Washington Healthcare Life Sciences Conference

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Affordable Care Act – Repeal Outlook
Timeline for ACA Repeal

Reconciliation Process

- Budget Resolution passed in January Establishes Framework
- Avoids the need for 60 votes to overcome a filibuster in the Senate
- Only Budget related provisions can be included, and, therefore additional legislation may be needed to address health insurance regulatory changes
- House leaders released Repeal/Replace plan on March 6
- House Committee Markups on March 8
- House Budget Committee markup on March 16
- House Rules Committee markup week of March 20
- Full House vote by end of March?
- Senate action in April?

Implementation of a Replacement Health Care Plan (Transition of at least 2-3 Years)

- Additional Replacement legislation may be needed (piecemeal over the next 12 months)
- Transition Period of 3+ years – to limit disruption for existing individuals in Exchange Plans / Medicaid Expansion (However, Conservatives in the House would like to see a shorter transition period of 1 year)
- Even with transition period – it is unclear if insurers would want to stay in exchanges in 2018 if they are likely to be repealed (Several have already announced plans to exit in 2018)
- Sensitivity to States – Particularly Medicaid Expansion state with large numbers of enrollees
  - Includes many Republican Governors who have supported Medicaid Expansion
- Sensitivity to Elections in 2018

Source: BofA Merrill Lynch Global Research
President Trump – Healthcare Proposals

Executive Order Issued on January 20, 2017

- Calls for Agencies to exercise all authority and discretion to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA — Executive Order is fairly broad but, could be used to slow or halt the implementation of several provisions of the Affordable Care Act, most notably, the individual and employer mandates. Since these mandates have already taken effect, the Administration could revise hardship exceptions, or modify enforcement timing of any penalties.

- Calls for agencies to exercise all authority and discretion available to them to provide greater flexibility to States and cooperate with them in implementing healthcare programs. We note that this section likely means greater flexibility in implementing Medicaid waivers where possible, as well as other state based health reform efforts.

- Calls for agencies to encourage the development of a free and open market in interstate commerce for the offering of healthcare services and health insurance.

- Requires that any changes in regulation should comply with notice-and-comment rulemaking, and comply with the Administrative Procedure Act. This likely means that any significant modifications to the ACA will likely develop over time as HHS and Treasury develop regulatory modifications that will include comments from industry.

Source: White House, BofA Merrill Lynch Global Research
American Health Care Act (House Republican Repeal/Replace)

Medicaid Provisions

- **Eliminates Medicaid Expansion Funding** – effective 2020
  - Grandfathers individuals so long as they stay on Medicaid (without a 30 day break in coverage)
- **Per Capita Caps** based on 2016 Medicaid spending increased by CPI-Medical to 2019 levels – effective 2020
- **Medicaid DSH Cuts** – repealed for non-expansion states; and repealed in 2020 for expansion states
- **Safety Net Funding** – $10 billion over 5 years For non-expansion states
- **Repeals essential health benefits requirements for Medicaid** - Effective in 2020


- **Modifies ACA Premium Subsidies** – in 2018-2019 – increasing subsidies for individuals under 50; decreasing subsidies for individuals over age 50;
- **Repeals ACA Premium Subsidies and Cost Sharing Subsidies in 2020**
- **Patient and State Stability Fund** -- $100 billion in funds to stabilize individual health insurance markets, high risk patient funding, reinsurance funds, patient cost sharing, etc. over 9 years (2018-2026) – with $15 billion each year in 2018 & 2019; and $10 billion per year 2020-2026
- **Revises community rating bands** – from 3:1 to 5:1 effective in 2018 (subject to state options)
- **Repeals actuarial value standards** for health plans effective 2020
- **Repeals Individual and Employer mandates** – Effective retroactively to 2016
- **Continuous Health Coverage Incentive** – Includes a 30% penalty for individuals without continuous coverage effective 2019

Source: BofA Merrill Lynch Global Research
American Health Care Act (House Republican Repeal/Replace)

New Tax Credits / HSA Provisions

- **New Tax Credits available** – effective 2020
  - Age based: $2,000 (under age 30); $2,500 (30-39); $3,000 (age 40-49); $3,500 (age 50-59); and $4,000 (over age 60)
  - Indexed to CPI + 1%
  - Tax credits phase-out for income over $75,000 (or $150,000 for joint filers)
  - Tax credits available for any individual health plan – on or off exchanges; or for short-term medical

Repeal of ACA Tax provisions

- **Repeals Medicare Payroll Tax increase / Net Investment Income Tax** – Effective 2018
- **Reinstates employer tax deduction for Part D retiree subsidy payments** – Effective 2018
- **Cadillac tax delayed until 2025**
- **Repeals Health Insurance Industry fees** -- Effective 2018
- **Repeals 2.3% Medical Device Industry fees** – Effective 2018
- **Repeals Pharmaceutical industry tax** – Effective 2018
- **Repeals OTC drug exclusion from HSA and FSA reimbursements** – Effective 2018

Source: BofA Merrill Lynch Global Research
American Health Care Act (House Republican Repeal/Replace)

Estimated Medicaid Reductions in House Republican Draft, $Billions (2018-2027)

Source: Center on Budget and Policy Priorities
Comparison of Subsidies in ACA vs. Tax Credits in House Republican Draft, 2020

Source: Kaiser Family Foundation Analysis
American Health Care Act (House Republican Repeal/Replace)

Provisions not included

- Revisions to Health Insurance Regulations – Since Procedurally not able to be included in Reconciliation
- Revisions to minimum essential health benefits
- Sale of insurance across state lines
- Medicare payment reductions (MB cuts / productivity factor cuts)
- Provider payment reforms repealed (Home health, Hospice, DME, etc)
- Other revisions to payment reforms (VBP, Readmissions penalties, HACs, bundled payments, ACO efforts, etc.)
- Biosimilars pathway authority
- Drug pricing provisions
- Medicare Part D donut hole coverage
- Limit on Tax Exclusion of Employer Provided Health Benefits (included in earlier versions)

Source: BofA Merrill Lynch Global Research
American Health Care Act (House Republican Repeal/Replace)

Modifications to Republican House AHCA

- Revise Medicaid Expansion Phase-out to be sooner / Pure Block Grant Option for States
- Revise Tax Credits
  - Increase means testing of tax credits (adjust by income levels)
  - Include geographic adjustments (key for high cost areas such as Alaska)
  - Increase overall levels of tax credits
- Revise / eliminate Continuous Coverage Penalty
  - AHCA would call for a 30% premium penalty if uninsured in previous 12 months
  - Provision may need to be removed to meet Byrd rule requirements
  - Health insurers are concerned that the penalty will limit enrollment — instead of encourage enrollment
- Insurance Regulatory Reforms
  - Most insurance regulatory reforms are not addressed in AHCA, but, Actuarial value requirements and shifting to 5:1 age rating bands (from 3:1) is included
- Elimination of Planned Parenthood funding under Medicaid
  - Provision may be stripped out — particularly in the Senate
Congressional Budget Office Score of AHCA

Health Care Coverage

- Estimates 14 million in reduced coverage in 2018;
- **24 million fewer covered in 2026**
  - Significant reductions in Medicaid coverage (14 million fewer Medicaid enrollees in 2026)
  - HC Exchange/Individual enrollment declines by 6 million in 2018, but, rebounds to only a 2 million decline in 2026
  - Employer-based coverage declines by 7 million in 2026

Budget Savings / Tax Cuts

- Overall deficit reduction of $337 billion over 10 years
- Tax reductions of $882 billion over 10 years
- Reduced coverage costs of $1.2 trillion over 10 years

Premium Increases

- CBO estimates individual market premiums will rise by 15-20% in 2018-2019 compared to current law
- However, by 2026, premiums will be roughly 10% lower than current law
- CBO notes that the individual insurance market will remain stable either under current law, or under AHCA

Source: BofA Merrill Lynch Global Research
AHCA – Medicaid Reform Efforts

Phase-down in Medicaid Expansion Matching Funds

- AHCA bill includes a phase-out of Medicaid matching funds for Expansion states – beginning in 2020 (likely will take 2-3 years for all Medicaid expansion enrollees to phase-off
- Opposition from Governors who have expanded Medicaid, including 16 states with Republican Governors
- CBO estimates total Medicaid expansion funding over 10 years = $1 Trillion (2018-2027)
- This issue remains a key problem for many Republicans in the Senate

Movement to Medicaid Block Grants or Per-Capita Caps, with State Flexibility

- Legislation includes capping federal Medicaid spending growth (as a per capita capped block grant)
- Eliminates essential health benefit requirements for Medicaid programs
- Key issues to be addressed:
  - Whether to set overall or per-enrollee caps;
  - What categories of Medicaid spending and eligibility categories to include in the spending limits;
  - Establishing a base year and what growth factor to use to increase the caps over time (CPI-Medical)
  - How much flexibility to grant to states to make changes to the program; and
  - States that have expanded vs. states that have not expanded Medicaid

Source: BofA Merrill Lynch Global Research
Medicare Reform—Not Included in AHCA Legislation

Medicare Premium Support

- Proposal has been championed by Speaker Ryan (and Tom Price) in the past, and would call for phasing in a competitive market for Medicare health plans to compete more directly with Medicare Fee for Service
- Potential to limit Medicare spending growth over long-term by capping government contribution (CPI+1%)
- Proposal calls for phasing in a competitive market for Medicare health plans, including competition for FFS Medicare
- Democrats remain staunchly opposed
- May not generate any near term savings – given long lead time
- Trump has not endorsed any Medicare reforms

Range of Other Medicare reforms not addressed:

- Revise and delay Medicare/Medicaid DSH reductions;
- Other payment adjustments – MB cuts, productivity factor reductions, etc.
- Repeal IPAB;
- Repeal / Limit CMMI;
- Repeal ban on physician owned hospitals;
- Increase eligibility age for Medicare to age 67, beginning in 2020.
Regulations to Limit Burden of ACA / Stabilize Marketplaces

Proposed Market Stabilization Efforts

- Regulation issued on February 15

- Provisions include:

  - Revised Open enrollment period to be November 1 to December 15 (previously, the open enrollment period was expected to be November 1 to January 31)
  - Special Enrollment Period Pre-Enrollment Verification
  - Guaranteed Availability - Allow issuers to apply a premium payment to an individual's past debt owed for coverage from the same issuer enrolled in within the prior 12 months
  - Revised Actuarial Value Levels of Coverage - Allow plans greater flexibility in benefit design by increasing the de minimis variation in the actuarial values increased to -4/+2%
  - Network Adequacy - Proposal would revise network adequacy review for qualified health plans (QHPs).
  - Essential Community Providers – Modify process to identify essential community providers (ECPs) who are not on the HHS list of available ECPs for the 2018 plan year; and also lowers the ECP standard back down to 20% (from 30% required ECPs).

- Other Modifications could come through revised guidance:

  - Modifications to Risk Adjustment model could be implemented in 2017 vs. 2018
  - CMS has already extended deadline for health plans to participate in Exchanges (back to June 21 from early May);
  - Administrative relief for health plans from mandatory quality reporting, benefit requirements, etc.

Source: White House, BoF A Merrill Lynch Global Research
Regulations to Provide More State Flexibility Under Medicaid

State Medicaid Flexibility Guidance from HHS/CMS

- **Guidance letter to Governors on March 14:**
  - States that “the expansion of Medicaid through the ACA to non-disabled, working age adults without dependent children was a clear departure from the core, historical mission of the program.”
  - Notes that the higher federal match rate for Medicaid expansion “deprioritized” other populations.

- **CMS encourages the use of Waiver and Demonstration requests by states:**
  - Will look to speed the process for states, with “fast-track” approval of waiver and demonstration extensions;
  - More consistent in approval of waivers, where states have been approved for similar approaches in other states.
  - Intends to use Section 1115 waiver authority to allow states to implement employment/training requirements.
  - Align Medicaid benefit design with private plan benefit design:
    - To include cost-sharing and HSA models for individuals of all income levels
    - Facilitate premium support models / enrollment in employer-sponsored plans
    - Premium contribution requirements
    - Waivers of non-emergency transportation benefit requirements; ER copayments
    - Waivers from requirements such as presumptive eligibility and retroactive coverage
  - Provide additional time for states to comply with HCBS transformation
  - Provide states with more tools to address Opioid epidemic with Section 1115 substance abuse treatment waivers

Source: White House, BofA Merrill Lynch Global Research
Additional Regulatory Actions Upcoming – “Phase II”

Additional Regulatory Actions from HHS/CMS

- Additional market stabilization rule, likely in mid-April.
- Additional regulation addressing essential benefits.
- Proposal allowing for "direct" enrollment, allowing insurance agents to log on to a health insurer's website to help the consumer enroll.
- Giving states more flexibility to restrict special enrollment and grace periods for paying premiums.
- Regulation to allow "Section 1332" waivers, in which a state can opt out Obamacare requirements
  - Allow states to reduce Medicaid expansion coverage down to 100% of FPL vs. 138% requirement

Source: White House, BofA Merrill Lynch Global Research
Additional Legislative Actions – “Phase III”

Additional Legislation Proposed by Congressional Republicans - As Part of Replacement Efforts

- McCarran-Ferguson Act reforms – Eliminating the Anti-Trust exemptions for health insurers;
- Small Business Fairness Act - Allowing for Association Health Plans’
- The Protecting Access to Care Act, which would ban the federal government from regulating stop-loss insurance;
- Trump Administration has also called for the following Legislative Proposals as well:
  - Sale of insurance across state lines;
  - Removing current healthcare law’s regulations on insurance;
  - New legal reforms to cut costs for patients and doctors;
  - Addressing Prescription Drug Costs.

Source: White House, BofA Merrill Lynch Global Research
Alternative Payment Models / Medicare Payment Reforms to Continue

Likely to See Continued Movement Towards APMs (ACOs, Bundled Payment, Value Based Purchasing, etc.)

- Currently 359,000 clinicians participating in APMs;
- 12 million Medicare beneficiaries served through APMs;
- 572 ACOs operating as of January 2017
- 131 ACOs now operating in a risk-bearing model

CMMI / Bundled Payments

- HHS Secretary Tom Price has been opposed to broad authority for CMMI Demonstrations
- CMS has announced a delay in the implementation of the expansion of CJR and Cardiac bundled payment program (slated to begin July 1, 2017)
- Calls for limiting size and scope of demonstrations – focus only on voluntary demonstration – Not Mandatory
- Calls for Congressional approval to expand any demonstrations
- Particular concern over Medicare Part B Drug Demo
- Opposed mandatory bundled payment demonstration: Comprehensive Care for Joint Replacement Model

Independent Payment Advisory Board

- HHS Secretary Price (along with most all Republicans) have opposed IPAB

MACRA – Value Based Purchasing / Alternative Payment Models for Physicians

- Concerns over regulatory impact of requirements placed on physicians
- But, MACRA has strong bi-partisan support

Source: HHS, BofA Merrill Lynch Global Research
AHIP Priorities for Repeal and Replacement:

- **Ensure no disruption in coverage** – maintaining cost sharing subsidies, and premium subsidies
- **Maintain market stability and consumer choice** – in both 2017 and 2018. Funding temporary, transitional programs, including cost-sharing reductions and reinsurance, through at least January 1, 2019.
- **Make reinsurance payments for 2016 as originally intended.**
- **Eliminate Health Insurance industry Tax and PCORI tax.**
- **Implement pre-enrollment verification** for consumers who sign up for coverage during special enrollment periods.
- **Limit inappropriate steering of Medicare/Medicaid enrollees** into the commercial insurance market.
- **Incentivize continuous coverage.** Replacing the individual mandate with strong, effective incentives, such as late enrollment penalties and waiting periods.
- **Promote risk pool stability through establishment of a transitional risk pool program (2017-2018)**
- **Maintain sufficient funding in Medicaid.**
- **Extend the timelines that health plans must meet.** Under current federal rules, health plans must file exchange products for the 2018 marketplace by May 2017 – Ensure that Exchange Plans have better outlook for 2018.
- **Consider actuarially sound methods for funding high-risk pools** or other risk mitigation arrangements.
- **Reduce rules, regulations, and red tape** in the areas of network adequacy, quality reporting, benefit offering requirements, grace periods, RADV, rate review, Summary of Benefits and Coverage, Renewal Notices and language taglines.

Source: AHIP
Other Key Health Care Policy Issues
Pharmaceutical Pricing Issues

**President Trump has at times called for Medicare to negotiate drug prices**

- Trump could try to extract voluntary agreements to limit drug price increases from Pharma CEOs – Some companies have already agreed to limit drug price increases
- Trump more recently has been working with Congressman Elijah Cummings (D-MD) on drug price negotiation efforts
- Republicans have historically opposed direct price negotiations, and Republican leaders (Ryan, McConnell, Hatch, and even Tom Price have been staunch supporters of Pharma)
- However, there are a few potential legislative efforts that have bipartisan support:
  - Efforts to speed generic drug approvals through FDA
  - Efforts to limit Branded drug companies from using Citizen’s Petitions or REMS process to limit Generic competition
  - Limit Branded-Generic Drug settlement agreements
  - Drug re-importation (not likely to pass)

**Administrative Actions from CMS / HHS to address Drug Prices**

- FDA Regulatory modifications – efforts to speed drug development / generic drugs
- CMMI Demonstrations for Part B or Part D
- Target Medicare Part B drug payment reforms – MedPAC has offered recommendations

**User Fee legislation (Must pass by September 30, 2017)**

- Prescription Drug / Medical Device / Generic Drug / Biosimilar User Fees
- May be a vehicle for legislative action

Source: BofA Merrill Lynch Global Research
President Trump Highlighted Several Areas of Interest:

- Looking to lower drug prices through more competition
- Speed development time for new drugs at FDA
- Reduce regulatory burden from FDA on pharma
- Move drug production/manufacturing back to US. Amgen reportedly agreed to add 1,600 jobs.
- Limit countries from “freeloading” with foreign price controls. Not clear what the mechanism will be for accomplishing this.
- Trump noted that he will be naming a new FDA Commissioner “soon”, who will look to streamline the Agency

Trump did not Endorse Medicare Drug Pricing Negotiations or Discuss Re-Importation

- Trump did not endorse his earlier support for Medicare Drug price negotiations – even arguing that “price fixing by Medicare” is part of the problem. He stated that he will “oppose anything that makes it harder for smaller, younger companies to take the risk of bringing a produce to a vibrantly competitive market.”
- Trump also did not discuss Re-importation of drugs from Canada or other countries, which he has supported in the past.

Overall, Fairly Benign Meeting / Positive View from PhRMA

- No new drug pricing proposals announced (or even previous proposals endorsed), and Trump focused helping to speed drug development through FDA, and looking to provide more competition – likely again looking to efforts to help generic drug approvals, and get to market sooner.
- PhRMA stated that the meeting was positive, noting that the focus was on Jobs, taxes, trade and regulations. PhRMA noted that industry growth could lead to 350,000 American jobs over next 10 years. And, will look to work with Trump Administration and Congress on “market-based” reforms to improve affordability of medications.

Source: BofA Merrill Lynch Global Research
Medicare and Medicaid and CHIP Program provisions to be extended (by September/December 2017)

- Medicare extenders include:
  - Ambulance add-ons
  - Extension of Home Health Rural Add-On
  - Medicare Part B therapy exceptions
  - Medicare Dependent Hospital Program extension
  - Extension of Work Geographic Practice Cost Indices Floor
  - Extension of Increased Inpatient Hospital Payment Adjustment for Certain Low-Volume Hospitals
  - Extension for Specialized Medicare Advantage Plans for Special Needs Individuals

- CHIP reauthorization – expires at end of FY2017
- Other Medicare/Medicaid proposals may also be included as offsets:
  - Post-acute VBP,
  - Hospital outpatient/site-neutral proposals
  - MedPAC recommendations for payment reforms/cuts for SNFs, IRFs, Home Health

Source: BofA Merrill Lynch Global Research
Additional legislation that will be addressed in 2017

Tax Reform Efforts

- Likely to see Corporate Tax Reform move in Congress in 2017 – could be paired with infrastructure spending
- Speaker Ryan would like to complete Tax Reform by August – This may be Optimistic
- Including:
  - One-time tax on overseas held cash
  - Reduce corporate rates down from 35% to 15-20%
  - Move away from worldwide taxation to territorial tax system
  - Include Border Adjustments (Import taxes)
- However, significant hurdles remain, including whether to include individual tax reforms, border adjustments, interest deductibility, other corporate tax reforms several very controversial elements

Source: BofA Merrill Lynch Global Research
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