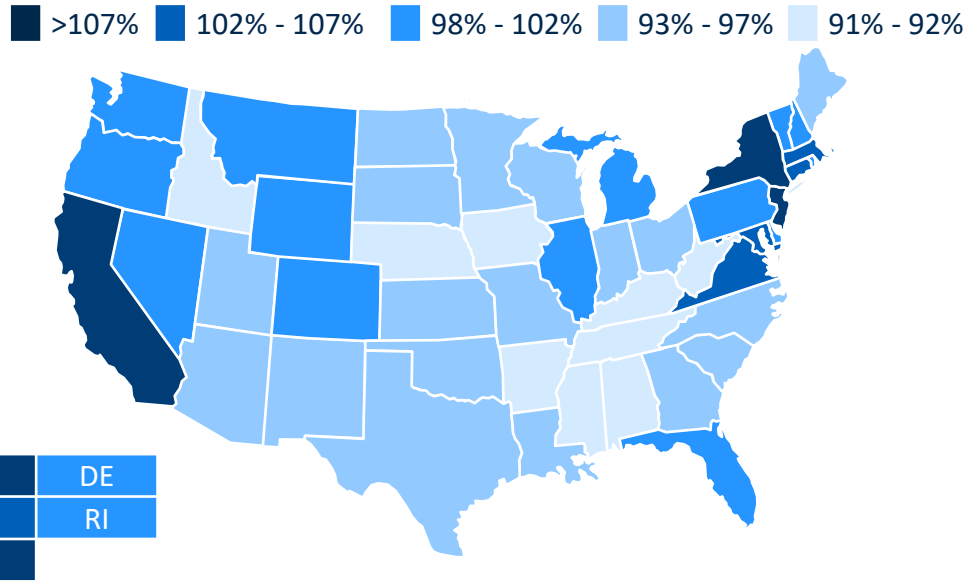
Source: BRG analysis of CBO, The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services / January 2022

State Medicare Rate And State Concentration Of Payer Market Interact W/ Commercial Rates

Statewide average Medicare FFS price ranged from 9% lower than national average in MS to 11% higher than the national in DC; Payer concentration and commercial rates somewhat congruent.

- Medicare rates adjusted for local costs
  - Higher Medicare rates generally track with higher commercial
    - 14 states 98%-102%
    - 10 states above 102%
    - 27 states below 102%

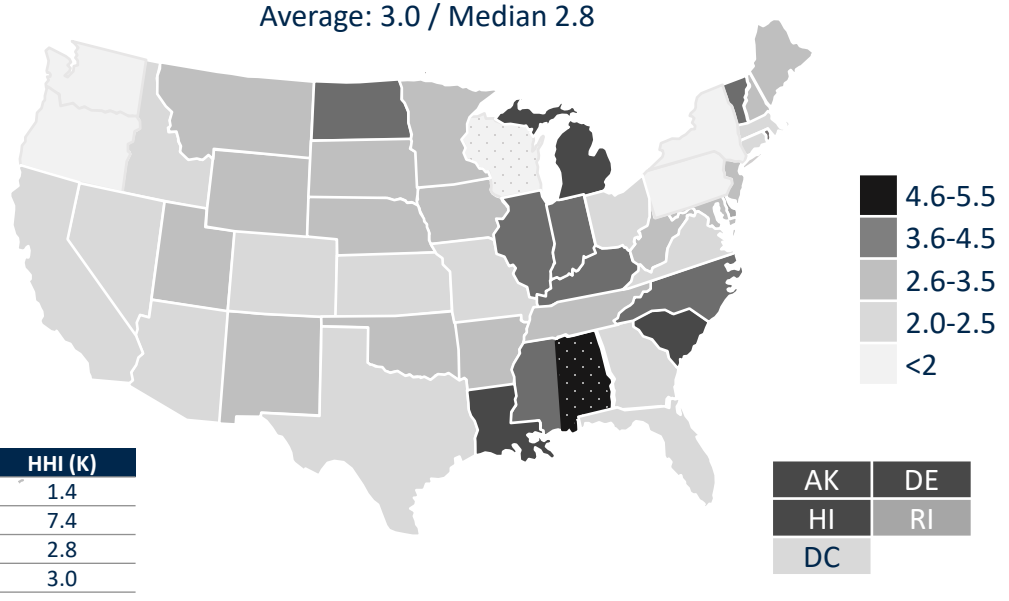
Medicare % By State



- WI has lowest payer concentration, highest commercial rates
- AL has highest payer concentration, lowest commercial rates
  - BCBS of AL has +90% market share

Payer Market Concentration (HHI), 2019

Average: 3.0 / Median 2.8



State	HHI (K)
Lowest	1.4
Highest	7.4
Median	2.8
Average	3.0

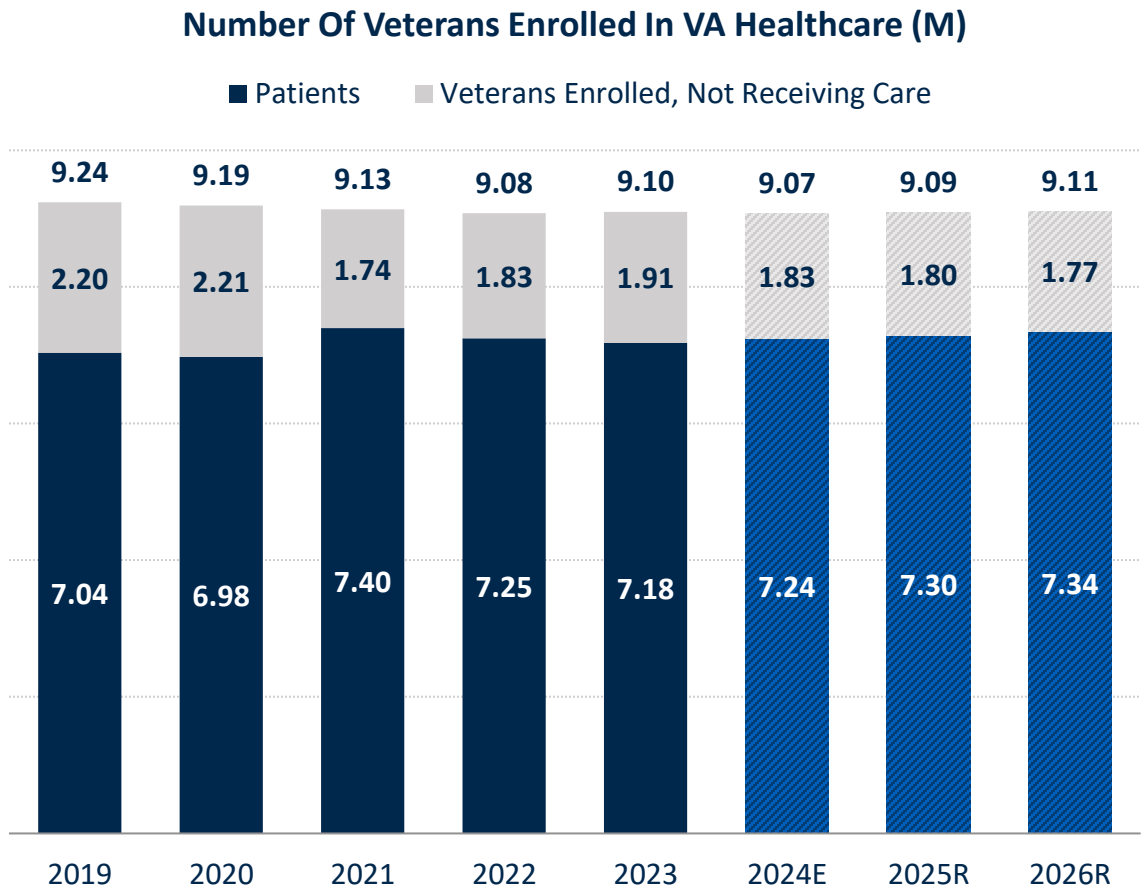
Source: BRG analysis of AMA: Competition in Health Insurance: A Comprehensive Study of U.S. Markets 2020 / CBO: Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services 2022

Additional Programs

Department Of Veterans Affairs

Veterans Affairs healthcare system is stable and has served more than 7M veterans annually over the last several years. The system is federally funded on an annual basis and services are provided at VA facilities or contracted providers.

VA Healthcare Characteristics	
Funding & Cadence	• VA healthcare is discretionary program, dependent on available appropriations • Requested annually through Presidential fiscal year budget
Eligibility	• Eligibility based primarily on veteran status, categorized into 8 priority groups
Delivery System	• FFS • Rate based on fee schedule, Medicare, or percent of billed charges
Facility Type	• Can either be provided by VA facilities or contracted providers through different programs
Utilization	• FY 2023, VA provided care to ~7.2M veteran patients
Labor & Facilities	• FY 2023, employ 433.7k full-time equivalent employees at ~1,765 VA facilities
Billing	• Veterans do not pay premiums for VA care • Some veterans required to pay copayments for treatment of nonservice-connected conditions • Veterans with significant service-connected disabilities exempt • Authority to bill most insurers for non-service-connected care • May authorize care in the community



Source: BRG analysis of U.S. Department of Veterans Affairs Annual Budget Submission

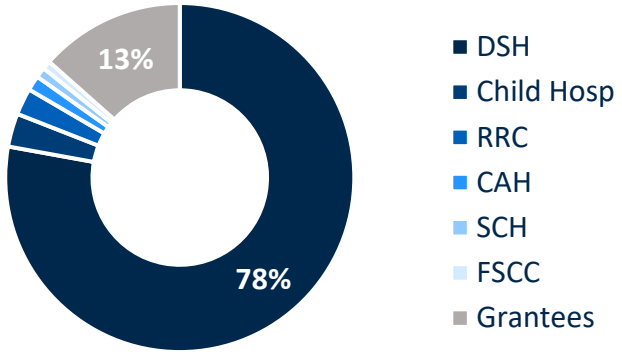
340B Is Crucial For Hospitals And Other Providers, Requires Discounted Pharmaceutical Prices For Covered Entities

340B program enables certain healthcare providers and programs (covered entities) to purchase outpatient drugs at discounted prices and resell to Medicare and Commercial plans at full price.

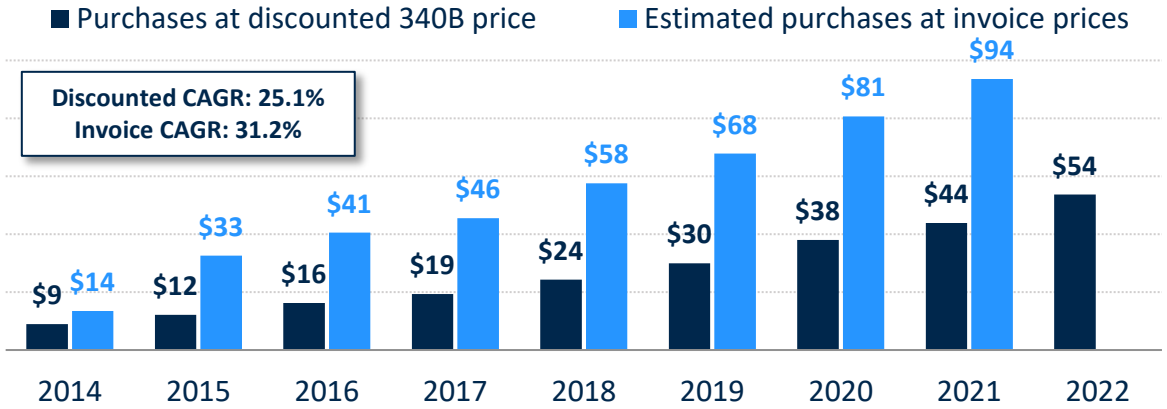
Element	Description
Definition	• Federally-mandated subsidy from drug manufacturers to covered entities
Purpose	• Allows CEs "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" to "at risk" populations
Pharmaceutical Manufacturers	• Required to participate and provide 340B pricing on all products if they participate in Medicaid
Covered Entities	• Eligible providers include certain Hospitals (Children's, Critical Access, Freestanding Cancer, DSH, SCH), FQHCs, AIDS clinics, Family Planning Providers, and other specialized clinics
Ceiling Price	• Maximum amount manufacturer can charge CE for 340B covered outpatient drug • Statutorily defined as AMP reduced by Unit Rebate Amount • HRSA obtains AMP and URA data from CMS as part of Medicaid program reporting

% Of Spending On Outpatient Drugs By 340B CE Type, 2022

($53.7B Total)



340B Drug Pricing Program And Purchases By CEs ($B)



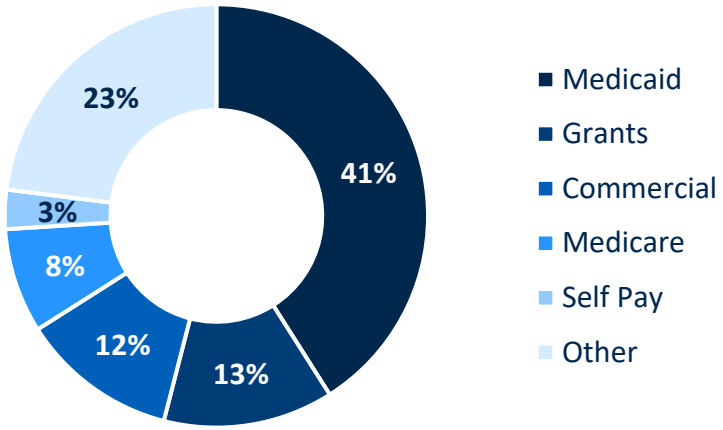
Source: BRG analysis of 340B Prime Vendor Program, August 2023 and Health Resources and Services Administration 340B data

Federally Qualified Health Centers

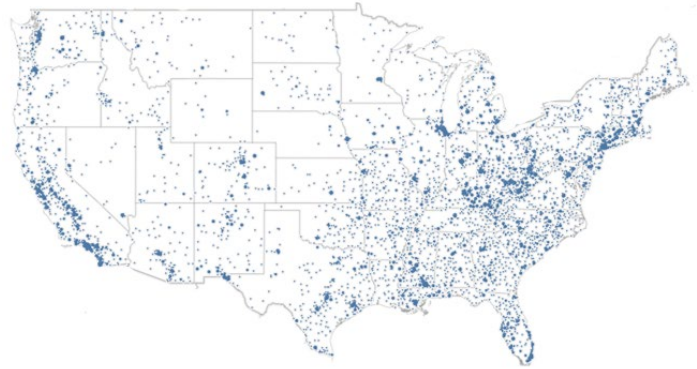
Federally Qualified Health Centers (FQHCs) provide comprehensive primary care services to underserved populations and underserved regions – Medicaid and Medicare both reimburse for FQHC services.

- **Medicaid programs reimburse using Federally-mandated methodology based on provider costs**
  - MEI used to adjust rates annually
- **Medicare pays FQHCs based on fee schedule, adjusted for local differences in practice costs**
  - Since 2017, updated annually by FQHC market basket
    - Base payment for 2023 is $187
  - Previously updated by MEI
  - Paid on lesser of charges or base rate for all services provided on same day

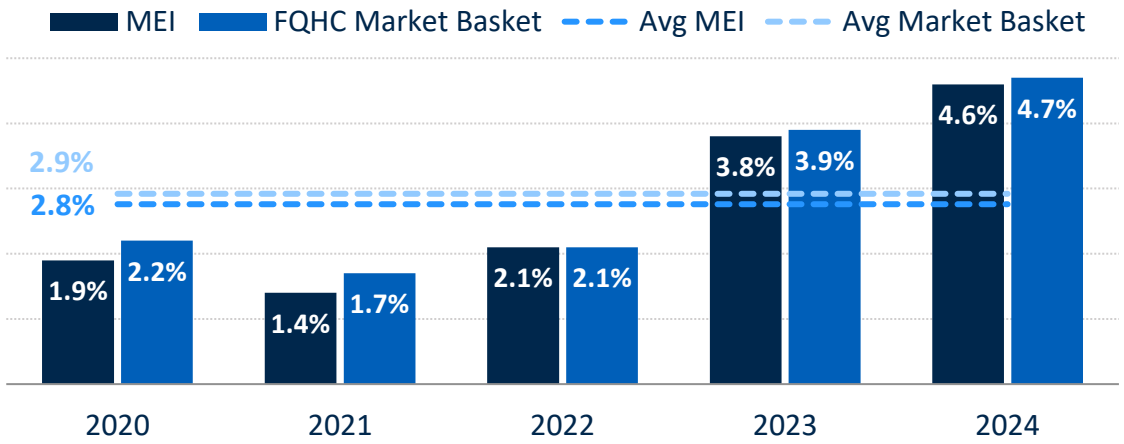
National FQHC Revenue Mix, 2021



FQHC & FQHCLA Clinic Locations



FQHC Payment Updates



Source: BRG analysis of Kaiser State Indicator Data and CMS Medicare Economic Index– Four-Quarter Moving Average Percent Change with Productivity Adjustment; Updates based on historical data though the second quarter of each previous year

PACE Is A Medicare-Medicaid Program Focused On Community-Based Care For The Elderly

Programs for All-Inclusive Care for the Elderly (PACE) offer comprehensive benefits in the community or in a PACE health center for people who would otherwise qualify for nursing home care.

Category	Description
Overview	• PACE organizations provide comprehensive medical and social services to individuals living in the community • PACE organizations have defined service areas
Enrollment	• Enrollment in PACE is voluntary, and individuals may leave a PACE program at any time

Eligibility	• Most participants are dually eligible for Medicare & Medicaid
	• To qualify for PACE, an individual must be
	  • 55 or older
	  • Live in the service area of a PACE organization
	  • Need nursing home-level care
	  • Be able to live safely in the community with help from PACE

Coverage	• PACE provides care in the home, community, and the PACE center (an adult day health center), administered by an interdisciplinary team • PACE benefits include, but are not limited to, all Medicare and Medicaid covered benefits
Reimbursement	• PACE providers receive monthly Medicare and Medicaid capitated payments for each enrollee • Medicare enrollees that are not eligible for Medicaid pay monthly premiums equal to the Medicaid capitation amount, but no deductibles, coinsurance, or any other type of cost sharing

Regulatory & Research Agencies

Healthcare System Regulated & Delivered By Agencies & Departments

Beyond the elements of the healthcare system that provider coverage & payment for healthcare consumption are an array of administrative, regulatory and research agencies within HHS.

- HHS agencies administer grants (SAMSHA, HRSA), conduct research (NIH, ARQH, CDC), regulate products (FDA), enforce program integrity (HHS OIG, HHS OCR), and many perform several of these functions
  - Most significant of these functions are the FDA's regulation of drugs and devices, NIH's scientific research and the program integrity functions of the HHS OIG and HHS OCR

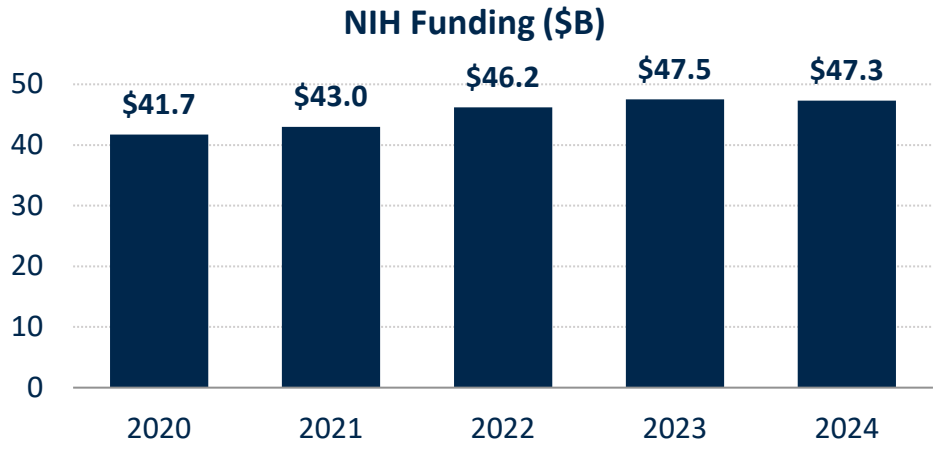
Role	Agency
Administer Grants	SAMHSA Substance Abuse and Mental Health Services Administration; HRSA Health Resources & Services Administration
Conduct Research	NIH National Institutes of Health; AHRQ Agency for Healthcare Research and Quality; CDC Centers for Disease Control and Prevention
Regulate Products	FDA U.S. Food & Drug Administration
Enforce Program Integrity	CMS Centers for Medicare & Medicaid Services; HHS Office of Inspector General (OIG); U.S. Department of Health and Human Services Office for Civil Rights

National Institute Of Health (NIH) & Food & Drug Administration (FDA)

NIH is made up of 27 Institutes and Centers focused on particular diseases or body systems; FDA regulates $1 trillion worth of products each year.

National Institute Of Health

- NIH funds 50K+ grants to 300K+ individuals at 2.5K+ research institutions
- Largest institutes are:
  - Cancer
  - Infections Disease
  - Aging
  - Heart& Lung
  - General Medicine

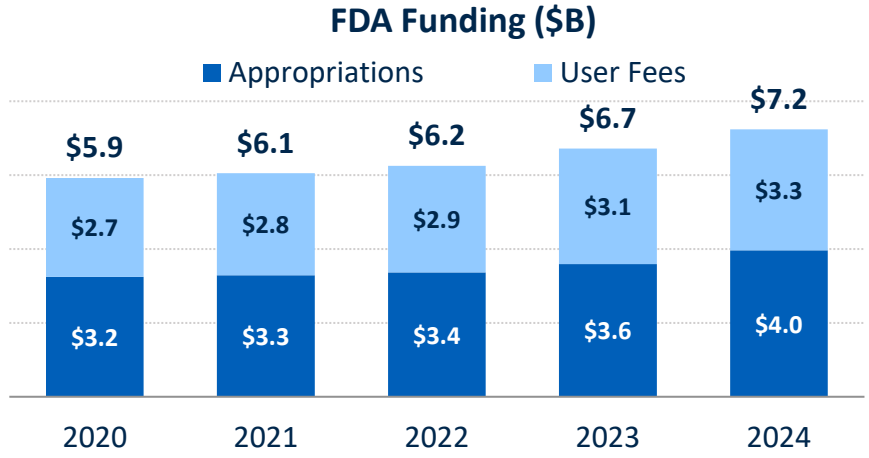


Food & Drug Administration

FDA Regulates:

- Food
- Devices
- Cosmetics
- Drugs/Biologics
- Animal drugs/Feed
- Tobacco

- Food and Drugs Act of 1906 was first of 200+ laws that constitute the medical regulatory structure
- Federal Food, Drug, and Cosmetic Act of 1938 regulated the safety of drugs and food
- Kefauver-Harris Amendments of 1962, strengthened drug safety and required effectiveness
- Medical Device Amendments of 1976 applied safety and effectiveness to devices
- FDA is funded with a combination of user fees paid by product applicants and appropriated funds
- FDA has accelerated approval of generic drugs and biosimilars in recent years



HHS Office Of Inspector General (OIG) & Office For Civil Rights (OCR)

OIG investigates fraud and abuse in Medicare, Medicaid and more than 100 other HHS programs; OCR enforces Federal civil rights laws, conscience and religious freedom laws, HIPAA Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule.

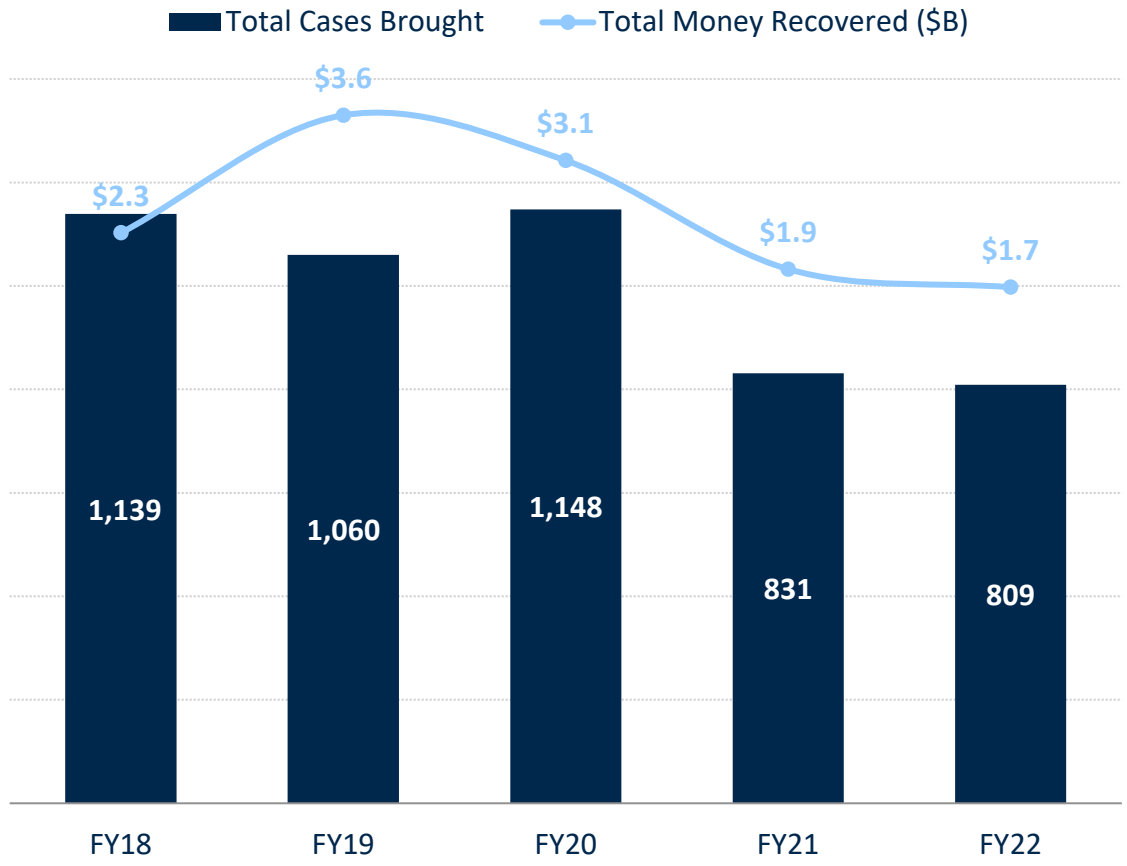
Office Of Inspector General

- Largest inspector general's office in federal government
- Most of OIG's resources go toward Medicare and Medicaid oversight
- OIG deploys nationwide network of audits, investigations, and evaluations
  - Generates recommendations for policymakers
  - Works with DOJ in development of case
- Each year OIG updates a 5-year strategic plan ("work plan") that delineates areas of program integrity focus
- OIG won or negotiated over $5B from healthcare fraud cases during FY 2021, with $1.9B returned to the federal government or private persons

Office For Civil Rights

- Since 2003, OCR has investigated and resolved over 29,837 cases by requiring changes in privacy practices and corrective actions by, or providing technical assistance to, HIPAA covered entities and their business associates
- OCR has settled or imposed a civil money penalty in 126 cases resulting in $134 million in fines
- OCR refers to DOJ for criminal investigation cases involving the knowing disclosure or obtaining of PHI
- As of 2022, OCR made 1,580 referrals to DOJ

Total OIG Cases Brought And Money Recovered

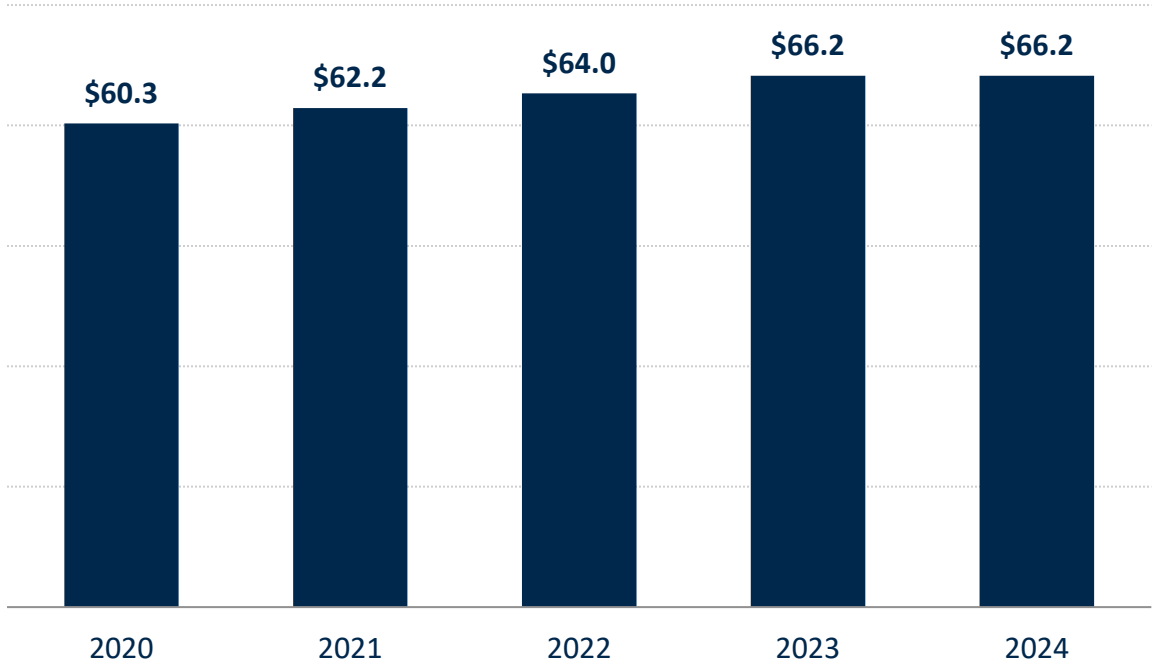


HHS Office of the National Coordinator for Health Information Technology (ONC) & Centers for Disease Control and Prevention (CDC)

ONC supports the adoption of health information technology standards and interoperability; CDC's mission is to protect public health and safety through the control and prevention of disease, injury, and disability in the US and internationally.

- Position of National Coordinator was established by Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009

ONC Budget ($M)



- CDC focuses on infectious disease, food-borne pathogens, environmental health, occupational safety and health

CDC Budget ($B)

Source: BRG analysis of CDC FY 2025 Congressional justification

Agency for Healthcare Research and Quality (AHRQ) & Substance Abuse and Mental Health Services Administration (SAMHSA)

AHRQ funds research and conducts research, primarily focused on quality outcomes. SAMHSA leads public health efforts to advance behavioral health.

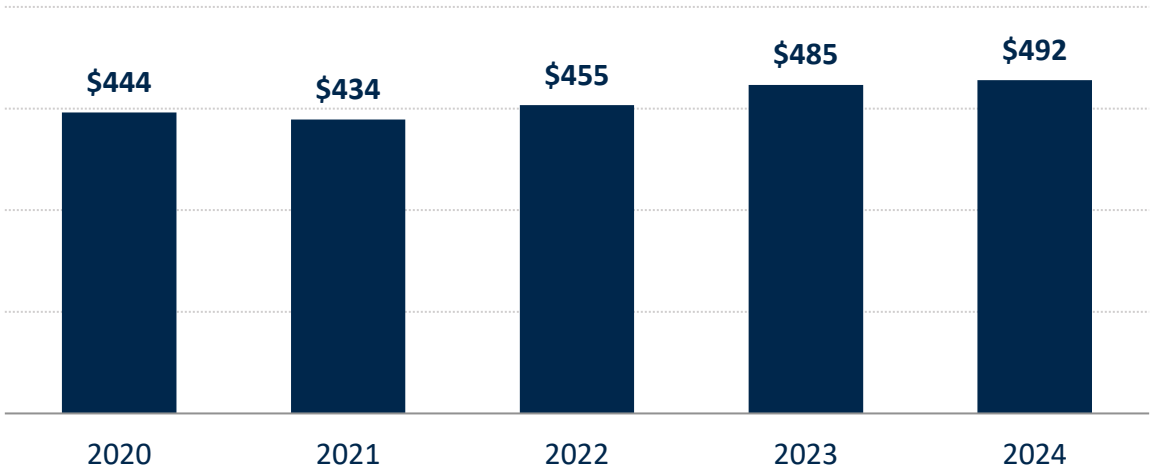
AHRQ creates tools/strategies to help providers deliver higher-value care

- AHRQ maintains healthcare databases
  - CAHPS, MEPS, HCUP, SRDR, USHIK

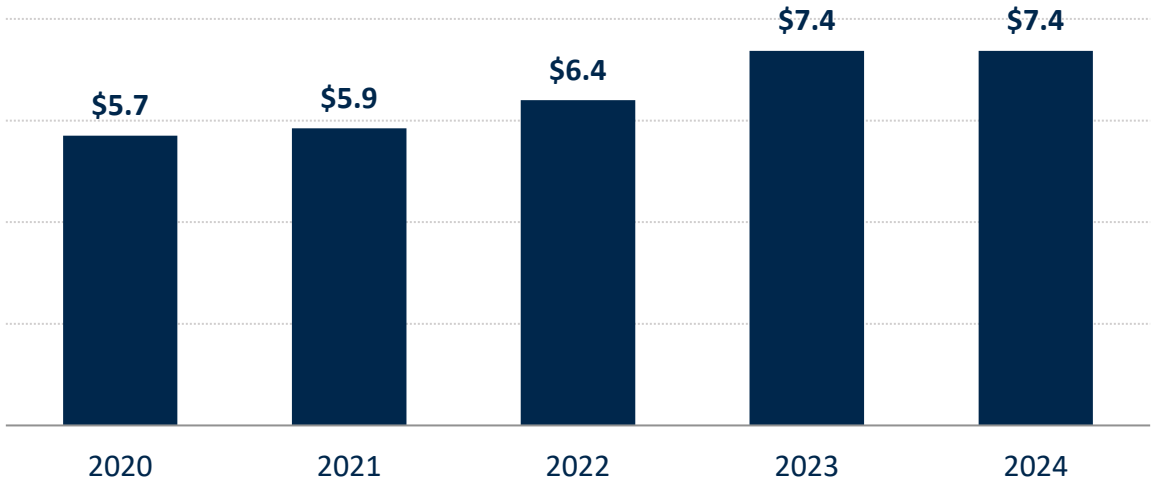
SAMHSA's goal is to reduce the impact of substance abuse and mental illness on America's communities

- SAMSHA administers grants to state and local government related to mental health and maintains a searchable online database and directory of mental health providers
- Conduct annual surveys including National Mental Health Services Survey to evaluate available services and utilization

AHRQ Budget ($M)



SAMHSA Budget ($B)



Source: BRG analysis of AHRQ and SAMSHA publications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