

Current Trends in Washington- The Political Landscape HCCA

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3 Actions to Take to Maximize your Agenda



Advocate
engage in aggressive advocacy on issues that are important to you and your company



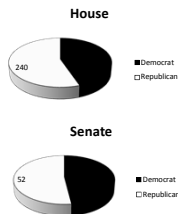
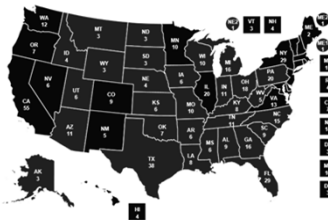
Collaborate
Reach out to key stakeholders and partners. Have an understanding of how your relationships might change as a result of new legislative action undertaken by the presidential administration and start to formulate a plan for how to address these changes.



Ideate
There will almost certainly be significant changes under the new administration, particularly as it relates to the ACA. Now is the time to be offering suggestions and new ideas for how to improve things. This wasn't necessarily done as aggressively when the ACA was initially passed.

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115th Congress Make-up



Current House Vacancies
UT 3: Rep. Jason Chaffetz (R) seat

ELECTORAL COLLEGE TALLY
Donald Trump: 304
Hillary Clinton: 227
*Paul (1), Kasich (1), Powell (1),
Sanders (1), Faith Spotted Eagle (1)

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Quick Facts

- What happened in 1994 and 2012??
- Moderate Republicans are retiring-more to come?
- 1 Senate Republican faces re-elect in state Clinton won*
- 10 Senate Dem elections in 10 states won by Trump - 5 by 19 points or more*

*Sources: Cook Political Report, 2017

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AHCA Stumbling Blocks

- Congressional Budget Office/JCT Score
 - House ultimately passed without score
- Increase in Uninsured
- Republican Party divisions:
 - Freedom Caucus: Not enough savings; too little flexibility
 - Tuesday Group: Too much cut; too much flexibility
- Public polling
- Senate make-up and procedure
 - State residents elect senators not the President

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AHCA Aftermath

- GOP now "owns" healthcare
 - "You will glow in the dark on this one."
 - 2018 election/House majority at stake
 - Unpopular bill; unpopular President
- Unhappy constituents
 - Townhalls
 - Democrats running ads
- Republican Party divisions:
 - Freedom Caucus: Not enough savings; too little flexibility
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Dynamics of the Players

- Lessons Learned: Land Deals are not Policy Deals
- Trump vs. Congress: MOCs are up for re-election, Trump is not
 - President does not schedule votes
 - What are roles for Members now in Admin: Kelly vs. Mulvaney?
- Republicans vs. Republicans:
 - Moderates, Freedom Caucus, Tea Party, and others
- Can they all get along? Where is a bipartisan agreement? Is there one?
 - Is it worth courting Democrats?
 - Reset the stage with Sec. Price Resignation

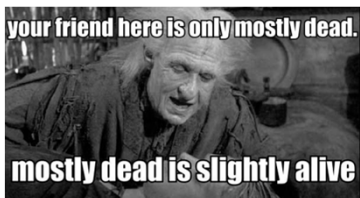
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ACA Repeal Impact on Hospitals

Repeal without Replace benefiting hospitals:

- Net impact would be \$165.8B (2018-2026)
- Medicare Inflation update reductions (inpatient/outpatient) if not restored – funding reduced by \$289.5B (2018-2026)
- Failing to restore Medicare/Medicaid DSH payment - \$102.9B

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Current Efforts

- Stabilization of Individual Market
 - Alexander/Murray-Bipartisanship
 - Multiple Hearings
 - Cost-sharing funding, flexibility for states to structure markets (1332 Waivers)
- Cassidy-Graham – will it rise from the ashes
 - Repeal/Recapture Tax Credits
 - Repeal Individual/employer mandate
 - Block Grants
 - \$136B; 2020/ \$200B; 2026

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FDA's Agenda and Priorities

- Faster Approvals
- Implementation of Cures (freeze lifted)
- Opioid Abuse and Prescribing
- Reduce barriers–Generic entry
 - Citizen petitions
- Clinical Trial requirements-lower costs
- ANDA requirements and prioritization
- R&D costs- JAMA vs Industry

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- Review Existing Regulatory

We need policies that are as modern as the products that we're being asked to evaluate, and a regulatory framework that uses efficient tools to achieve our vital consumer protection role.

-Anna Abrams, FDA's deputy commissioner for policy and planning

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Prescription/Generic Drug User Fee Act (PDUFA/GDUFA)

Fast Facts:

- Created by Congress in 1992
- Authorizes FDA to collect fees from companies that produce certain human drug and biological products
- August 18, 2017 the President signed the FDA Reauthorization Act of 2017, which reauthorized and expanded until September 2022

Timeline (Based strongly on PDUFA V/GDUFA I):

- **July 2015:** Interested parties met with FDA
 - Drug industry representatives
 - Consumer Advocates
 - Healthcare professionals
- **July 2016:** FDA closed the formal process
- **Dec. 2016:** FDA compiled "enhancements" based on stakeholder engagement and submitted their recommendations to Congress
- **Jan. – Aug. 2017:** Congress to consider and revise recommendations into legislation
- **August 2017:** Passed and Signed by President

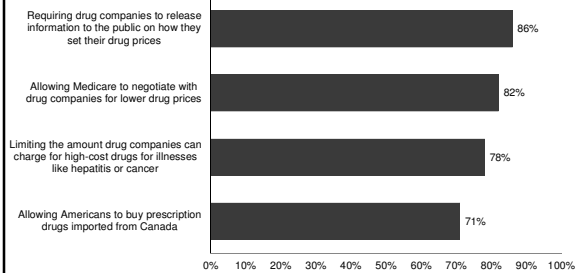


BIR Tip:
Stakeholders from all corners of affected industry will position themselves with various influential members of Congress for maximum input into process!

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Most Americans favor action to keep drug prices down

Percent who say they favor each of the following in keeping prescription drug costs down



Source: Kaiser Family Foundation Health Tracking Poll (conducted Sept 14 – 20, 2016)

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Drug Pricing in 115th Congress

- Campaign promise from Republicans and Democrats
 - Was public's number 1 healthcare concern
- Proposed legislation:
 - *CREATES Act* reintroduced would allow generics to sue for the samples needed in generic drug development (S. 974/H.R. 2212)
 - Sens. Collins, McCaskill: *Increasing Competition in Pharmaceuticals Act* to promote competition in generics (S. 297/H.R. 749)
 - *C-Thru Act* addresses transparency in PBM rebates
 - Multiple House and Senate bills to allow more drug importation from Canada
 - Raised during User Fee negotiations-some see as missed opportunity

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Drug Pricing: Industry in Crosshairs

- Recognizing criticism, PhRMA revamped its membership to demand member companies spend \$200M on R&D/10% of global sales -3 yr avg.

- 22 members (7 full, 15 associate members)

- Don't forget about 340B

- High Profile legal battles
 - CT and 19 other states sue Teva, Mylan, and other companies
 - WA and NM investigating Eli Lilly's insulin prices

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Trump on Drug Pricing

"GETTING AWAY WITH MURDER"

After polling showed drug pricing to be voters' most pressing healthcare concern, both parties have pledged to address the issue through legislation.

- Trump has called for negotiating Medicare prices.

- His advisor also has said, "To repeal and replace Obamacare and not have a conversation about drug pricing seems not like a reasonable prospect".

- Executive Order – Fake or Real Draft? Where is it?

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Hospital Drug Prices on the Rise

While drug pricing controversies mainly focus on pharmacy prices, hospitals have seen their drug spending raise at higher rates.

- Hospital drug spending increased <23% since 2013
 - Pharmacies report 9.9% increase in same time period

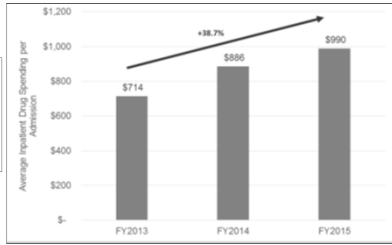
- More than 90% of hospitals report strained budgets

- Most of impact from off-patent older drugs with no generic alternative

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Hospital Inpatient Spending

Inpatient Drug Spending per Admission Has Increased Substantially Since 2013



Source: AHA-FAH Drug Survey, 2012-2014 AHA Annual Survey

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Legislative Priorities: Debt Ceiling, Budget, Taxes & More

Congress and Trump have called for a major tax reform overhaul including:

- Tax brackets
- Simplification
- Marriage penalty
- Corporate Tax/International

- **AHCA Impact on Tax Reform**
 - Created revenue
 - Health Insurance Tax
 - Cadillac Tax (delayed until 2020)
 - Medical Device Tax
 - Medicare Tax

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Medicare/Medicaid

- **Medicare**
 - 340B delays
 - Post-Acute Care
 - MACRA – Will CMS fulfill implementation
 - Delivery System Models, Pilots, etc.
 - Chronic Care models and payment
 - Telemedicine
 - Hospital Extenders: MDH, LVA, Outpatient Therapy Caps

- **Medicaid**
 - SCHIP Reauthorization, Expired October 1, 2017
 - Block Grant, partial vs full
 - Expansion via 1115 waivers

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