Donald Trump and the Future of the Affordable Care Act Repeal, Replace, or Rebrand?

December 2016

Repeal, Replace, or Amend?

Interlocking provisions of the ACA make repeal of even targeted provisions a tricky prospect



Stated Areas of Focus:

- Advance research and development
- Reform the FDA
- Modernize Medicare
- Give greater power to the states in administering Medicaid
- Increase competition
- Remove individual and employer mandates

From President Elect Trump:

The Administration recognizes that the problems with the U.S. health care system did not begin with – and will not end with the repeal of – the ACA.

- Greatagain.gov

Are you going to make sure that **people with pre-conditions are still covered**? - "Yes. Because it happens to be one of the strongest assets. Also, with the children living with their parents for an extended period,......Adds cost, but it's very much something we're going to try and keep."

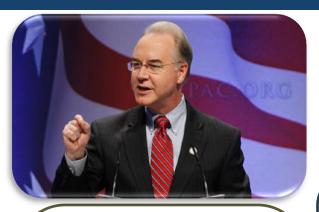
- "60 Minutes" interview on CBS

"Either Obamacare will be amended, or repealed and replaced," Mr. Trump told the Wall Street Journal in an interview published Friday (11th Nov).

"How the ACA Could be Impacted w/o Repeal

- The ACA is built on a number of interlocking provisions and funding mechanisms. Implications of unraveling any aspect of the bill must consider secondary repercussions.
- Rather than repeal, the Trump administration and Congress could simply defund certain aspects of the bill.
- Similarly the administration could chose to not enforce certain punitive aspects of the bill aimed at those seeking to circumvent provisions.

HHS (Health and Human Services) Head Nominee: Tom Price



Powers of HHS Office:

- Nation's top health official that employees about 8,000 people and one of the largest funding source for medical research globally.
- Head and run the government's largest social programs, including Medicare, Medicaid and the Children's Health Insurance Program.
- Direct and indirect authority over FDA, CDC, NIH and other major health agencies.
- Though funding is appropriated by Congress, the office controls implementation and oversight.

Who is Tom Price

- A 62-year-old six-term congressman and former orthopedic surgeon for nearly 20 years before being elected to Congress.
- A go-to Republican on quality health care policy In 2015, Price wrote the language for a bill that is now seen as one of the main paths forward to repeal or decode portions of the ACA.
- Politically, Price is conservative and had voted against federal funding for abortion; Planned Parenthood; and FDA regulating tobacco as a drug

Voiced Opinions on Healthcare

"It's time for a better way to **put patients, families, and doctors back in charge of medical decisions**. President Obama and Democrats must put their pride and politics
aside so that we can start over with a Better Way—a step-by-step plan to give every **American access to quality, affordable health care**."

"Republicans want to address the real cost drivers of health care price spikes, not necessarily sicker patients, but a heavy regulatory burden, taxes and lawsuits against medical professionals."

- tomprice.house.gov

What it could mean for the ACA:

- A pro-physician and fierce critic of the ACA, Tom Price has earlier stated that any possible repeal and replace to Obama's health care law will bear a "significant resemblance" to a 2015 measure that was vetoed by the president.
- That bill would have gutted some of the ACA's main features: Medicaid expansion, subsidies for middle-class to buy private policies, tax penalties for individuals who refused to get coverage and several taxes to support coverage expansion.
- However, Price has insisted the Republican can keep both the provisions that covers
 people with pre-conditions are still covered and allow young people to stay on their
 parents' health insurance.

CMS (Center for Medicare & Medicaid) Head Nominee: Seema Verma



Powers of CMS:

- Federal agency under the HHS office that administers Medicare and in coordination with state governments Medicaid.
- As the largest health insurance payer in the United States in terms of covered lives and payment.
- Under the past administration, the CMS has been at the forefront of shifting payment models from a fee for service model to value based compensation structures.
- Through the Affordable Care Act, CMS had launched a number of pilot initiatives to concept test various healthcare modernization strategies.

Who is Seema Verma

- President and founder of healthcare consulting firm SVC, Inc, her firm has worked with a number of state governments regarding public health, Medicaid, and insurance policies.
- Under vice president elect Mike Pence, and former governor of the state of Indiana, she helped develop a consumer directed Medicaid program called Healthy Indiana Plan (HIP).
- Ms. Verma has also been commissioned for her consultative services by the states of Iowa, Ohio, Kentucky, Michigan, and Tennessee.

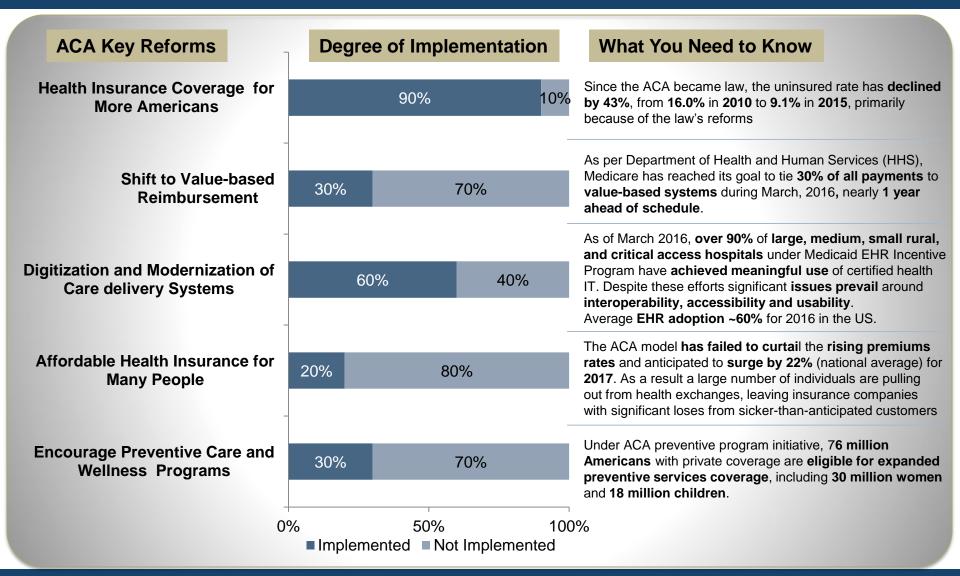
Background on Healthy Indiana Plan (HIP)

- HIP 2.0 under Governor Pence was unique in its emphasis on personal responsibility.
 Enrolees to the program were required to make contributions ranging from \$1-27 a month that went into a Health Savings Account (HAS) like pool that could be applied towards personal wellness services.
- Receiving a \$2,500 deductible health plan along with a \$2,500 HAA like account was intended to incentivize enrolees to think judiciously about the choices they made.
- Article co-authored by Ms. Verma on the benefits of the plan: <u>Healthy Indiana 2.0 Is</u>
 <u>Challenging Medicaid Norms</u>

What it could mean for the ACA:

- A While the Affordable Care Act expanded funding for Medicaid programs, those funds came with certain requirements and had to be executed by the states. While many Republican leaning states chose not to participate, some like Indiana customized plans for their state. Requiring federal approval, the Obama administration's approval of the Indiana plan demonstrated a degree of flexibility in working with individual states.
- Given Ms. Verma had worked with various states to optimize Medicaid expansion for their state's population, it is possible rather than repeal of expansion which many had been assuming we could see the office work with the states currently not participating to devise an approach similar to Indiana's for their state.

ACA key reforms measures and their degree of impact to date



ACA Provisions – Likelihood of Repeal or Amendment

President Trump's vague vision on Healthcare reforms will continue to keep the industry trading waters

Selected Provisions	Likelihood of Repeal/Amendment	Analyst Comment
Individual and Employer Mandate	LowHigh	Potential to eliminate the individual and employer mandates through the budget reconciliation process. This may preclude ACA's incentives to maintain health insurance coverage through penalty mandates.
Cadillac Tax	LowHigh	This tax has never been popular and has been delayed to go into effect in 2020. Likely to receive bipartisan support from house representatives to reform and/or repeal of this provision.
Public Health Exchanges	Low High 1 2 3 4 5	Considering only about 4% of American registered on the health exchanges, President Trump's administration will more likely dismantle the state level Public Health Exchanges model with structured legislative reforms to promote free market driven price transparency on insurance policies.
Wellness Program Incentives	Low High 1 2 3 4 5	The administration possibly amend the wellness and preventive care initiatives and link the incentives to Health Savings Accounts (HSAs) which is has been a central to the Republicans' health reform approach as they plan to expand the HSAs for all Americans.
Medical Device Excise Tax	LowHigh	In June, 2015, this tax had already been suspended until 2018 with 46 Democrats and 234 Republicans votes. It is nearly a certainty this suspension of the tax is made permanent.
Medicaid Expansion	Low High 1 2 3 4 5	A sticking point for many states who have openly sought to defy the ACA, the Trump administration could alter the bill to give greater freedom to the states in choosing how to manage their Medicaid dollars.
Lower Prescription Drug Costs	LowHigh	Free market policies could revert efforts in controlling prescription drug prices. Proposals which sought the government to wholesale bargain with companies, allowing the importation of drugs, and creating greater transparency into the drug costs could be abandoned.

7 Ways Trump Could Impact Healthcare Reform

Trump's healthcare plan will be focused on lowering costs and driving competition

#	Key Themes	Likely Action Plans
1	Structural Amendment to ACA	 Coverage for pre-existing conditions and dependents up to age 26 covered by parents provisions will remain. Remove the Individual and Employer Mandate, as no one should be forced to buy health insurance. Reduce the growth rate of Medicare spending by implementing new taxes and fees.
2	Emphasize the use of Health Savings Accounts	 Expand Health Savings Accounts (HSAs) to for all individuals, where the contributions would not only be tax-free but will also accumulate over time. Allow HSAs to become a part of a person's estate and would be passed on to heirs without any penalty.
3	Making premiums tax deductible	 Allow individuals to fully deduct their premiums from their tax returns under the current tax system, facilitating a free market to provide insurance coverage to companies and individuals. May abolish APTCs and let individuals use pre-tax money to purchase individual market insurance. The aim is to provide people with an incentive to pay for coverage when they are healthy, and not make it mandatory.
4	Funding Medicaid through block- grants	 Dismantle State Health Exchanges and fund Medicaid all over the country through block grants Under this, the federal government would give a fixed amount of money to states and let them fund their programs. The rationale behind this is that state governments know best about their population and should have the sole authority on how the money should be spent and will fare better without federal administration overhead.
5	Health insurance companies to sell plans across states	 Allowing health insurance companies to sell their plans across the state lines - Any vendor that complies with the state guidelines can offer insurance plans in that state. Objective is to promote a competitive environment, to optimize the insurance cost and customer satisfaction.
6	Increased price transparency	 The goal is to make individuals aware of the best prices of procedures, tests, and other medical procedures. How and to what effect will it be implemented is uncertain so far, thus impacts of this are unknown.
7	Free market for drug providers	 Donald Trump believes that the cost of care could be reduced to a great extent if Medicare negotiated with pharmaceutical companies. He wants to remove the existing barriers to entry into the free markets for drug companies.

Opportunities & Challenges – Pharma & Biopharma

Short-term relief on prescription drug pricing restriction; Long-term possible negative impact on supply chain and operation

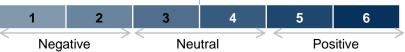






- Apparent relief that aggressive drug price restrictions will not be imposed in the near term.
- Drug-importation: Pharma will continue to lobby hard to block these legislations. Some states could push through with restrictions on country of origin (Canada or European locations are most favored). Hence impact would be modest.
- Tax: Both Congress and Pharma need significant dialogue and alignment on tax issues. Repatriation (if any) would be capped and will increase M&A deal volumes.
- FDA: In general, Trump administration is expected to review/loosen FDA's NDA processes that lead to high drug development costs. Even a relatively small (3-5%) drop in clinical development costs can positively impact pharma industry's bottom line.

- Possible restrictions on global trade new tariffs or custom duties may be instated, driving up prices of imported product and negatively affecting supply chains for foreign drug manufacturers with operations in the United States.
- More power may be bestowed to Medicare to negotiate drug prices.
- Number of insured people could decrease, which would impact prescription fills and adherence.
- TPP: This is dead deal. It would have helped pharma to retain 12 year exclusivity and put a firewall against back drop of extensive biologic patent expiries during 2017-2020. This will increase competition and erode bottomline.



Opportunities & Challenges – Medical Technologies

Likely repeal of the pending medical device excise tax

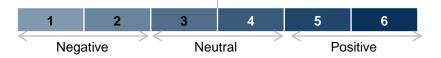






- Possible amendments to suspension or further delay the medical device excise tax.
- More regulatory relaxation for companies focused on consumer health products
- Trump will likely lower US corporate tax (which is among the highest in the world); this will benefit large cap medical technology companies that are earlier in their development cycle with major operation and sales in the US market (such as Baxter International, Edwards Lifesciences, Intuitive Surgical and Zimmer Biomet).
- Medical technologies companies will be in an unique position to integrate and build healthcare networks to capture data, report outcomes and increase adherence.

- More likely trade restrictions from low cost medical device manufacturing hubs such as Mexico, China and other Central/South American countries will negatively affecting supply and operating cost of medical device OEMs operational in the United States.
- Increased budget constraints for hospital under bundled payments will force Health systems to pass this pricing pressure and performance risk to medical devices and imaging OEMs.
- More liberal regulations will reduce the entry barrier for non-traditional companies increasing the competition for traditional players.



Opportunities & Challenges- Diagnostics

Limited disruptions in the short-term subjected to uncertain around future policies and guidelines

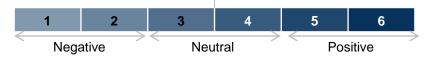






- Trump's administration may delay implementation of recently proposed CMS' preliminary pricing plan that aims to reduce payments for multiple molecular tests in 2017.
- President Trump aims to provide a retail like experience for healthcare services; considering this innovative and clinically vetted DTC diagnostic testing services are expected to thrive under his regime.
- Trump's administration may also consider to reassess or further delay, recently proposed FDA risk-based regulatory framework for LDTs affecting 60,000 genetic tests and 2000 different laboratories in US.
- Diagnostic manufacturers large and small will benefit immensely from permanent repeal of the Medical Device Excise Tax.

- May impair Obama administrative driven federal funding for Precision Medicine Initiatives (PMI) which is a key growth driver for molecular diagnostic and emerging genomics test.
- Possible changes to ACA preventive care mandates and incentives, may reduce the overall volume for diagnostic screening tests impacting the revenue for diagnostics labs.
- Measures towards pricing transparency could accelerate a pricing war between several laboratories offering laboratory services and clinical diagnostic tests.
- Emerging testing technologies primed to support value based care shifts could be in limbo as the industry pauses for greater clarity on how those might be amended.



Opportunities & Challenges– Healthcare IT

Limited disruptions in the short-term subjected to uncertain around future policies and guidelines

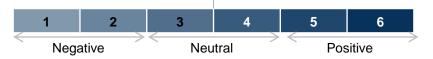






- Trump administration will have negligible effect on current healthcare information technology policy initiatives already in motion.
- Digitally-enabled healthcare transformation will stay the course so we can expect limited disruption in the need to continue investments in EHR, Patient Engagement, RCM, cybersecurity, data analytics, population health management, and other core health IT solutions.
- Three key health IT market segments expected to emerge in a stronger position under President Trump include; health insurance IT especially health insurance marketplaces; consumer health IT; private health insurance exchanges, and telehealth.

- Increasing security risks will encourage the federal government to expand surveillance technologies, leading to potential legal and ethical conflicts.
- NIH funding may be cut and projects like the Cancer Moonshot, Precision Medicine, and the Center for Medicare and Medicaid Innovation may be scaled back.



Opportunities & Challenges-Providers (Hospitals)

More push for bundled payment models; In a future where cost is paramount, having meaningful control over care delivery will be a key differentiator.

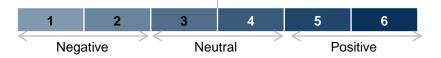






- Like other sectors, possible ACA repeal or amendments may reduce the taxes and lower payment rates for hospitals.
- Hospitals that have already invested in transparent pricing systems or currently providing bundled pricing for healthcare services will have a competitive edge subjected to limited disruptions due to future uncertainties.
- Federal requirements may replace piecemeal transparency approaches at the state level.
- Unlike the ACA, MACRA the new Medicare physician quality payment program, which is the result of broad bipartisan agreement and is therefore unlikely to be altered.

- With a Trump administration we will see increased emphasis in attention to balance sheets and cost cutting across the healthcare ecosystem.
- Repeal and amendment of ACA will increase the uninsured rates which would reduce revenues and increase uncompensated care for hospitals.
- Hospitals with higher Medicare population and subsidies may face higher uncertainties if GPO pushes to shift towards premium –support models.
- Implementing additional reforms and amendments into to existing ACOs framework will be a complex and time consuming task for large health systems while incurring a lot of overhead.



Opportunities & Challenges- Payers

Maximum disruption in the near-term; more opportunity with open market policies and transparent pricing

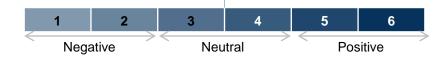






- Open market policies to allow health insurance companies to sell their plans across the state lines will increase market penetration for dominate players.
- Trump along with the Speaker of the House, Paul Ryan may attempt to privatize Medicare which may create new opportunities for commercial insurance companies.
- Dealmakers believe President Trump will favour domestic M&As; which may bring new dynamics into recently blocked mega mergers between Anthem-Cigna and Aetna-Humana Mergers

- Dismantling health insurance exchanges will result in short-term loss of the enrolees in Medicaid managed plans under Medicaid expansion
- Competition could increase and drive down margins as out-of-state insurers now compete for in-state enrolees.
- Consumer-centric insurance plan will make them savvier shopper and in long-run will lower the costs for covered services leaving payers with very thin margins.



Opportunities Challenges- Consumers

Promise to make healthcare more consumer-centric

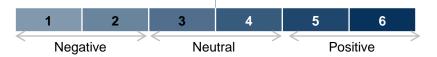






- Continuation of ACA provision to provide coverage for pre-existing conditions and dependents up to age 26 covered by parents provisions
- Trump's administration will support consumer-driven health plans by providing increased choice with tax deductible portable and affordable incurrence plans.
- Extension of HSAs for all individual will provide more flexibility to young and healthy individuals to optimize their premium amount by putting their money in a special fund, without paying any federal taxes.
- Trump administration is likely to enforce a six weeks of paid leave following childbirth for women whose employers do not offer paid maternity leave benefits.

- By replacing Public Health Exchanges 25.1 million people would lose their insurance, including 5.5 million of those who would have been eligible for Medicaid in ACA days.
- Adding a tax deduction will result in 15.6 million fewer people getting health insurance.
- Funding Medicaid through block-grants may result in major budgetary cut for some states healthcare spending.
- More than 80% of ACA customers receive federal subsidies to pay for their premiums, possible repeal or amendment will significantly affects them.



What to Watch Out for in the Next 100 Days



What Initiatives will be Stated by New Heads of CMS and HHS

Executive appointments to key leadership positions such as HHS, CMS, and FDA will have significant autonomy in implementing future initiatives. President elect Trump seems inclined to focus on big picture themes and delegate the majority of execution to his staff.

Inauguration and Day 1 Pledges

Already backing off certain campaign pledges on executive orders he would enact on day 1, President Trump could initially target issues of interest to social conservatives such as abortion and reproductive rights as opposed to key elements of the ACA.

Open Enrolment & Public Exchanges

The election has created significant uncertainty as to the long term viability of the public exchange marketplace. Many states including those that voted for Trump in a majority are in favour of keeping Medicaid expansion measures of the ACA.

Health Plan Mega Mergers

Proposed mergers between Anthem and Cigna, as well as Aetna and Humana will head to court over the next several weeks. The pending administration shift could impact how the payers approach their cases.

Affordable Care Act Taxes

Taxes on high cost health insurance plans (Cadillac Tax), medical device excise tax, employer and individual mandates, medical deduction threshold, and other measures are now under potential for repeal.

Future Policy Specifics

By February or March of 2017, there should be greater clarity from the administration on their own plans for replacing elements of the ACA, and timelines for implementation.