US Healthcare Reimbursement & Regulatory Diligence 101



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7. Appendix



Agenda 1. Introduction 2. Macro View of the US Healthcare System 3. Federal/Medicare 4. State/Medicaid 5. Commercial Insurance 6. Wrap-up discussion and Q&A

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6 CONTINENTS

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Healthcare Transactions and Strategy

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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



Macro Context

US Per Capita Healthcare Spending Increasing; Particularly For Aged Population



Spending on U.S. health care has grown steadily, rising from \$2,900 per person in 1980 to \$11,200 per person in 2018

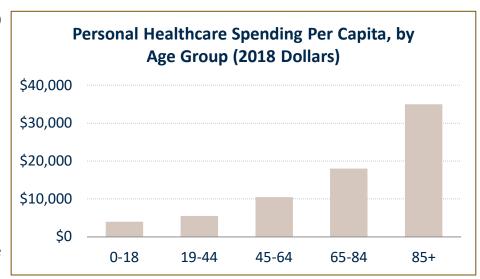
- +290% increase
- Growth since 1980 has been 3.6% real per capita
- From 2005 to 2018, growth has been slower at 2.0%

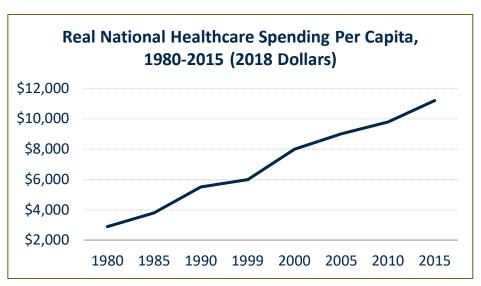
The aging of the U.S. population drives increasing spend

- \$18,100 for an average person 65 to 84 years old
- \$35,000 on an average person 85 or older
- \$4,000 on an average person 18 or younger

Rising prices are also a significant factor:

- Labor intensive industries, such as healthcare, tend to have constantly rising prices
- This phenomenon is known as Baumol's cost disease
 - Baumol, an economist, observed that labor intensive sectors with relatively 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
 - Baumol's original example was an orchestra. The same musicians are needed to play a symphony today as were needed in the 19th century
 - The productivity of musicians has not increased and won't increase
 - But the real wages of musicians have increased a 21st century violinist can't be paid 19th century wages
 - Healthcare's labor force is similar to musicians and thus healthcare has a built-in price driver



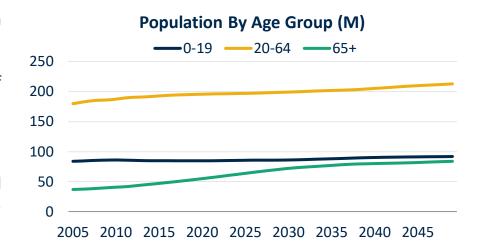


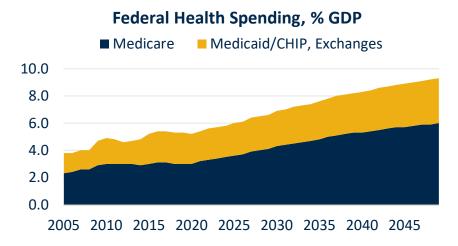
Aging Demographics Increase Demand For Healthcare



The percentage of the population age 65+ is projected to rise in the coming decades.

- CBO projects that by 2049, 22% of the population will be age 65 or older
 - This age group currently accounts for 16% of the population
 - 80+ cohort also growing
- An aging population is likely to increase the 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





51% Of US Population Insured Through Private Plans, 40% Insured Through Government Programs, 9% Uninsured



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

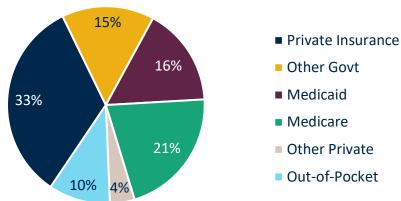
51%	Private Plans		
31/0	165M Lives		
 More than half of Americans have commercial coverage – most have large group or self-funded (ERISA) plans, ~35M have individual market or small group (for employers with 2-50 employees) 		or self-funded Il market or small	
Individual Market/ Exchanges		18M lives, 5%	
Small Group		17M lives, 5%	
Large Group/ ERISA 130		130M lives, 40%	

409/	Government Programs			
40%	138M Lives			
 Expansion of Medicaid and growth in Medicare pop A growing number of these plans are privately managed (about 75% of Medicaid; 33% Medicare) 		rivately		
Medicaid/ CHIP	75M lives, 23%	Duels: 014, 20/		
Medicare	58M lives, 18% Duals: 9M, 3%			
Tri-Care, VA, IHS	5M lives, 2%	5M lives, 2%		

9%	Uninsured
3 %	28M Lives

- 9% do not have health coverage as of 2018
- Reduced from 15% prior to ACA
- 85% 19 to 64 years of age
- 45% 26 to 44 years of age
- 55% male
- 58% earn less than 200% FPL; 79% below 400% FPL
- 25% non-citizens

U.S. Health Care Expenditure By Payer, 2019

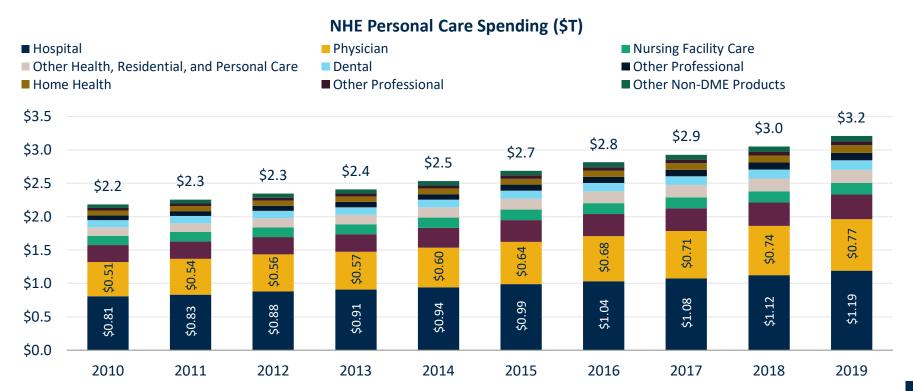


Hospital Spending Is The Biggest Component Of PHC And Among Top 3 Fastest Growing; Home Health Growing 6% Annually



Hospital spending is the biggest component of PHC and has risen from \$609B (36% of PHC) in 2005 to \$1.2T (37%) in 2019. Physician spending has remained around 24% of PHC over this period but has grown 87% since 2005.

- Home health and residential care, historically smaller categories, have grown 5-6% annually since 2005 to combined \$307B in 2019
 - Nursing home growth (3% CAGR) most impacted by home health growth, but still increasing
- Fastest growing category is "Other Non-DME Products" which has grown 131% since 2005 \$82B in 2019 this is largely out-of-pocket spending on products such as OTC drugs



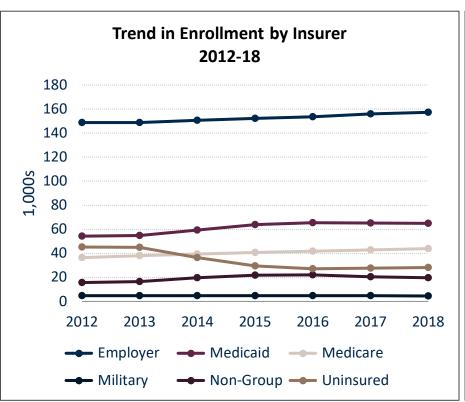
Source: NHE

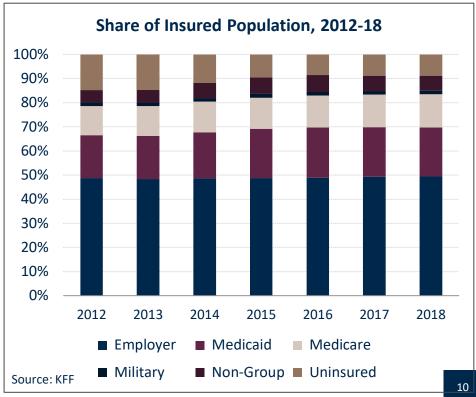
Employer Coverage Dipped Following 2008 Recession, Medicare Covered Lives Continue To Grow As Boomers Age Into System



Employer sponsored insurance has been steady numerically, but declined slightly as a percentage of the population to just under 50%

- In 2014, Medicaid coverage increased due to ACA expansion and has continue to grow in total numbers and as a percentage of the population Medicaid is now clearly the second largest source of coverage
- Medicare has steadily grown in total numbers and percentage --- but without any ACA bump
- The uninsured dipped due to ACA in 2014 and has remained lower





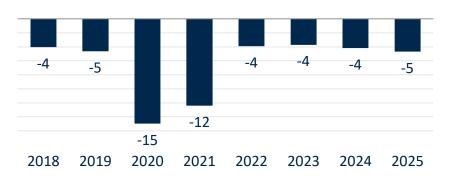
CBO Projects Increasing Deficits & Debt Due To COVID Recession; Pressuring Mid-2020s Spending



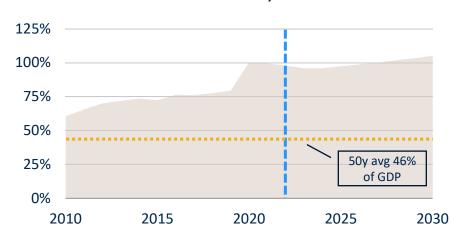
Deficits, debt, and entitlement program funding shortfalls eventually bring pressure to reduce the rate of spending growth for healthcare programs in the late-2020s; all Medicare, including Part B, would be impacted.

- Deficit reduction involves reductions in the rate of increase – not absolute declines
 - Medicare and Medicaid impacted
- After 2024 election and COVID-19, policy agenda likely begins shift to addressing deficits and debt
- Attention to deficits and debt likely increases after 2024 election cycle
 - Entitlement program finances pressured
- Deficit projected to spike 300% to 400% in 2021-2022 then revert to pre-COVID projections
- Debt projected to increase to over 100% of GDP and then continue increasing throughout decade

Federal Deficit, % Of GDP



Public Federal Debt, % Of GDP





Medicare

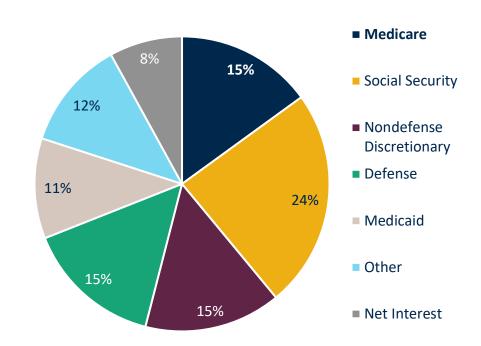
Medicare – Insurance For Older Americans, Those With Disabilities, And Those With ESRD



40%	GOVERNMENT PROGRAMS	
Of Total Lives	138M Lives	
Medicare	58M Lives, 18% of US Population	

- Medicare is a health insurance program for
 - People 65 years of age and older
 - People under age 65 with certain disabilities
 - People with End-Stage Renal Disease (ESRD)
- Administered by Centers for Medicare & Medicaid Services (CMS)
- Some individuals (called dual eligibles) are eligible for Medicare due to age or disability and are also eligible for Medicaid
 - Primary healthcare services covered by Medicare, with their beneficiary cost sharing and other medical benefits (e.g., long-term nursing) covered by Medicaid

Medicare As Share Of Federal Budget, 2018



Medicare Program Has Four Components



- Medicare Part A and Part B are traditional fee-for-service Medicare
- Part D is the retail prescription drug benefit
- Part C combines A, B and D in a single private plan

Medicare Part A	Patients in facility settings: Hospital, skilled nursing home stays, home health services, and hospice care
Medicare 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
Medicare Part D	Covers prescription drug costs through enrollment in private Part D or MA health plans

Medicare Benefit Payments, 2008-2018



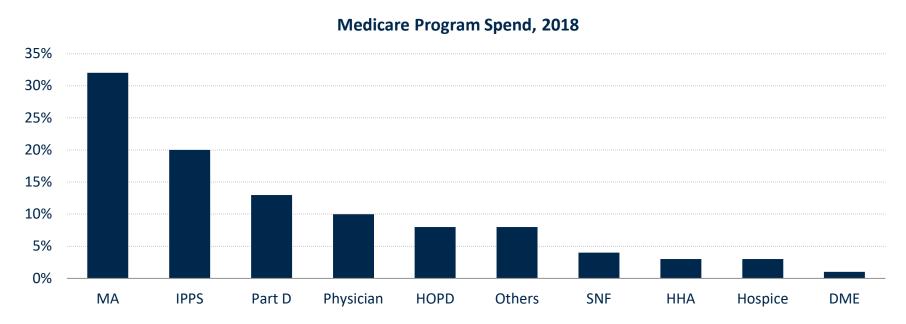


Medicare Spending Remains Majority FFS, Medicare Advantage Rapidly Growing



While MA spend has grown rapidly in recent years, 55% of total Medicare spending is FFS.

- Hospitals (inpatient and outpatient) and physicians account for about 40% of FFS spend
- PAC spending even in aggregate is only about 10% but is a focus of policymakers seeking more efficient care
- MA is approximately one-third of spending and increasing as more beneficiaries opt to enroll in MA
- Part D drugs are 13%
 - Part B drugs grouped within "Other" category



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 a method of reimbursement in which Medicare payment is made based on a 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 payments agreed upon in a capitated contract by a health insurance company and a medical provider. They are fixed, pre-arranged monthly per patient enrolled in a health plan, or per capita.
- A fee schedule is a complete listing of fees used by Medicare to pay doctors or other providers/suppliers. This comprehensive listing of fee maximums is used to reimburse a physician and/or other providers on a fee-for-service basis
- Cost-plus reimbursement pays the provider their reported costs plus a fixed percentage

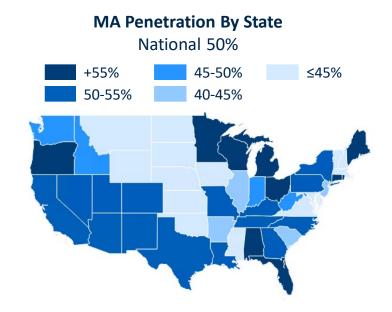
			FFS		
Capitated	PPS		Uniberial DDC/FC	Foo Cobodulo	Cook Dive
	Episode of Care	Per Diem	Hybrid PPS/FS	Fee Schedule	Cost-Plus
MA	Inpatient	Hospice	ASC	PFS	CAH
Part D	LTCH	IPF	Outpatient	CLFS	Part B
ACOs	IRF		Dialysis	DME	
	SNF		FQHC	Ambulance	
	Home Health				

MA Penetration Continues To Grow – Projected To Reach 55% By 2026

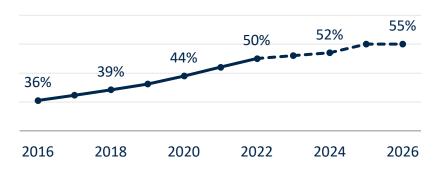


National MA penetration rate currently 50% of eligible beneficiaries but varies across states; penetration projected to reach 55% by 2026.

- Annual payment updates (avg: +5.0% 2016-22) continue to increase MA plan reimbursement
- Within each state, penetration varies by county
- 3 leading insurers United, Humana, and CVS/Aetna
 cover more than half of all MA beneficiaries
- BRG calculated MA penetration as MA enrollees as a percent of those eligible to enroll in the program
 - Program eligibility is defined by an individual enrolled in Medicare Part A and Part B



National MA Penetration



National Market Share Top MA Plans

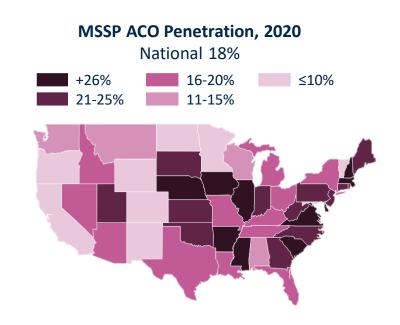


Roughly 10M (18%) Of Medicare Beneficiaries Are Enrolled In An ACO Nationally

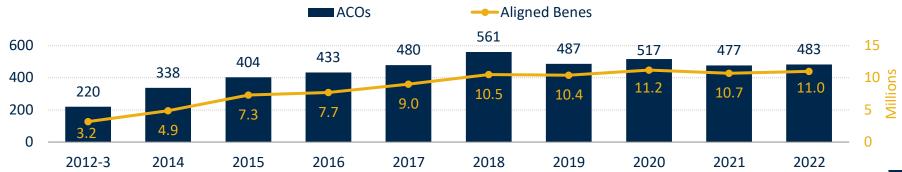


Medicare ACOs offer additional care coordination and preventative services to beneficiaries aimed at reducing total cost of care.

- 2022 Medicare ACOs required to take on more downside risk
- Direct Contracting newest ACO experimental model from CMMI for 2021 to 2026 test period
- Decline in 2021 enrollment brings ACO beneficiary levels closer to 2019 status
 - Decrease stems from combination of factors
 - Trump administration implemented additional risk-taking arrangements
 - Freeze for new participants in 2021
- CMS substantially revised the MSSP tracks to move ACOs into downside risk arrangements in 2019



Number Of MSSP ACOs And Aligned Beneficiaries

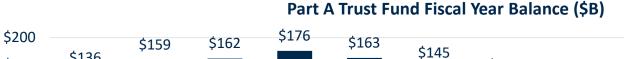


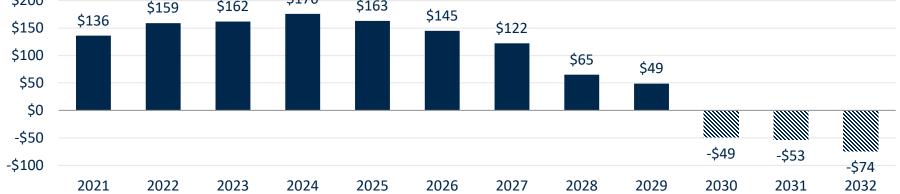
Medicare Trust Fund Shortfall FY 2030; Congressional Action Late 2020s



Medicare Part A covers inpatient hospital stays, SNF stays, some home health visits, and hospice care and is financed primarily (90%) through a payroll tax; Medicare Part B covers outpatients services such as physician care and is paid from the general fund of the US treasury.

- To a certain degree, the Part A trust fund for Medicare is just an accounting device
- Congress is very unlikely to allow the mechanical operation of the trust fund to result in Medicare services being curtailed or providers not being reimbursed
 - However, the trust fund does signal financial stress on the program and in the context of the larger fiscal challenges it is likely to spur action by Congress, in the late 2020s and into the 2030s, to enact some combination of spending reductions and tax increases
- Trust fund is currently projected to experience a short-fall in 2030. Ironically, increased inflation has "helped" the trust fund by raising nominal wages and thus nominal payroll tax revenue projections
 - Date of trust fund exhaustion could move 2 to 4 years earlier









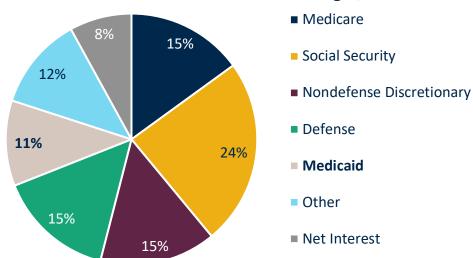
Medicaid



40%	GOVERNMENT SPONSORED INSURANCE
Of Total Lives	138M Lives
Medicaid/ CHIP*	75M Lives, 23% of US Population

- 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 (LTSS), to a diverse low-income population, including children, pregnant women, adults, individuals with disabilities, and people aged 65 and older.
 - Medicaid spending grew 3.0% to \$597.4 billion in 2018, or 16% of total NHE
- States administer their Medicaid programs under broad Federal guidelines
 - Eligibility levels, the use of managed care, and payment methods and rates all vary
 - Federal government provides each state with funding called the Federal medical assistance percentage (FMAP)
 - Federal funding ranges from a floor of 50% to nearly 80% of individual state programs
- Eligibility is determined by states subject to Federal minimums

Medicaid As Share Of Federal Budget, 2018



What it means in diligence

- State-specific coverage and rates vary widely
- Many services mandatory for kids
- Medicaid MCOs often negotiate rates
- State budgets and politics play roles

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.

- An 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 the 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			Optional Services				
•	Hospital	•	Labs, X-Rays	•	Drugs	•	Personal care/ nurse
•	EPSDT	•	Pregnancy related	•	Therapy (PT, OT, SP)	•	Hospice
•	Nursing facilities	•	Transportation	•	Respiratory	•	Case Management
•	Home health	•	FQHC/Rural Clinics	•	Podiatry	•	Elderly IMD
•	Physicians, CNPs			•	Optometry/Eyeglasses	•	ICF for IDD
				•	Dental/dentures	•	HCBS
				•	Chiropractic	•	Health homes
				•	Prosthetics	•	IPFs for youth

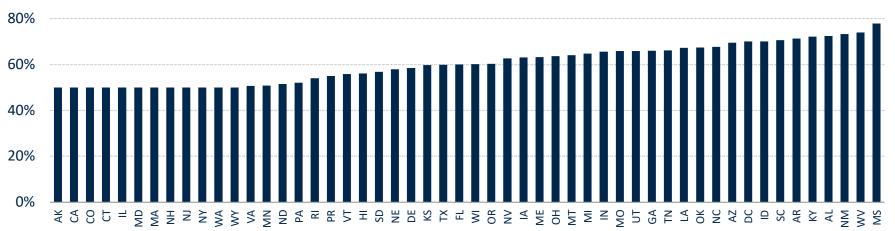
Medicaid Financing Is Shared By State and Federal Governments



The amount of Federal payments to a state for medical services depends on two factors: the actual amount spent that qualifies as matchable under Medicaid and the Federal Medical Assistance Percentage (FMAP).

- FMAP is computed from a formula that looks at the average per capita income for each state relative to the national average
 - By law, the FMAP cannot be less than 50% and the maximum is 83%
- FY 2020, FY 2021, and FY 2022 FMAPs reflect higher federal matching funding made available through the Families First Coronavirus Response Act
 - Additional funds are available to states from January 1, 2020 until the end of the PHE
 - Provided a 6.2 percentage-point increase to all FMAP rates for all states, including DC
- FY 2023 FMAPs below do not reflect the 6.2 percentage point increase of the FFCRA however, PHE was renewed through mid-January 2023

FMAP By State, FY 2023



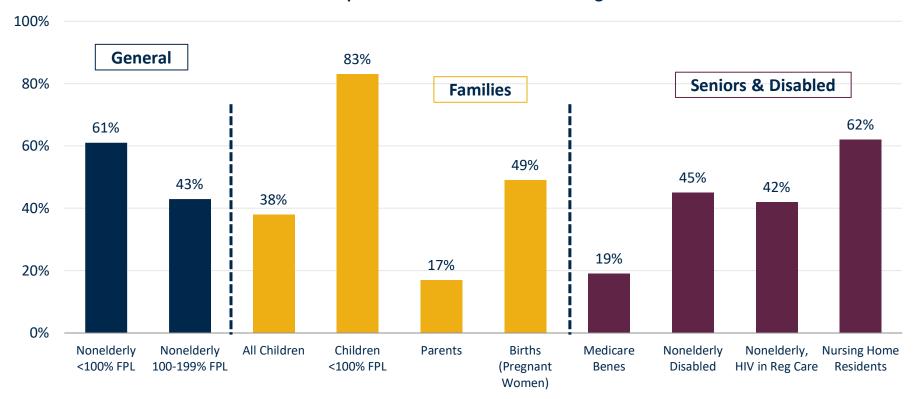
Medicaid Plays A Key Role In Covering Selected Populations



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
- In 2017, Medicaid provided health coverage for large portions of different populations

% Populations With Medicaid Coverage



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

	States Administer Medicaid Benefit In 1 Of 2 Ways:
Medicaid Fee-For-Service	 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
Medicaid Managed Care (MCO)	 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

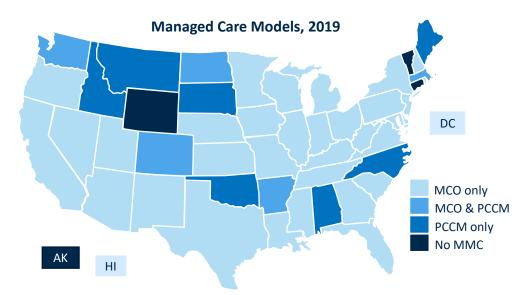
Managed Care Covers Most Beneficiaries, Steadily Growing

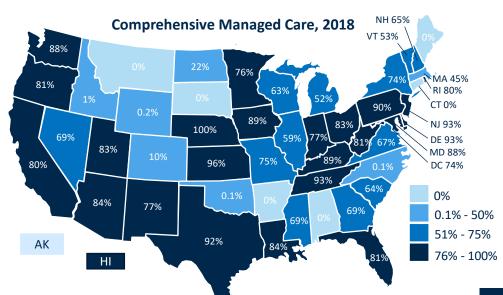


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Medicaid enrollees get most or all services through organizations contracted with the state.

- As of 2017 about 69% of beneficiaries were in comprehensive managed care.
 - States contract with managed care organizations (MCOs) to provide comprehensive acute care at a fixed monthly premium for each enrollee
- Primary care case management (PCCM) pays primary care providers a monthly management fee to provide care coordination
 - Providers continues fee-for-service payments
 - Sixteen states operated PCCM programs in 2016, with enrollment of 5.4 million
- Limited benefit plans provide only one or two services such as behavioral or dental
 - Thirty-three states have limited-benefit plans
 - Behavioral health limited-benefit plans
 - Non-emergency transportation vendors
 - Dental plans
 - MLTSS limited-benefit plans



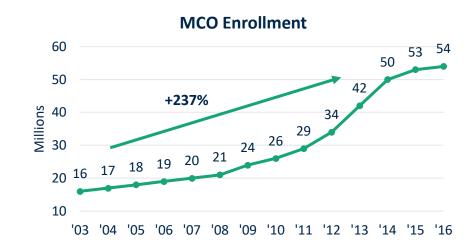


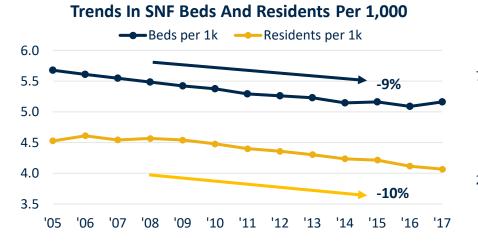
Medicaid Has Grown Larger, More Managed, Less Facility-Based, More Home-Based

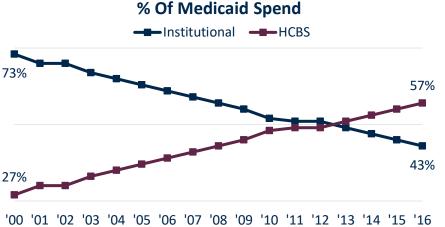


Medicaid has grown significantly larger from an average of 40M beneficiaries per month in 2008 to over 60M in 2018 – the second largest source of coverage after employer sponsored plans.

- Within that total growth have been several meaningful trends
 - Managed care has increased to cover more than 80% of beneficiaries
 - Nursing facility capacity and utilization has steadily declined on a per capita basis
 - Home based care has increased significantly







Certificate of Need / Scope of Practice / Workers' Comp



35 states currently have CON laws, and 3 states have regulations that are functionally similar to CON.

- The types of facilities subject to CON reviews vary by state
- A CON review is typically required for the establishment of a new healthcare facility or change in ownership
- The process typically involves an application, hearings, and review by a state health planning agency
- National trends have been towards limiting or repealing CON requirements



Scope-of-practice laws are state-specific restrictions that determine what tasks healthcare providers may undertake.

- Practitioners are licensed to perform a specific profession in a state
- Medicare payment policies intersect with State laws and overlay scope of practice concepts onto coverage and payment rules
- CMS is currently examining payment regulations that are more restrictive than State scope of practice in order to increase efficiency

Workers' compensation is insurance providing wage replacement and medical benefits to employees injured during employment.

- Each state (except Texas) has its own workers' compensation system
- WC premiums have been declining in recent years, largely as a result of reductions in costs due to fewer accidents and thus less lost wages
- All but 6 states have WC fee schedules dictating rates
- A majority of states also offer managed care that negotiate rates
- Providers often specialize in serving the workers' comp market
- There are also 4 Federal workers compensation programs, the most significant being EEIOCPA for workers in the nuclear weapons program



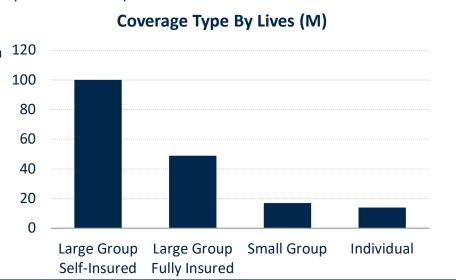


Commercial Insurance –



51%	COMMERCIAL INSURANCE		
of Total Lives	165M Lives		
Individual Market/ E	xchanges	18M lives, 5%	
Small Group		17M lives, 5%	
Large Group/ ERISA		130M lives, 40%	

- The individual insurance (nongroup) market is reflected in the demographic make-up of those who purchase coverage from it: many individuals with nongroup insurance are individuals who are unlikely to have access to employer coverage
- In addition, some people use the 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 120
 AVs, essential benefits etc.
 - Established credits to subsidize purchase of plans
- Total individual market enrollment, measured on an average monthly basis, increased from 10.6 million in 2013 to a peak of 17.4 million in 2015, before declining to 13.8 million in 2018
 - Much of this decline was concentrated in the off-exchange market, where enrollees were not eligible for Federal premium subsidies and therefore were not cushioned from the significant premium increases in 2017 and 2018
 - About 80% of exchange participants receive subsidies



ACA Regulated And Subsidized Individual Insurance Market



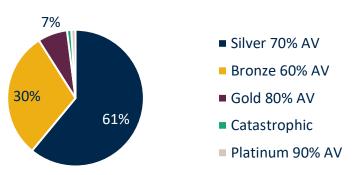
ACA provides refundable and advanceable premium credits to eligible individuals and families with incomes between 100-400% FPL to purchase insurance through the Exchanges.

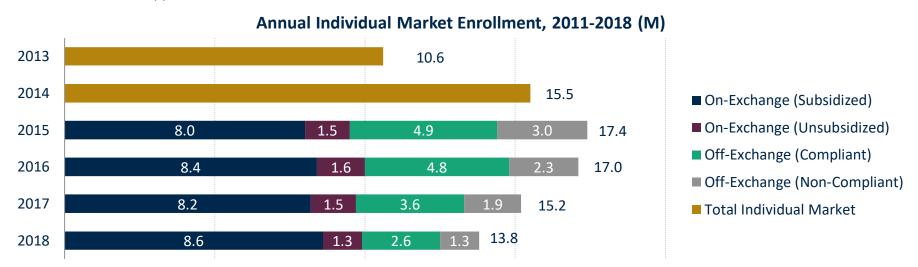
- Premium credits tied to the second lowest cost silver plan in the area and will be set on a sliding scale such that the premium contributions by the beneficiary are limited to the following percentages of income for specified income levels:
 - 150% FPL: 3 4% of income 200% FPL: 4 - 6.3% of income

Up to 133% FPL: 2% of income 250% FPL: 6.3 – 8.05% of income 300% FPL: 8.05 – 9.5% of income 400% FPL: 9.5% of income

- Annually, increase the 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

Exchange Enrollment By Plan, 2019



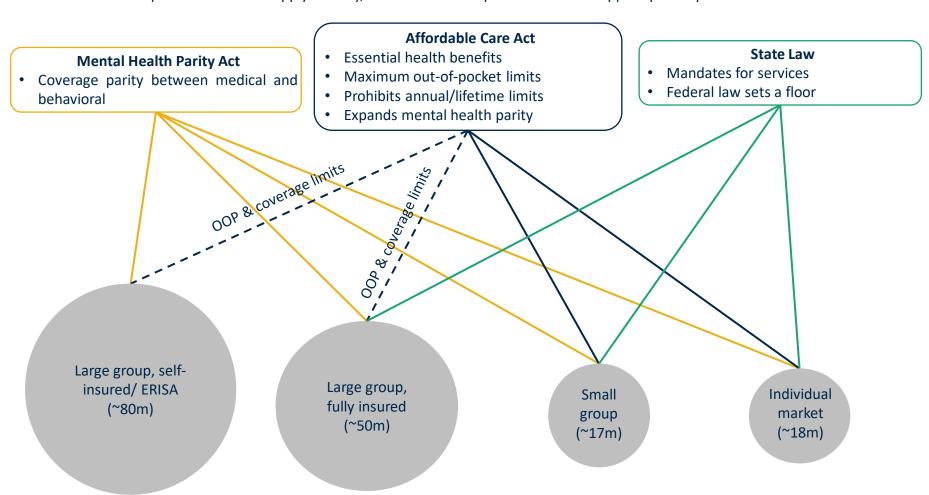


Multiple Laws Have Varied Interactions With Commercial Health Plans



MHPA establishes parity between medical and behavioral services; ACA established essential health benefits and prevented limits on benefits; states are allowed to mandate additional coverage

• Solid line represents laws that apply entirely, and dotted line represents law that applies partially

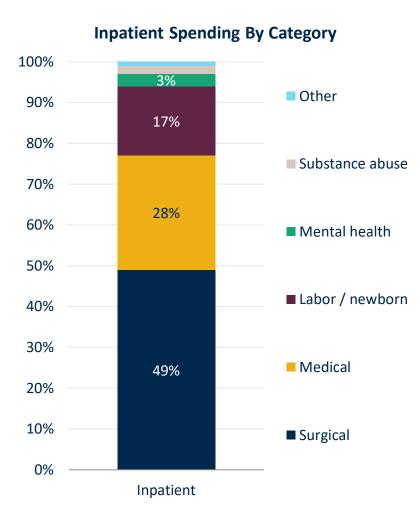


Commercial Inpatient Spending (40% Of Hospital Spending) Driven By Surgical Spending



Surgical spending makes up close to half of inpatient spending. Other major categories are medical services and labor/delivery/newborn care.

- Inpatient spending grew 14.4% from 2015-19, driven entirely by rising prices
 - Prices ↑ 30.8%
 - Utilization ψ -12.5%
- Prices increased all inpatient categories 2015-19; utilization declined from some categories and grew in others
- Surgical admissions had the highest average price (\$43,810 in 2018)
 - Average price of a labor/delivery/newborn admission was lower (\$9,851), but they were the plurality of acute inpatient admissions (37%)
- Patient out-of-pocket costs rose for all categories other than surgical admissions
 - Patient costs were highest (and grew the most) for substance use admissions



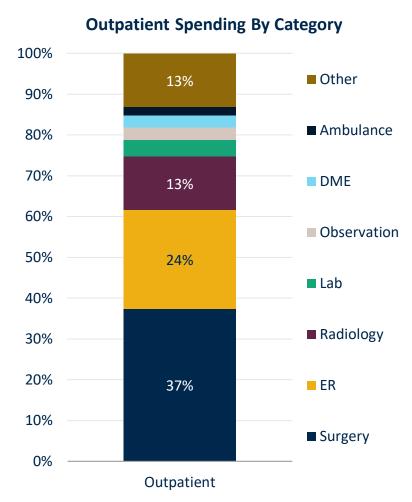
Source: HCCI data, 2018

Commercial Outpatient Spending (60% Of Hospital Spending) Driven By Surgery And ER Visits



Surgery + ER visits make up 60% of outpatient spending. Radiology procedures contribute 13%.

- Outpatient services and prescription drugs had the largest increases in spending per person over 2015-2019
- Among visits, the 2014-2018 increase in average price was largest for outpatient surgery, rising from \$4,407 to \$5,291
- Out-of-pocket spending on visits increased the most in the ER, rising from \$368 in 2014 to \$503 in 2018
- Among procedures, ambulances had the highest average price (\$696 in 2018), but radiology prices grew the most (from an average price of \$510 to \$630)
 - Radiology procedures had the highest average out-ofpocket cost (\$119 in 2018) among outpatient procedures



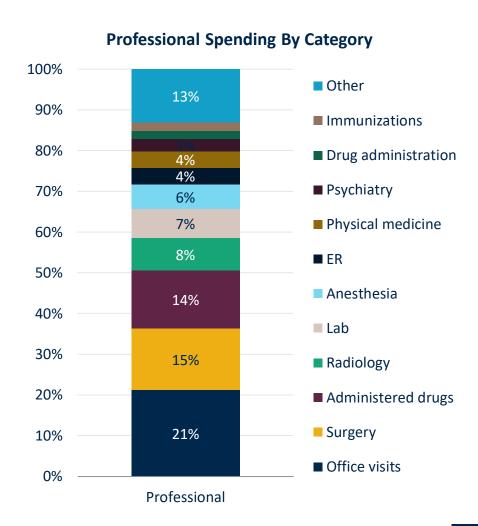
Source: HCCI data, 2018

Commercial Physician Spending Driven By Office Visits, Surgery, Administered Drugs



In contrast to hospital spending, increases in utilization of physician services accounted for a larger share of spending growth than the increase in average price from 2017-18.

- The largest growth in spending occurred in the category of administered drugs
 - While utilization fell, the average price of an administered drug in a professional setting nearly doubled over 2014-18, from \$470 to \$813
 - Over the 5-year period, the increase in spending on administered drugs accounted for 39% of the increase in spending among professional services
- Lab services made up the largest component of professional service volume in 2018 (29%), but only 7% of spending
- The largest increase in out-of-pocket price was for emergency room services
 - These professional services are in addition to facility/outpatient payments for ER care



Source: HCCI data, 2018



V

Specialized Programs/Systems

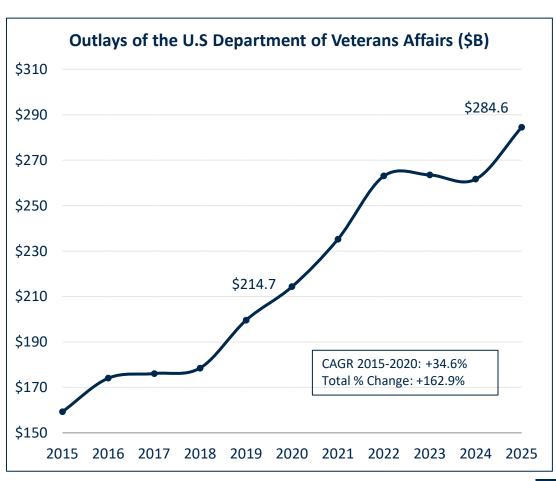
Department of Veterans Affairs



The 2020 VA budget is \$214.7 billion and within that is the Veterans Health Administration (VHA) the largest integrated health care system in the US.

- 2020 VHA budget of \$85 billion
- 170 medical centers
- Serving 9 million Veterans
- Veterans that qualify for VHA healthcare do not pay premiums or deductibles, but may have copayments
- To be eligible for VA health care benefit programs one must have served in the active military, naval or air service and separated honorably
- By Federal law, eligibility for benefits is determined by a system of eight priority groups
- VHA directly employs most providers
- VHA contracts with provider vendors to acquire medical equipment, supplies, some services, and pharmaceuticals.

- 1,255 health care facilities
- 1,074 outpatient sites



340B Program Subsidizes Safety Net Providers



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.

- 340B program is a Federally mandated subsidy from drug manufacturers to covered entities
 - To permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"
- The program has expanded dramatically and now 40% of all hospitals and over 12,000 providers are CEs
- Pharmaceutical manufacturers are required to participate in 340B if they also participate in the Medicaid program
- The 340B ceiling price is the maximum amount that a manufacturer can charge a covered entity
- The 340B Program provides 25% to 50% savings on drugs
- In CY 2018, the 340B Program provided \$24 billion in discounted medications to safety-net providers

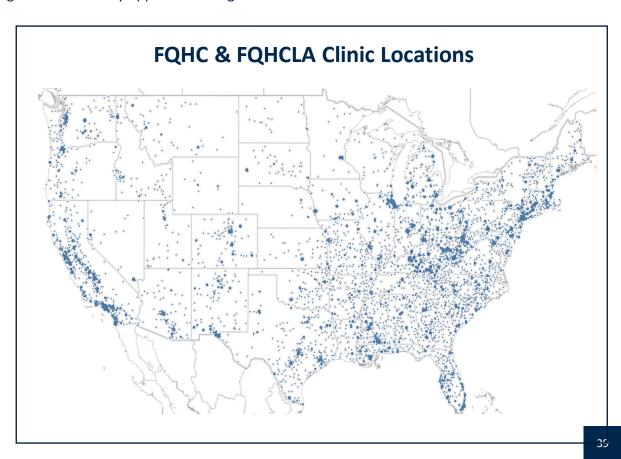


FQHCs, RCs, CMHCs & Indian Health Service Provide Primary & Preventive Care In Underserved Areas



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

- 1,370 FQHCs/81 FQHC look-alikes with 14,194 clinics serving 25 million patients -- 92% below 200% of FPL
 - FQHC Look-Alikes do not receive grants but do receive cost-based reimbursement for their services
 - Medicaid is about 45% of FQHC revenue and 50% of patients
- Income-eligible, uninsured patients are charged on a Federally approved sliding fee scale
- Medicaid, including MCOs, reimbursement is based on a per-visit payment rate for each FQHC based on costs.
- Medicare reimburses FQHCs paid 80% of their charges
- Rural Health Clinics (RHC)
 - 4,300 clinic locations
- Community Mental Health Centers are Federally funded and provide mental health services to uninsured and underinsured individuals
- The Indian Health Service (HIS) provides comprehensive primary health care and disease prevention services to approximately 2.6 million beneficiaries through a network of over 605 hospitals, clinics, and health stations



PACE Is A Medicare-Medicaid Program That Focuses 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



V

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	SANHSA Subtance Above and Mental Health Services Administration U.S. Deportment of South and Human Federices WHRSA Health Resources and Services Administration
Conduct Research	NIH) Agency for Healthcare Research and Quality
Regulate Products	THE SERVICES . LOS SE
Enforce Program Integrity	Office of Inspector General U.S. Department of Health and Human Services

Food & Drug Administration & National Institute of Health

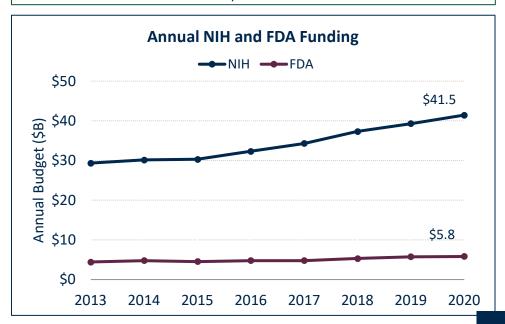


The Food & Drug Administration (FDA) regulates \$1 trillion worth of products each year.

- Food
- Drugs/Biologics
- Devices
- Animal drugs/feed
- Cosmetics
- Tobacco
- The Food and Drugs Act of 1906 was the first of more than 200 laws that constitute the medical regulatory structure.
- The Federal Food, Drug, and Cosmetic Act of 1938 regulated the safety of drugs and food
- The Kefauver-Harris Amendments of 1962, strengthened drug safety and required effectiveness
- The Medical Device Amendments of 1976 applied safety and effectiveness to devices
- FDA is funded with a combination of user fees paid by product applicants (\$2.6b) and appropriated funds (\$3.2b)
- FDA has accelerated approval of generic drugs and biosimilars in recent years

The **National Institutes of Health (NIH)** is made up of 27 Institutes and Centers focused on particular diseases or body systems.

- NIH funds over 50,000 grants to more than 300,000 individuals at more than 2,500 research institutions.
- The largest institutes are:
 - Cancer \$6.4 billion
 - Infections Disease \$5.8 billion
 - Heart& Lung \$3.6 billion
 - Aging \$3.5 billion
 - General Medicine \$2.9 billion



HHS OIG & HHS OCR

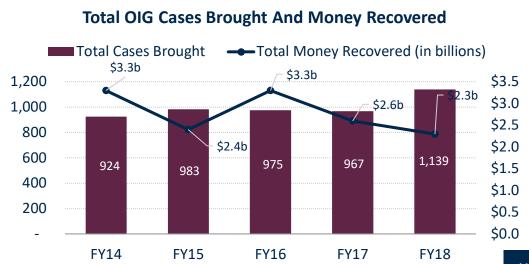


Office of Inspector General (OIG) OIG investigates fraud and abuse in Medicare, Medicaid and more than 100 other HHS programs.

- HHS OIG is the largest inspector general's office in the Federal Government, with approximately 1,600 employees.
- A majority of OIG's resources go toward the oversight of Medicare and Medicaid
- OIG deploys a nationwide network of audits, investigations, and evaluations
- OIG generates recommendations for policymakers based on their audits and investigations.
- OIG also works with the DOJ in the development of cases for criminal, civil and administrative enforcement.
- Each year OIG updates a 5-year strategic plan ("work plan") that delineates areas of program integrity focus
- OIG recovered \$5.9 billion from fraud investigations during fiscal year 2019

Office for Civil Rights (OCR) enforces Federal civil rights laws, conscience and religious freedom laws, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule.

- Since 2003, OCR has investigated and resolved over 27,908 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 75 cases resulting in \$116 million in fines.
- OCR refers to DOJ for criminal investigation cases involving the knowing disclosure or obtaining of PHI. As of 2020, OCR made 896 such referrals to DOJ.



HHS ONC & Centers for Disease Control

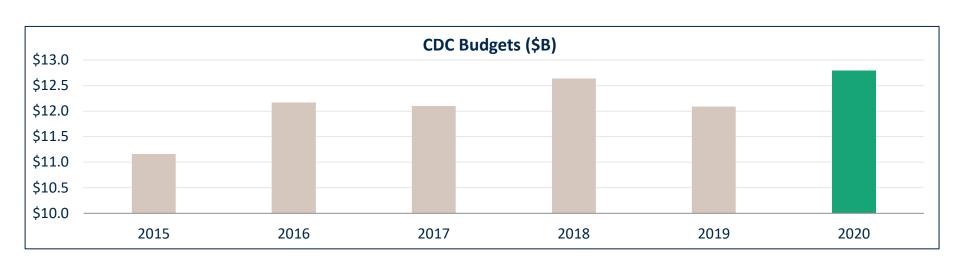


Office of the National Coordinator for Health Information Technology (ONC) supports the adoption of health information technology standards and interoperability.

- The position of National Coordinator was established by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009
- ONC's 2020 budget is \$60 million

The Centers for Disease Control and Prevention (CDC) mission is to protect public health and safety through the control and prevention of disease, injury, and disability in the US and internationally.

- CDC focuses on infectious disease, food-borne pathogens, environmental health, occupational safety and health
- CDC budget for 2020 is \$ 12.7 billion
 - \$4.4 billion devoted to vaccines for children
 - \$1.7 billion for infectious disease prevention
 - \$1.2 billion for chronic disease prevention



AHRQ & SAMSHA



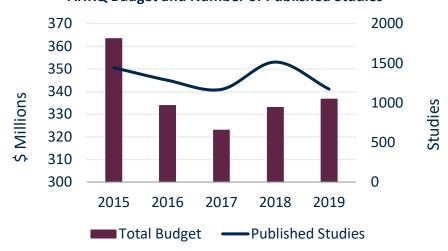
The Agency for Healthcare Research and Quality (AHRQ) funds research and conducts research, primarily focused on quality outcomes.

- AHRQ creates tools and strategies for providers to help deliver higher-value healthcare
- AHRQ maintains healthcare databases, CAHPS, MEPS, HCUP, SRDR, USHIK
- AHRQ budget \$450 million
 - Primary Care \$196
 - Patient Centered Care \$106 million

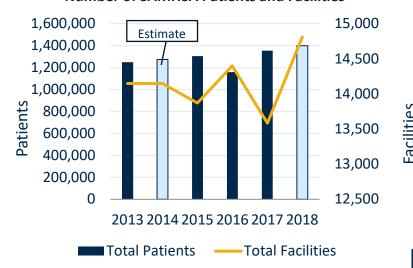
The Substance Abuse and Mental Health Services Administration (SAMHSA) leads public health efforts to advance behavioral health. SAMHSA's seeks to reduce the impact of substance abuse and mental illness on America's communities.

- SAMSHA administers grants to state and local government related to mental health and maintains a searchable online database and directory of mental health providers.
- Total budget \$5.8 billion
 - Substance abuse programs \$3.8 billion
 - Mental Health \$1.7 billion

AHRQ Budget and Number of Published Studies



Number of SAMHSA Patients and Facilities



BRG

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