

2016 Federal Election Primer



The key races, and what they mean for
healthcare policy.

Overview

➤ **The White House**

- A presidential election defined by a volatile electorate

➤ **The Senate**

- Several Senate Republicans are defending seats in blue states
- Down-ballot voting in key races could determine Senate control

➤ **The House**

- House Republicans should maintain a majority, which likely portends some form of divided government



Campaign Projections

- Take everything you knew about presidential elections and throw it out of the window
 - This election is unlike any other in modern history, as most analysts expected Hillary Clinton to cruise to the Democratic nomination and Donald Trump to be little more than a sideshow

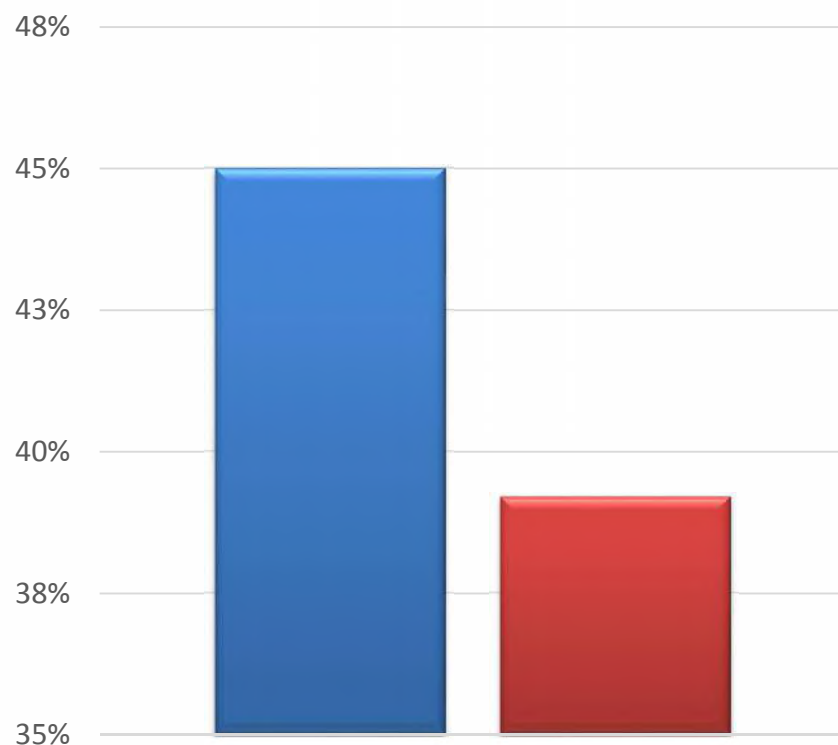
- The most likely outcome – regardless of who wins the White House – is the Senate remaining nearly evenly split and the House continuing to be led by Speaker Paul Ryan (R-WI)

- Thus any major healthcare legislation must have bipartisan support to get 60 votes in the Senate and be sent to the new President's desk



Current General Election Polls

National Average 6/2 – 6/19



Clinton v. Trump

Source: RealClearPolitics Polling Average

Battleground States

| State | Clinton | Trump |
|--------------|---------|-------|
| Florida | 45.0% | 42.0% |
| Ohio | 43.0% | 40.3% |
| Pennsylvania | 43.0% | 42.5% |
| Virginia | 43.8% | 39.8% |
| Wisconsin | 45.0% | 34.0% |



Historical Polls

| Year | Democratic Candidate - June % | Republican Candidate - June % | Democratic Candidate – Actual (Popular Vote) | Republican Candidate – Actual (Popular Vote) |
|------|-------------------------------|-------------------------------|--|--|
| 2000 | Al Gore – 41% | George W. Bush – 46% | Al Gore – 48.4% | George W. Bush - 47.9% |
| 2004 | John Kerry – 49% | George W. Bush – 43% | John Kerry – 48.3% | George W. Bush – 50.7% |
| 2008 | Barack Obama – 48% | John McCain – 41% | Barack Obama – 52.9% | John McCain – 45.7% |
| 2012 | Barack Obama – 47% | Mitt Romney – 45% | Barack Obama – 51.1% | Mitt Romney – 47.2% |

Source: Gallup Polling – Early June



Demographics

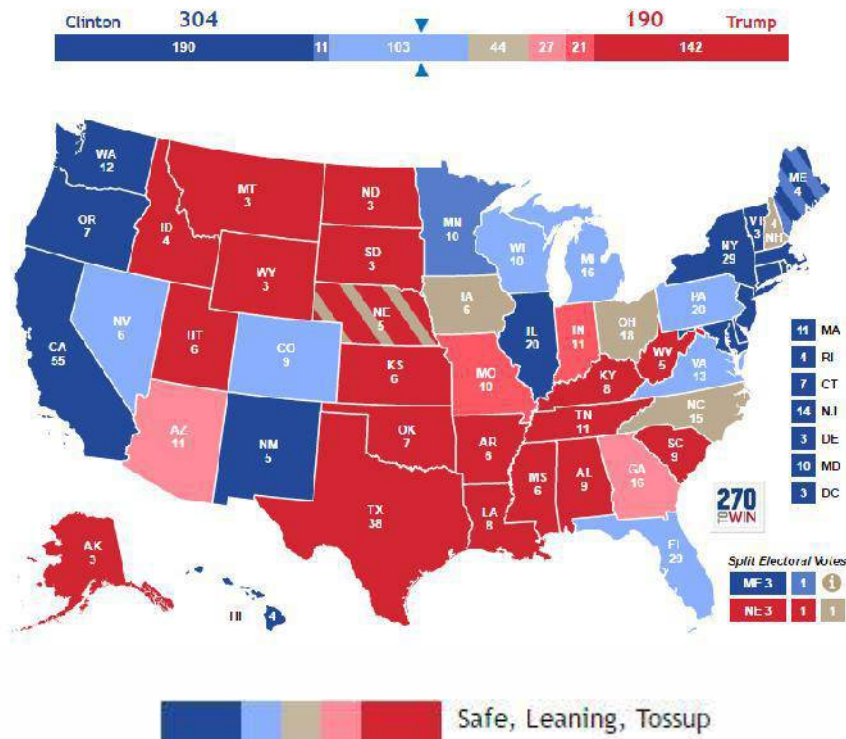
- Traditional demographic trends give advantage to Democrats in swing states with high minority populations
 - Polls suggest Trump will lose Hispanic, African-American, and Asian populations by wide margins to a Democrat candidate, even compared to President Obama's victory in 2012
 - Could be a deciding factor in New Mexico, Colorado, Nevada, Virginia, and even Republican-stronghold Arizona

- But Trump's populist strategy is geared toward bringing traditionally-blue Rust Belt states into play
 - Wisconsin and Pennsylvania have not voted for a Republican president since 1988, but are considered competitive this November



Electoral Predictions

Current Battleground Map



2012 Electoral College Results



Source: Cook Political Report, 5/25/16



Democratic Healthcare Priorities



Hillary Clinton

- Supports direct negotiation with Medicare
- Reduce biologic exclusivity from 12 to 7 years
- Support bundled payments and other delivery system reforms
- Defend and build on ACA to further reduce uninsured



Bernie Sanders

- Supports direct negotiation with Medicare
- Extend Medicaid drug rebates to Part D
- Close Part D coverage gap for brand and generics by 2017
- Adopt single payer, “Medicare for All” system



Trump Healthcare Priorities

| Donald Trump | Other Republican Positions |
|---|---|
| <ul style="list-style-type: none"> • Highly varied views on health policy • Support Medicare direct negotiation • Opposes cuts to Medicare /Medicaid • Repeal ACA | <ul style="list-style-type: none"> • Support value-based payments in Medicare • Oppose any price controls • Accelerate approval for drugs that have already been approved in other countries • Change Medicare to premium support model • Repeal ACA |



A New Administration

Clinton Administration

- **A Clinton presidency could mean more of the same**
 - Defend Obama healthcare legacy while allowing for additional tweaks to the ACA
 - A fresh mandate to make further reforms, possibly on drug pricing

Trump Administration

- **A Trump presidency would bring a much greater degree of change**
 - Repeal of ACA within first few months, but would need support from Congress
 - Several programs could be halted or changed through regulation

For both, cabinet turnover and new leaders in the Administration present chances to educate and inform decision-makers on key issues



Senate Control on the Line

- **Current breakdown:**
 Republicans own a 54-44 majority (2 independent Senators caucus with the Democrats)

- **Competitive elections: 9**
 - 7 of which are currently held by Republicans
 - Democrats need to gain 5 seats to win control (If Democrats win the White House they need to pick up 4 Senate seats and the VP would break a 50-50 tie)



Senate Majority Leader Mitch McConnell (R-KY)



Sen. Chuck Schumer (D-NY) – Likely Majority Leader in Democrat Senate



Competitive Senate Races

| Vulnerable Democratic Seats | Vulnerable GOP Seats |
|--|--|
| Seat vacated by Sen. Harry Reid (D-NV) (Toss-Up) | Sen. Mark Kirk (R- IL) (Toss-Up) |
| Sen. Michael Bennet (D-CO) (Leans D) | Sen. Kelly Ayotte (R-NH) (Toss-Up) |
| | Sen. Ron Johnson (R-WI) (Toss-Up) |
| | Sen. Pat Toomey (R-PA) (Toss-Up) |
| | Sen. Rob Portman (R-OH) (Toss-Up) |
| | Sen. Marco Rubio (R-FL) (Toss-Up) |
| | Sen. Richard Burr (R-NC) (Leans R) |



House of Representatives

- The GOP currently maintains a House majority of 246-188
- Rothenberg Report identifies 32 competitive races
- Democrats are expected to pick up 5-20 seats, not nearly enough to win back the House
- The potential impact of historically unpopular candidates at the top of both tickets is yet to be seen.
 - Modern elections have seen falling numbers of “split-ticket” voters



Speaker of the House Paul Ryan (R-WI)



Key Healthcare Issue Remaining in 2016



*Senate HELP Committee Chairman
Lamar Alexander (R-TN)*

- With campaign season upon us, there are not many legislative days or vehicles left for Congress to pass bills around an issue as contentious as healthcare
- However, there is still some remaining priorities: the Cures/Innovation package and opioid-related measures
 - The Cures/Innovations bills focus mostly on reforms to the FDA, ways to spur innovation as well as battle over increased funding for the NIH. If Congress cannot come to agreement on a final package in 2016, these issues will take center stage and become part of the PDUFA VI, which will be authorized next year.



Administrative Action on Healthcare

- Even with Congress unlikely to pass significant healthcare legislation, policy changes can still happen

- The Administration has maintained a busy regulatory agenda and could pursue legacy-building programs through the end of the Obama Administration



President Obama with Health and Human Services Secretary Sylvia Mathews Burwell



National Cancer Moonshot

- Announced in President Obama's 2016 State of the Union Address
- \$1 billion initiative to jumpstart research on a cure for cancer
 - \$195 million in new NIH cancer funding for FY 2016
 - President's FY 2017 Budget includes \$755 million in mandatory funds for cancer-related research at both NIH and FDA
- White House Cancer Moonshot Task Force chaired by Vice-President Joe Biden
 - Brings together range of federal departments and agencies
 - First report and recommendations due December 31, 2016



Vice-President Joe Biden reacts to President Obama's call for cancer moonshot in 2016 State of the Union (AP file)



Moonshot Priorities

Treatment

- Speed the development and optimization of cancer vaccines targeting unique features of individual cancers
- Extend successes of immunotherapy and combination therapies to all solid tumors
- Promote greater understanding of cancer genomics in coordination with President's Precision Medicine Initiative

Detection

- Invest in development of screening assays to enable more sensitive diagnostic tests
- Enhance data sharing to promote public-private partnerships and maximize knowledge about genetic abnormalities

Research

- Intensify efforts to collect and analyze tumor specimens from the rarest of cancers, particularly childhood cancers
- Create virtual Oncology Center of Excellence to expedite development of combination products and support integration
- Initiate Vice President's Exceptional Opportunities Cancer Research Fund to bring together scientists and industry for high-risk, high-return research



Part B Drug Payment Model - Introduction

- Five-year demo under CMMI's wide-ranging ACA authority to test alternative payment methods and waive Medicare rules
- Two phases are proposed, which involve:
 - **Phase I:** Reduction of Part B ASP add-on to 102.5 percent (from 106 percent) plus a flat fee of \$16.80 per drug per day; and
 - **Phase II:** Application of to-be-finalized value-based purchasing (VBP) tools
- Testing Questions:
 - Does current ASP plus six percent result in prescriber selection of more expensive drugs; and
 - Does the modified payment approach (with or without VBP tools) drive changes in practitioners' prescribing of effective and high-value drugs?



Part B Drug Payment Model – Probable Outcomes

- CMMI is most likely to finalize Phase I as-is and implement it this fall as planned
 - Accelerated implementation (fall 2016) reduces probability of major changes
- VBP tools are more ambiguous and controversial, and subject to refinement during the public comment period
- All lead Republicans for healthcare committees have already expressed concern with demo
 - PhRMA and oncology groups designing aggressive “no” campaign



Potential Changes to Part D, Protected Classes/Drug Pricing

- Under pressure from Part D plans, the Administration continues to study additional ways to alter Part D
- MedPAC went forward with their recommendation to remove immunosuppressants and antidepressants from coverage under Medicare's six protected classes policy
 - Congress will likely ignore the recommendation
 - The real threat comes from CMS feeling emboldened by the recommendation and reissuing their proposed regulation to alter or eliminate the six protected classes policy
- These are the types of policies CMS could pursue in the second half of this year and why it is imperative that key stakeholders remained engaged as the current Administration winds down



What Does It Mean for Healthcare Policy?



- Despite anti-establishment rhetoric, a Hillary Clinton win and Republican Congress would change little in regards to the industry
 - Drug pricing will continue to be an issue, and a Democrat president would be more inclined to use the bully pulpit to force action
- The presidential nominees matter, and ultimately could play a significant role in determining which party controls the Senate
 - But it's too early for any definitive statements on what happens next



Conclusions

- In all likelihood, the dynamics of a divided government will remain
 - The Administration will still struggle with implementing healthcare reform unilaterally

- However, possibilities for a new era remain
 - A shift in Senate leadership could uncork some of the current bottleneck and raise new opportunities and risks on Capitol Hill
 - A new President could use a fresh mandate to launch new initiatives
 - The FDA “UFA” reauthorization bills and legislation to extend CHIP and a package of Medicare provisions present two must-pass vehicles for healthcare-related proposals next year

