

Post-Election Analysis of Health Care Legislative & Regulatory Trends

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Available Resources

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- Health care and life sciences law super-boutique founded 1973
 - 125 health care attorneys
 - Nationwide reach
- Legal practice driven by federal and state law and regulation
 - Market Access
 - Policy
 - Compliance

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 - Policy
 - Regulation
 - Payment & Reimbursement
- Multi-disciplinary
 - Business Strategy
 - Public Policy
 - Medicine & Science
 - Data Security

- Bipartisan health care and life sciences consultancy dedicated to the provision of legislative and regulatory advocacy
- The National Health Advisors are:
 - Legislative Policy Experts
 - Health Lawyers
 - Federal Regulatory Veterans

Agenda

- I. New Political Footprint**
- II. The Affordable Care Act: Repeal and Replace or Replace and Repeal?**
- III. New Health Laws**
- IV. Opportunities for the Health Care Industry Under the Trump Administration and 115th Congress**
- V. Health Care Trends Immune from Change**
- VI. Appendix**

New Political Footprint



Key figures in the Republican Party

- Donald J. Trump – President
- Mike Pence – Vice President
- Mitch McConnell (R-KY) – Senate Majority Leader
- Paul Ryan (R-WI 1) – Speaker of the House
- Kevin McCarthy (R-CA 23) – House Majority Leader



Key figures in the Democratic Party

- Chuck Schumer (D-NY) – Senate Minority Leader
- Nancy Pelosi (D-CA-12) – House Minority Leader
- Steny Hoyer (D-MD-5) – House Democratic Whip



Key health care appointments that require Senate confirmation

- Dr. Tom Price – Department of Health and Human Services Secretary (confirmed on 2/10/17)
- Seema Verma – Centers for Medicare & Medicaid Services Administrator (confirmed on 3/13/17)
- Scott Gottlieb – U.S. Food and Drug Administration Commissioner (not yet confirmed)

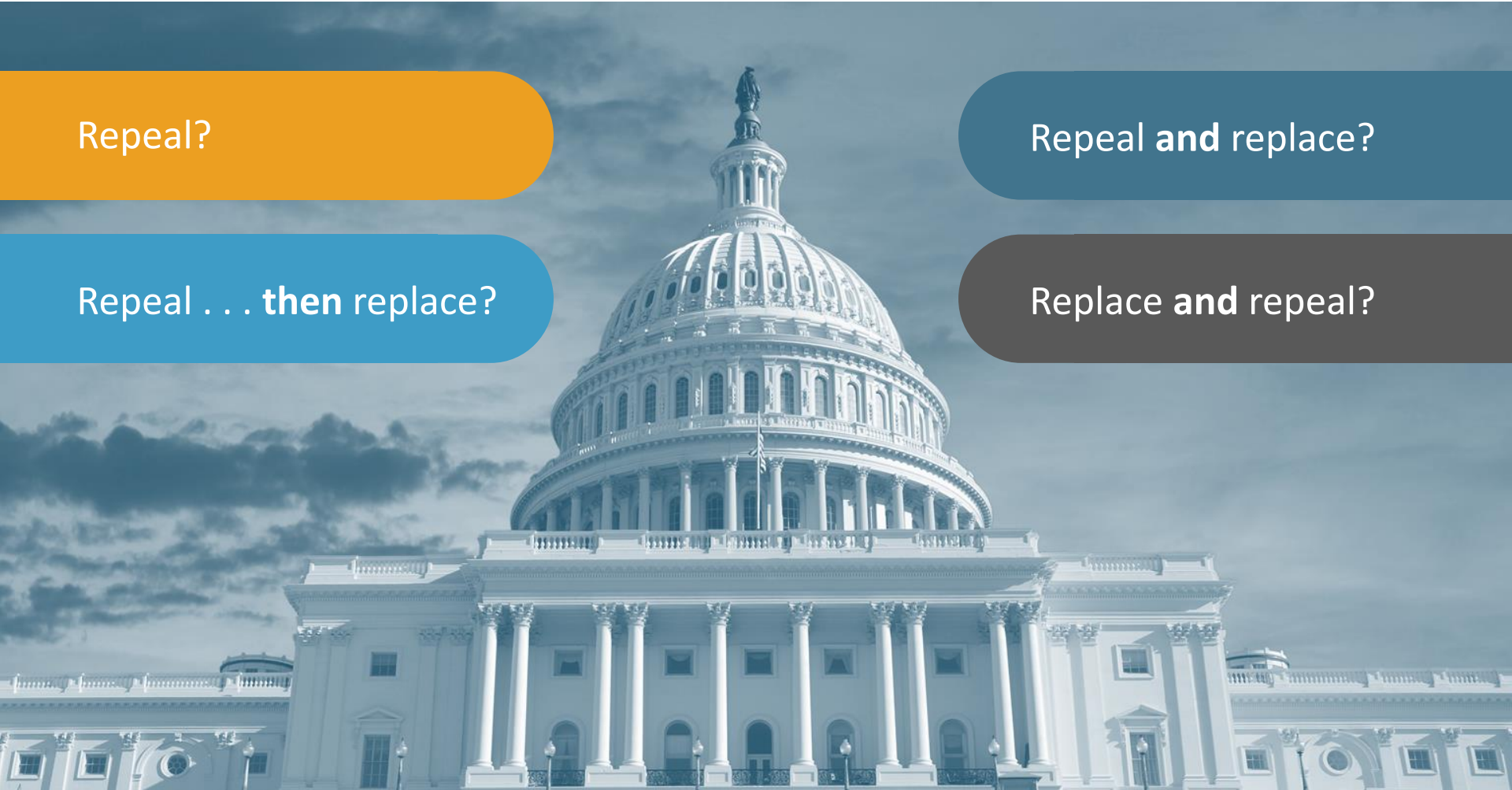
Congress

Repeal?

Repeal . . . **then** replace?

Repeal **and** replace?

Replace **and** repeal?



New Congressional Balance Is Republican

President Obama – January 20, 2009 – January 20, 2017

President Trump – January 20, 2017 – January 20, 2021

	112th Congress (January 2, 2011 – January 3, 2013)	113th Congress (January 3, 2013 – January 3, 2015)	114th Congress (January 3, 2015 – January 3, 2017)	115th Congress (January 3, 2017 – January 3, 2019)
Senate	47 Republicans 53 Democrats	45 Republicans 55 Democrats	54 Republicans 46 Democrats	52 Republicans <i>Must defend 8 seats in 2018 re-election. Of those, 7 are from states Trump won.</i> 48 Democrats <i>Must defend 25 seats in 2018 re-election. Of those, 10 are from states Trump won.*</i>
House of Representatives	191 Republicans 241 Democrats 3 Vacant	233 Republicans 205 Democrats 3 Vacant	247 Republicans 188 Democrats	241 Republicans** 194 Democrats***

* The 10 Democrat seats up for re-election in Trump won states include Florida, Indiana, Michigan, Missouri, Montana, North Dakota, Ohio, Pennsylvania, West Virginia, and Wisconsin.

**Four vacant seats formerly held by Republicans in Georgia, Kansas, Montana, and South Carolina.

***Only approximately 50 seats that may be competitive - where the House winner had 55% or less of the vote.

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The Affordable Care Act: Repeal and Replace or Replace and Repeal?

ACA Title I Enrollment to Date

Health Insurance Marketplaces Open Enrollment

January 31, 2017: 9.2 million
March 31, 2016: 11.1 million
January 16, 2015: 9.5 million
September 2014: 8 million



Medicaid Increase

Between July/September 2013 and September 2016, among the states that have implemented the Medicaid expansion:

- Enrollment increased by 13.3 million or 35.7%;
- 22 states saw increases in enrollment of at least 25%
- Top six states: CA, NY, IL, MI, NJ, OH, PA

CBO's Analysis of the Republican Bill:

24 million more people would be **uninsured**. It would **reduce** the deficit by **\$337 billion** over 10 years. The **losses** in coverage **after 2018** mainly come from **Medicaid**.

The Parts of Obamacare Republicans Will Keep, Change or Discard

Passed the House Energy and Commerce and Ways and Means Committees (March 9, 2017)

Under Obamacare

House Republican bill

Individual mandate

The Affordable Care Act requires people who can afford it to obtain health insurance or face tax penalties. This part of the law was meant to keep insurance affordable for those who are older or sick.

Repeal

The Republican bill would eliminate the individual mandate, which means that people would not have to pay a penalty if they went without insurance. One possible effect, though, is that healthy people might be less likely to buy insurance, driving up prices for those who need it most, like older people and the sick. To limit this, the plan proposes a “continuous coverage incentive,” which would charge people in the individual market a 30 percent penalty for lapses in health insurance coverage.

Employer mandate

Larger companies must provide affordable insurance to their employees or face financial penalties.

Repeal

Subsidies for out-of-pocket expenses

The federal government provides tax credits to help some people pay deductibles and make co-payments.

Repeal

Would repeal this so-called cost-sharing subsidy in 2020.

Premium subsidies

The federal government provides tax credits to middle-income Americans on a sliding scale according to income, to help offset the cost of premiums and deductibles.

Change

Would change the way subsidies are distributed by using age, instead of income, as a way to calculate how much people receive. Tax credits would be available in full to individuals earning less than \$75,000 and households earning less than \$150,000, but they would be capped for higher earners. The subsidy would be \$2,000 for a person under 30, and double that for people over 60. The bill would also expand the health plans that qualify for subsidies.

Source: The New York Times (Mar. 8, 2017)

Replacement Options

NO REPUBLICAN CONSENSUS ON THE AMERICAN HEALTH CARE ACT

	Ryan (AHCA bill)	House Freedom Caucus	Senator Rand Paul (R-KY)	Senate Conservatives	Senate Moderates	Expansion State Senators
Individual & Employer Mandate	X	X	X	X	X	
Alternative Incentive for Continuous Coverage	√	AHCA is "ObamaCare 2.0"	√ supports generally, but AHCA is "ObamaCare lite"	√	√	
Offering insurance across state lines	√		√	√	√	
Support and expand HSAs	√		√	√	√	√

Key: √ = supports; X = opposes

Replacement Options

NO REPUBLICAN CONSENSUS ON THE AMERICAN HEALTH CARE ACT

	Ryan (AHCA bill)	House Freedom Caucus	Rand Paul	Senate Conservatives	Senate Moderates	Expansion State Senators
Repeal of Medicaid Expansion	√	√	√ Wants separate vote on expansion before voting on a replacement bill	√	X	X May withhold vote over this provision
Per Capita Caps	√		X State flexibility through waivers	√ Some support block grants		
Guaranteed Issue					√	
On parent's plan until 26	√				√	
Preexisting Conditions	√		√		√	

Replacement Options

NO REPUBLICAN CONSENSUS ON THE AMERICAN HEALTH CARE ACT

	Ryan (AHCA bill)	House Freedom Caucus	Rand Paul	Senate Conservatives	Senate Moderates	Expansion State Senators
Premium subsidies	√	X AHCA is “a new entitlement”	X	X	X	
Repeal of most ACA taxes	√	√ Opposed to AHCA’s keeping ACA taxes in place until 2018, but generally supports	X	√	√	√
Equalize tax deduction for health coverage expenses	√	√	√			

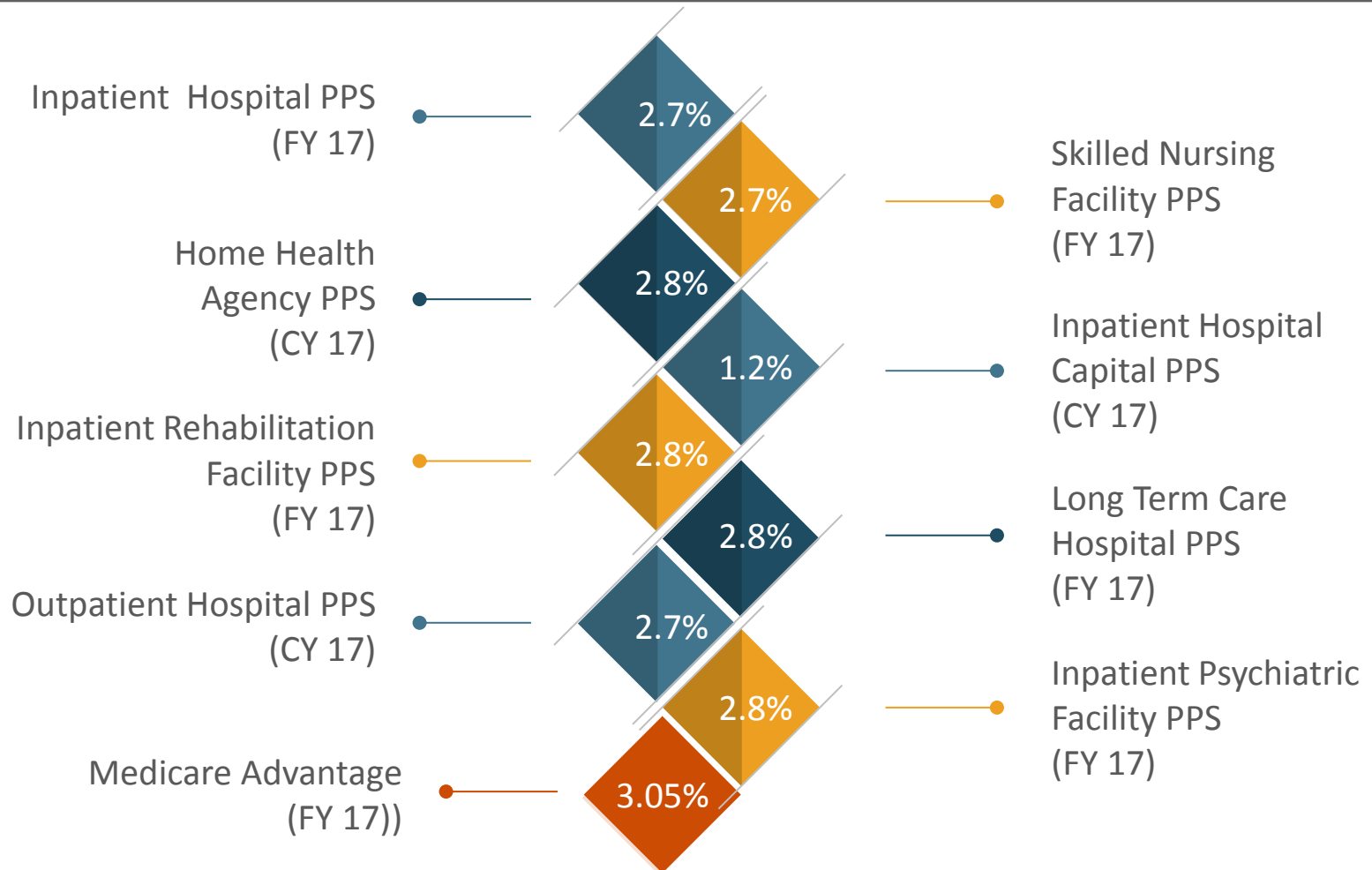
The Future of the Healthcare System

INDUSTRY REACTIONS TO THE REPUBLICAN'S BILL

Organization	AHA	AHIP	AMA	AARP	Pharma Industry
Outlook	<i>Negative</i>	<i>Positive / Negative</i>	<i>Negative</i>	<i>Negative</i>	<i>Neutral</i>
Reasons for Outlook	<ul style="list-style-type: none"> Concerned about repealing the Medicaid expansion after 2019. Concerned about coverage losses. Concerned about eliminating funding from some sources, but leaving in reductions to payments for hospital services. 	<ul style="list-style-type: none"> Bill includes positive steps to stabilize the market. Supports continuing premium tax credits, funding for states to stabilize risk pools, and providing states more flexibility. Medicaid funding needs to be adequate to meet the healthcare needs of beneficiaries, and AHIP is concerned that key components of the proposed new funding formulas starting in 2020 could result in unnecessary disruptions in coverage and care beneficiaries depend on. AHIP appreciates that the bill acknowledges states need time to prepare for Medicaid changes. 	<ul style="list-style-type: none"> Concerned about repealing the Medicaid expansion after 2019. Does not support the way the tax credits are structured. Does not support the repeal of the Prevention and Public Health Fund or the limitations placed on patient's ability to choose a provider. 	<ul style="list-style-type: none"> The bill would weaken Medicare's fiscal sustainability and dramatically increase health care costs for those aged 50-64. Concerned about repealing the fee on manufacturers/importers of branded prescription drugs. Opposes per capita cap financing structure in Medicaid. 	<ul style="list-style-type: none"> No statements have been issued about health reform.

Medicare Fee for Service

MARKET BASKET UPDATE FY 17 & CY 17 AND MA UPDATE



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New Health Laws

Reduction in Opioid Addiction

SIGNED INTO LAW JULY 22, 2016; PASSED SENATE 92-2; PASSED HOUSE 407-5



Comprehensive Addiction and Recovery Act (CARA)

- Signed by former President Obama on July 22, 2016 and establishes a comprehensive, coordinated strategy through enhanced grant programs that would expand prevention and education efforts while also promoting treatment and recovery for opioid addiction



Summary

- Authorizes grant programs for abuse prevention and education, including prescription monitoring
- Expands access to treatment and recovery options, including medication-assisted treatment and overdose reversal drugs
- Expands law enforcement grants and prescription drug take-back programs
- Next Steps: drafting of Federal Regulation
- Public health officials still want an increase in federal support beyond CARA
- \$37 billion included in stopgap bill to fund the government to address the opioid epidemic



Opportunities

- Invest in companies that create Opioid substitutes
- Create Private Public Partnerships
- Ex. Pfizer and the city of Chicago agreed to a set of standards governing marketing of prescription opioids with the city

21st Century Cures – Lame Duck

SIGNED INTO LAW DECEMBER 13, 2016; PASSED SENATE 94-5; PASSED HOUSE 392-26



Discover

- Cures will provide the NIH with \$4.8 billion in new funding that is fully offset
- *Note, President Trump's proposed federal budget cuts the NIH budget by \$5.8 billion*



Development

- Cures will advance new therapies for patients
- Modernize clinical trials;
- Support broader development of biomarkers
- Provide more consistency for innovators developing of new technology
- Incentivize the development of drugs for pediatric diseases and medical countermeasures
- Provide FDA with \$500 million for regulatory modernization



Delivery

- Cures will help improve delivery by ensuring electronic health record systems are interoperable for seamless patient care and help fully realize the benefits of a learning health care system



Mental Health Reform

- Cures will create a new Assistant Secretary for Mental Health and Substance Use to replace the Administrator at SAMHSA
- Establish the National Mental Health and Substance Use Policy Lab
- Improve mental health care for children with serious emotional disturbance, or adults with serious mental illness

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Opportunities for the Health Care Industry Under the Trump Administration and 115th Congress

Payors & Providers: Opportunities and Challenges

Threats/Headwinds & Opportunities

 **Managed care/insurers**

 **Mental health parity**

 **Hospitals**

 **Compliance/fraud and abuse enforcement**

 **Physicians**

 **Personalized medicine**

 **Post-acute/home care**

Pharma, Biotech, & Medical Device Industry: Opportunities & Challenges

Opportunities

- Scott Gottlieb – President Trump’s nominee to lead the FDA
- Permanent repeal of the device tax
- CMS non-interference with drug pricing between drug manufacturers, pharmacies, and plans
- Faster drug approvals
- Implementation of the 21st Century Cures Law
- Anticipated loosening/elimination of existing regulations
- Tort reform

Threats/Headwinds

- Re-importation
- Pay-fors
- How will the FDA maintain safety?
- How will the federal government hiring freeze impact the already understaffed FDA?
- FDA’s use of big data to track drugs on the market
- Trump’s statements to create a chilling effect on price increases

Opportunities for Change

AREAS OF RISK & POTENTIAL FOR GROWTH IN MEDICAID

Waivers



- States can seek federal waivers to test new approaches to operating their Medicaid programs outside of regular federal rules, with federal Medicaid matching funds.
- Waivers create laboratories in the States.

Block Grants



- States receive a pre-set amount of funding for Medicaid based on the state and federal Medicaid spending in that state.
- The grant would grow each year to account for inflation.

Per Capita Cap



- Federal funding per enrollee would be capped.
- Under AHCA, U.S. allows up to fixed \$ amount per Medicaid enrollee, starting in 2020, based on 2016 spend

How will this impact key stakeholders? Medicaid dental, skilled nursing, home and community based care, specialty drug industry, post-acute care, non-medical transportation, oxygen, hemophilia factor, etc.

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Health Care Trends Immune from Change

Agenda

- I. Payment Reforms**
- II. CMS Collaboration With Other Payors**
- III. Pricing Pressures**

New Quality Payment Methods Will Continue

PAYMENT TREND

Medical Access and CHIP Reauthorization (MACRA) of 2015

- Replaced SGR reimbursement with Quality Programs
 - Merit-Based Incentives
 - Alternative Payment Models

Payment Methods

- Mandatory bundle under the Comprehensive Care for Joint Replacement (CJR) model
- Bundled Payments for Care Improvement (BPCI) is still ongoing
- Coordinated Cardiac and Hip Fracture Care

Value Based Program Initiatives

- Bundled Payments
- Hospital Specific Initiatives
- Post-Acute Initiatives
- Primary Care/Outpatient Initiatives

Common Quality Metrics

- Clinical process of care
- Patient experience
- Outcome
- Efficiency
- Communication
- Care Coordination

The Future of the Healthcare System

Collaboration Between CMS and Other Payors Will Continue

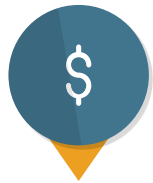


Health Care Payment Learning & Action Network (“HCP LAN”) composed of CMS and private payors



Goal: align government and commercial payors in moving from FFS to alternative payment models (“APMs”)

Figure 1. APM Framework (At-A-Glance)



Category 1

Fee for Service – No Link to Quality & Value



Category 2

Fee for Service – Link to Quality & Value



Category 3

APMs Built on Fee-for-Service Architecture



Category 4

Population-Based Payment

- A. Foundational Payment for Infrastructure & Operations
- B. Pay for Reporting
- C. Rewards for Performance
- D. Rewards and Penalties for Performance


- A. APMs with Upside Gainsharing
- B. APMs with Upside Gainsharing / Downside Risk

- A. Condition – Specific Population – Based Payment
- B. Comprehensive Population – Based Payment

Pricing Pressures

PAYMENT TREND

Government as a dominant purchaser provides pricing pressures for the entire health care and life sciences industry



Congress must act on the **debt ceiling** by sometime in **October/November 2017** or the United States will **default** on some of its legal obligations – payments to bondholders, federal contractors, Social Security recipients, tax filers owed refunds, etc.

Debt Ceiling – efforts to reduce spending

- On March 15, 2017 the latest suspension of the debt ceiling expired

Deficit Reduction

- Current sequestration – 2% cut to Medicare, but Medicaid carved out
- Other sequestration numbers:
 - National defense, discretionary spending: 7.7%
 - National defense, mandatory spending: 7.8%
 - Security, discretionary spending: 1.0%
 - All other programs, discretionary spending: 5.1%
 - All other programs, other mandatory spending: 5.2%

Stay tuned...

Thought Leadership Resources



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Questions?



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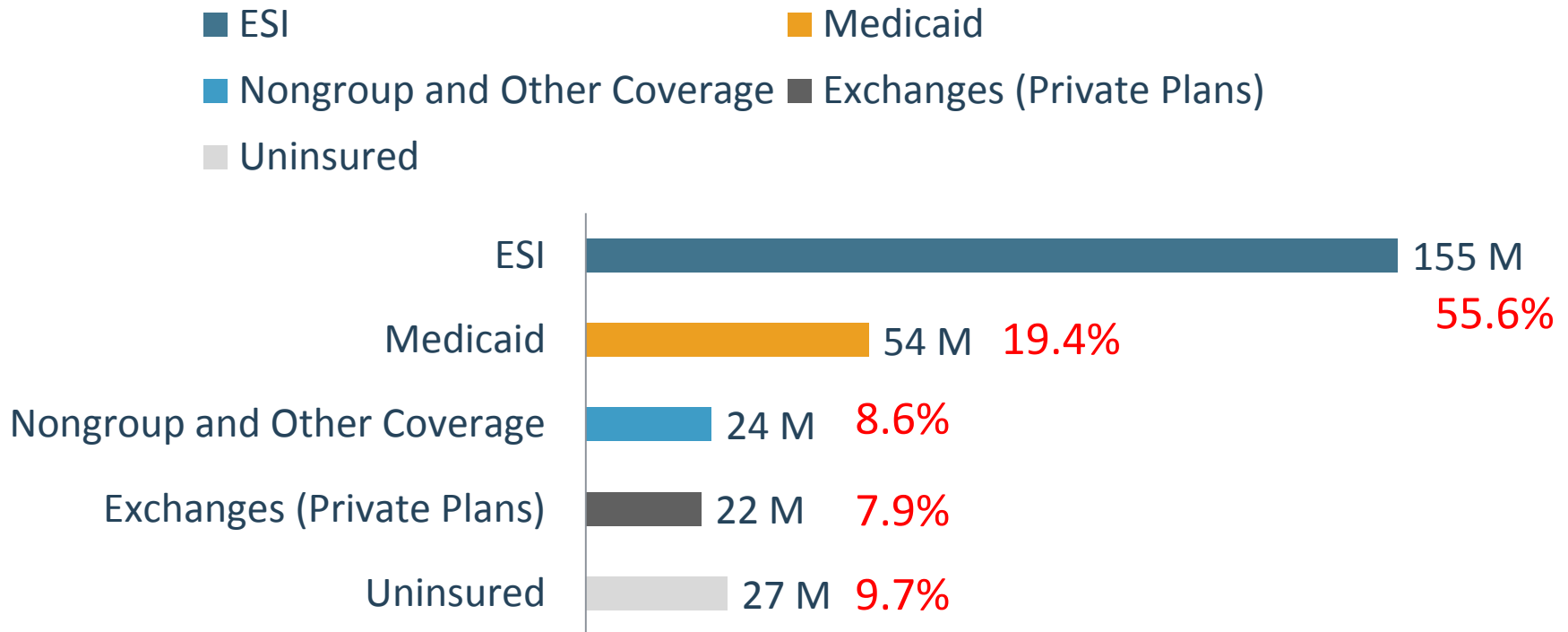
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The 2017 Health Care Market

The Market

PROJECTED SOURCE OF INSURANCE COVERAGE, YEAR 2024

Among 279 million UNDER AGE 65



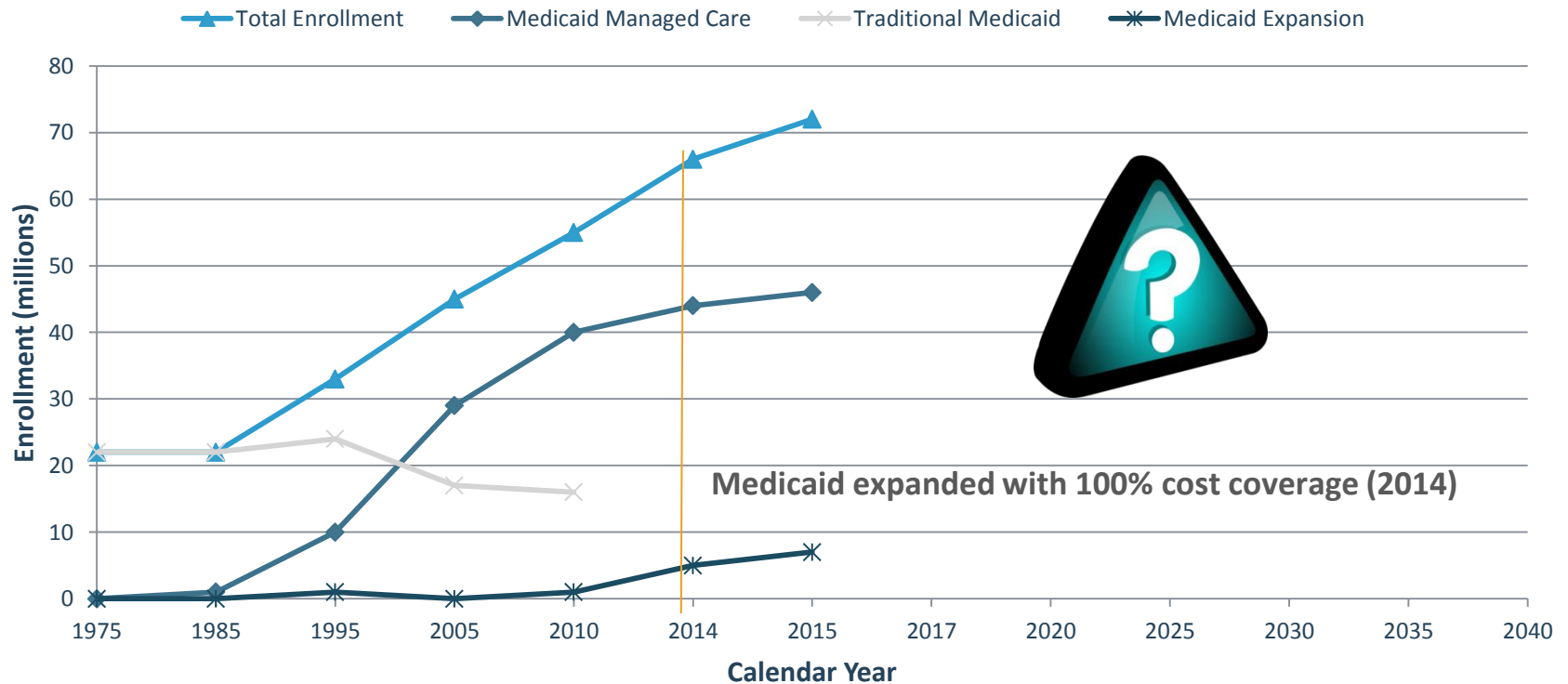
•Note: ESI is Employer-Sponsored Insurance

•Source: Congressional Budget Office, Federal Subsidies for Health Coverage for People Under 65: 2016-2026 --March 2016 (Mar. 24, 2016), available at <https://www.cbo.gov/publication/51385>.

The Market

FEDERAL GOVERNMENT WILL EXERCISE MORE CONTROL OVER MEDICAID AS MEDICAID GROWS

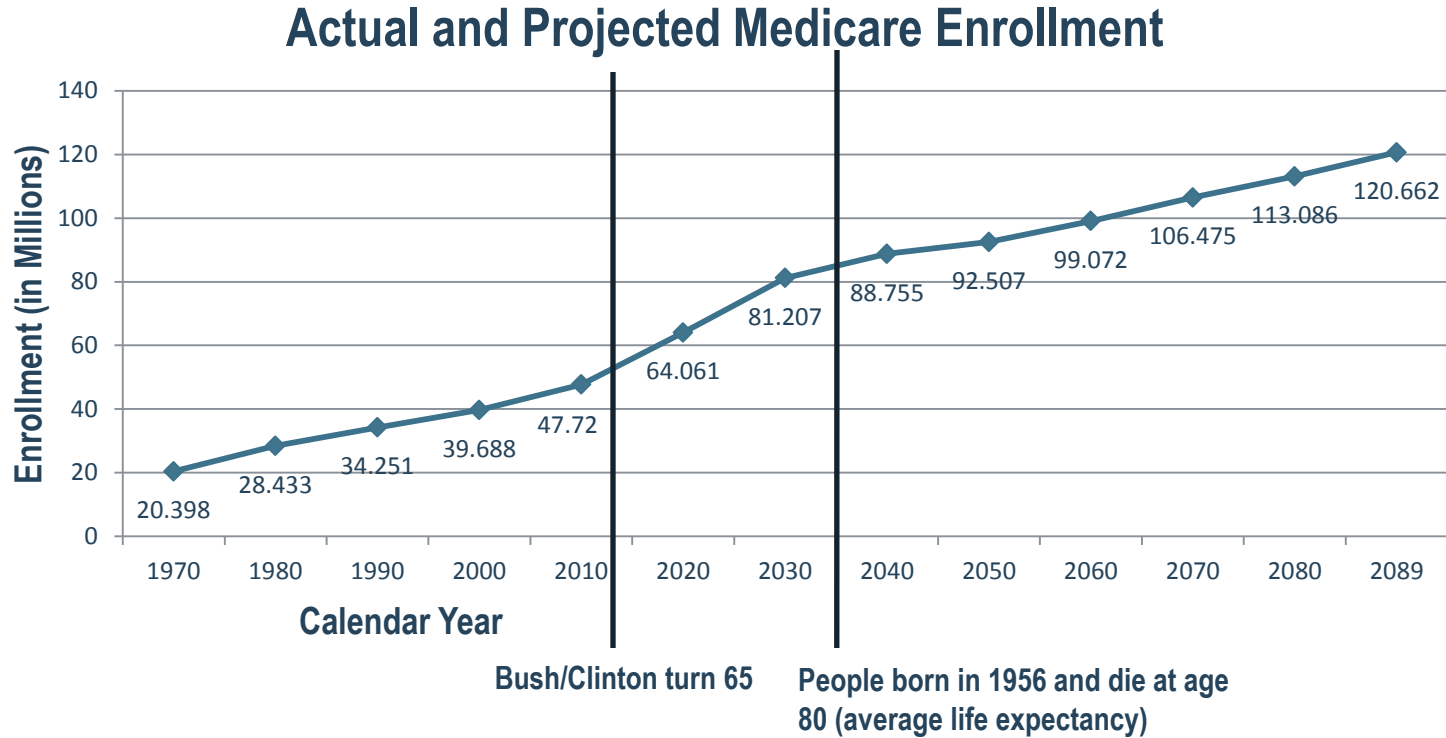
Medicaid Enrollment



Source: Centers for Medicare & Medicaid 2013 Statistical Supplement, Table 13.4; AIS Medicare and Medicaid Market Data, 2015; Kaiser Family Foundation, Total Monthly Medicaid and CHIP Enrollment for May 2014 and May 2015; CMS, Medicaid Managed Care Penetration Rates as of December 31, 2010; CMS National Summary Of Medicaid Managed Care Programs And Enrollment as of July 1, 2010; CMS, Total Medicaid Enrollees - VIII Group Break Out Report, March 2015, Reported on the CMS-64. Coverage Gains Under Recent Section 1115 Waivers: A Data Update, S. Artiga and C. Mann, Kaiser Family Foundation, August 2005. *Enrollment was above zero but under 500,000, thus was rounded down.

The Market

OVER 65 POPULATION – MEDICARE

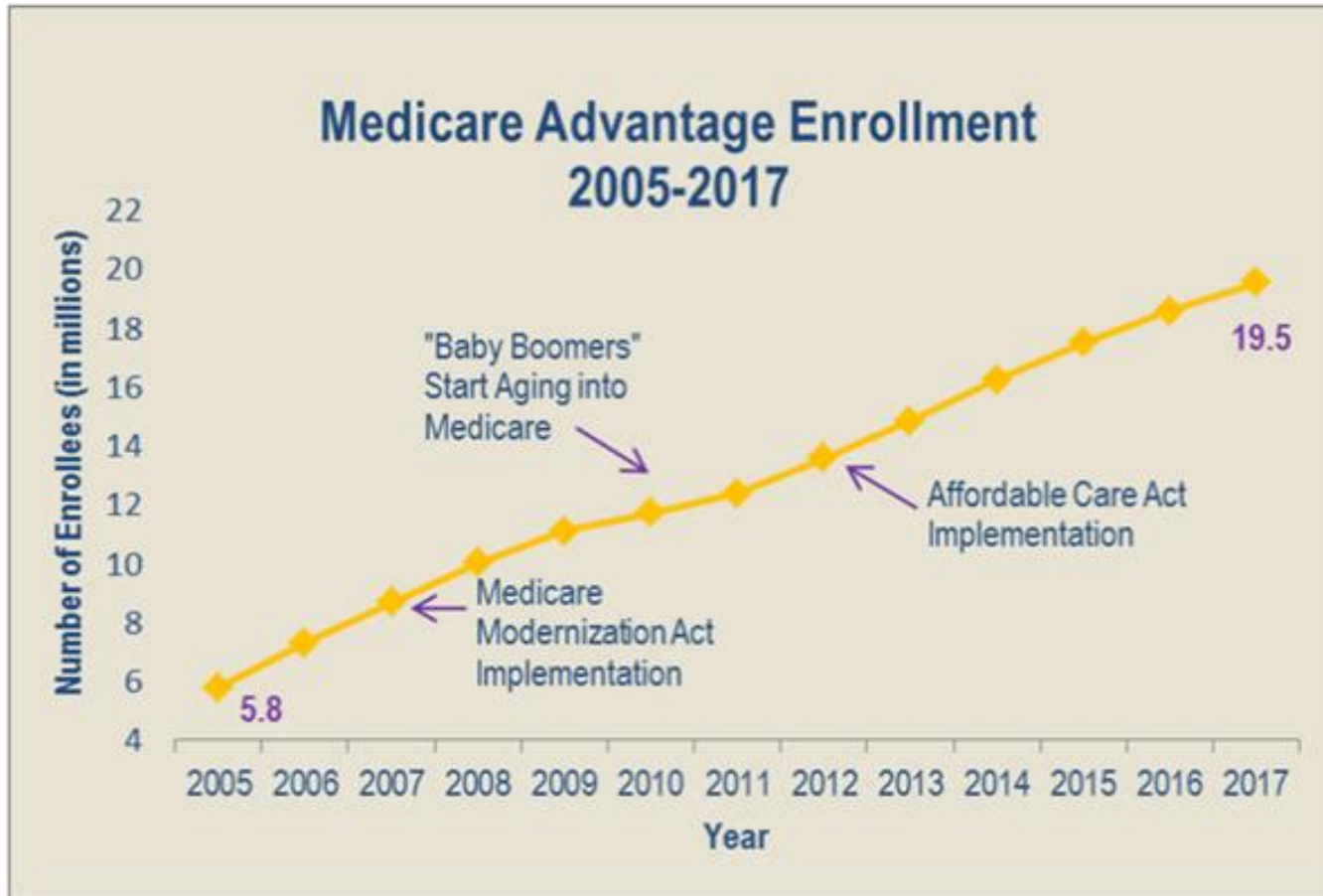


Key fact: Current President Donald J. Trump's birthday: June 14, 1946. Former President George W. Bush's birthday: July 6, 1946. Former President Bill Clinton's birthday: August 19, 1946.

Note: Enrollment numbers are based on Part A enrollment only. Beneficiaries enrolled only in Part B are not included.
Source: CMS Office of the Actuary, 2016 Medicare Trustees Report. Data current through 2015.

Payer Trends

MEDICARE ADVANTAGE ENROLLMENT

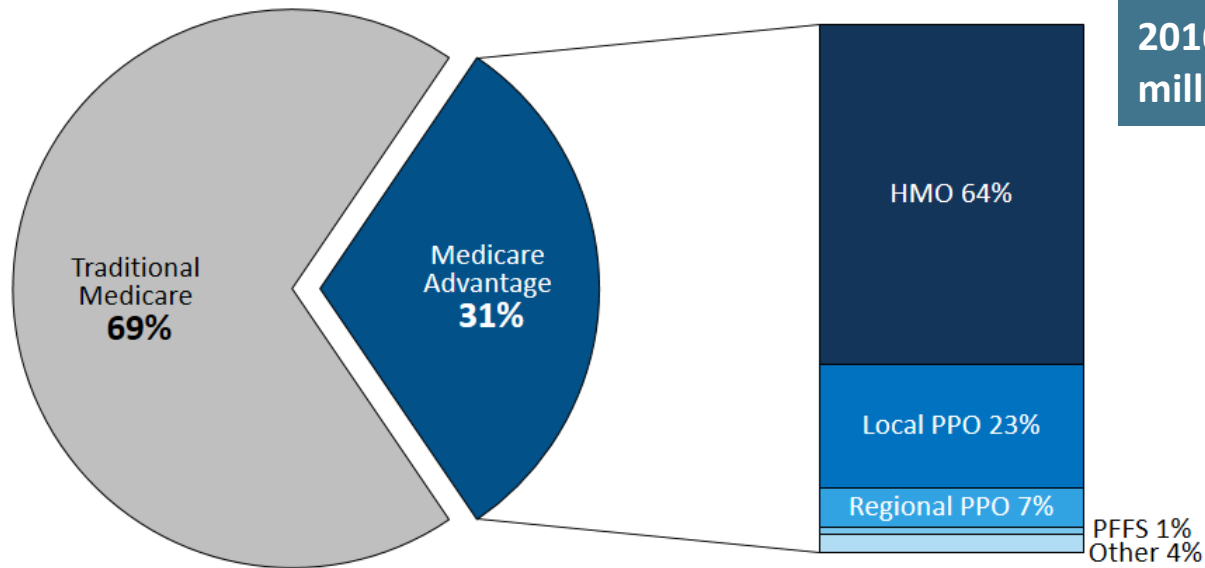


The Market

FEE-FOR-SERVICE ENROLLMENT V. MEDICARE ADVANTAGE ENROLLMENT

Figure 3

Distribution of Enrollment in Medicare Private Plans, by Plan Type, 2016



According to CMS, enrollment in original Medicare as of December 2016 was 38.6 million.

Total Medicare Advantage Enrollment, 2016 = 17.6 Million

NOTE: PFFS is Private Fee-for-Service plans, PPOs are preferred provider organizations, and HMOs are Health Maintenance Organizations. Other includes MSAs, cost plans, and demonstration plans. Includes enrollees in Special Needs Plans as well as other Medicare Advantage plans. Excludes beneficiaries with unknown county addresses and in territories other than Puerto Rico. SOURCE: Authors' analysis of the Centers for Medicare and Medicaid Services (CMS) Medicare Advantage enrollment files, 2016.

