# Table of Contents

1 | Voter Sentiments

2 | Federal Outlook and Implications

3 | State Policy Implications

4 | Looking Ahead
According to Exit Polling, Healthcare Was the Top Issue on the Minds of Voters in the 2018 Midterms

Which are [the voters’] leading concern?

- Healthcare: 41%
- Immigration: 23%
- Economy: 21%
- Gun Policy: 11%

Voters Express Concerns Over Healthcare Costs, Particularly Unexpected Bills

How Worried, If at All, Are You About Being Able to Afford Each of the Following?

<table>
<thead>
<tr>
<th>Category</th>
<th>Very Worried</th>
<th>Somewhat Worried</th>
<th>Not Too Worried</th>
<th>Not at All Worried</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpected Medical Bills</td>
<td>38%</td>
<td>29%</td>
<td>16%</td>
<td>16%</td>
</tr>
<tr>
<td>Health Insurance Deductible</td>
<td>24%</td>
<td>29%</td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td>Prescription Drug Costs</td>
<td>22%</td>
<td>23%</td>
<td>23%</td>
<td>31%</td>
</tr>
<tr>
<td>Rent/Mortgage</td>
<td>22%</td>
<td>19%</td>
<td>21%</td>
<td>35%</td>
</tr>
<tr>
<td>Gasoline or Other Transportation Costs</td>
<td>20%</td>
<td>26%</td>
<td>25%</td>
<td>28%</td>
</tr>
<tr>
<td>Monthly Utilities</td>
<td>19%</td>
<td>24%</td>
<td>27%</td>
<td>30%</td>
</tr>
<tr>
<td>Monthly Health Insurance Premium</td>
<td>18%</td>
<td>24%</td>
<td>25%</td>
<td>32%</td>
</tr>
<tr>
<td>Food</td>
<td>17%</td>
<td>20%</td>
<td>25%</td>
<td>38%</td>
</tr>
</tbody>
</table>

Democrats Gained a Majority in the House, While Republicans Increased Their Senate Majority

MAKEUP OF THE 116TH CONGRESS

As of November 28, the election for US House district California-21 has not been called.
Congress Will Be Divided For The First Time In 4 Years, Fostering a Challenging Legislative Environment

In the **House**, there will be new leadership and changes in oversight priorities.

Despite some opposition from Democrats, Nancy Pelosi (D-CA) is expected to be the next **Speaker of the House**.

Control of the **Senate** will remain stable, but there will be key changes in committee leadership.

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Reuters: Pelosi expected to get speaker nomination; rebels waiting for January. [link](https://www.reuters.com/article/us-usa-house-pelosi/pelosi-expected-to-get-speaker-nomination-rebels-waiting-for-january-idUSKCN1NW12M)
The 115th Congress May Seek to Pass Several Measures Before the 116th Is Sworn In

- Healthcare Related Items
  - Medicare Part D Changes
  - The CREATES Act
  - PAHPAI
  - Health Insurance and Medical Device Tax

- Non-Healthcare Related Items
  - Appropriations
  - Border Wall Funding
  - Farm Bill
  - Tax Reform
  - USMCA

CREATE: Creating and Restoring Equal Access to Equivalent Samples Act; PAHPAI: Pandemic and All-Hazards Preparedness and Advancing Innovation, USMCA: US-Mexico-Canada Agreement
Healthcare Debate in Congress Driven Increasingly by Politics as 2020 Approaches
Election Outcomes Could Lead to 650,000 Additional Medicaid-Covered Lives Across ID, KS, ME, NE, UT, WI

Of the 36 gubernatorial elections, Democrats held 9 offices and picked up an additional 7 offices. Republicans held 19 and picked up 1 office.

Newly elected Democratic Governors in KS, WI, and ME all support Medicaid expansion, and are likely to pursue expansion.

ID, UT, and NE all passed ballot initiatives to expand Medicaid.

*As approved by CMS in September 2018, a VA State Plan Amendment (SPA) authorizes the state to expand Medicaid effective January 1, 2019.

** ME passed a ballot initiative in 2017 directing the state administration to expand Medicaid. Following a ME Supreme Judicial Court decision requiring the governor to request permission to expand, ME submitted an SPA request to CMS on August 31; however, in an accompanying letter, current ME Gov. LePage requested CMS reject the request.

***Medicaid expansion in MT is scheduled to expire on June 30, 2019; the November ballot referendum would have made expansion permanent.

CMS Granted State Officials New Flexibilities to Shape State Healthcare Markets Using 1332 Waivers

CMS RELAXED 4 GUARDRAILS THAT MUST BE MET FOR 1332 WAIVER APPROVAL IN ORDER TO GIVE STATES MORE FLEXIBILITIES. THOSE 4 INCLUDE:

1. Coverage
   - Many forms of private coverage, including STLDI, AHPs, ESI, and individual plans

2. Affordability
   - The proposal’s total effect on affordability, with high-cost and low-cost populations considered in aggregate

3. Deficit Neutrality
   - A 10-year budget plan, highlighting the changes in projected federal spending and revenues based on the plan

4. Comprehensiveness
   - Waiver plan coverage comprehensiveness compared to the state’s selected EHB benchmark

ACA: Affordable Care Act; AHP: Association Health Plan; CMS: Centers for Medicare and Medicaid Services; EHB: Essential Health Benefits; ESI: Employer-Sponsored Insurance; STLDI: Short-term Limited Duration Insurance
Regulatory Action Will Shape Policy Outlook, Regardless of Post-Election Environment

Timeline of Key Policy and Legislative Dates /

- **Dec 24:** Comments Due on IPI Model ANPRM
- **Dec 17:** Comments Due on DTC Advertising Proposed Rule
- **Jan 3:** Start of 116th Congress
- **Feb:** President’s FY2020 Budget Request
- **Dec 7:** End of CR Funding the Federal Government
- **Dec 17:** Comments Due on Medicare Parts C/D Part 1
- **Dec 31:** Comments Due on Medicare Parts C/D Part 1
- **Jan 25:** Comments Due on Medicare Parts C/D Part 2
- **Jan 25:** States Drug Pricing Legislation
- **Potential Proposed Rulemaking on NBPP, Rebates**

AKS: Anti Kickback Statute; NPRM: Advanced Notice of Proposed Rulemaking; CR: Continuing Resolution; DTC: Direct to Consumer; FY: Fiscal Year; NBPP: Notice of Benefit Payment Parameters; IPI: International Pricing Index

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Presidential Candidates for the 2020 Elections Will Begin Announcing Bids in the Near Future

Timeline of 2016 Presidential Bid Announcements/

- April 7, 2015: Rand Paul
- April 12, 2015: Hilary Clinton
- April 13, 2015: Marco Rubio
- April 28, 2015: Bernie Sanders*
- May 4, 2015: Carly Fiorina
- June 15, 2015: Jeb Bush
- June 16, 2015: Donald Trump
- June 22, 2015: Jill Stein

*Senator Sanders (I) sought the Democratic party nomination for President in 2016.
About Us

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Diagnostics Regulation and Personalized Medicine

National Health Council
Washington Representatives Retreat
Annapolis, MD

November 30, 2018

Cynthia A. Bens
Senior Vice President, Public Policy
Personalized Medicine Coalition
What is Personalized Medicine?

Personalized medicine, often referred to as precision medicine, is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for their patients. By combining the data from those tests with an individual’s medical history, circumstances, and values, health care providers and patients can develop targeted treatment and prevention plans.
The Personalized Medicine Coalition is comprised of innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.
Benefits of Personalized Medicine

1. Shifting the emphasis in medicine from reaction to prevention
2. Directing targeted therapy and reducing trial-and-error prescribing
3. Reducing adverse drug reactions
4. Revealing additional targeted uses for medicines and drug candidates
5. Increasing patient adherence to treatment
6. Reducing high-risk invasive testing procedures
7. Helping to control the overall cost of health care
Barriers to Personalized Medicine

• Scientific and product development challenges

• Regulatory

• Coverage and reimbursement

• Clinical adoption
Current Diagnostics Regulation

Diagnostic tests, can be evaluated and regulated on three criteria:

• **Analytical Validity**: Refers to how well the test predicts the presence or absence of a particular gene or genetic change.

• **Clinical Validity**: Refers to how well the genetic variant(s) being analyzed is related to the presence, absence, or risk of a specific disease.

• **Clinical Utility**: Refers to whether the test can provide information about diagnosis, treatment, management, or prevention of a disease that will be helpful to patients and their providers.
The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have the primary authority to regulate genetic tests.

- **CMS Regulation**: Implements regulations to control the analytical validity of clinical diagnostic tests. It regulates clinical laboratories that conduct clinical diagnostics testing, through its CLIA program.

- **FDA Regulation**: FDA considers diagnostics tests to be a special type of medical device. FDA has chosen to apply "enforcement discretion" to the vast majority of genetic tests. Whether FDA regulates a test is determined by how it comes to market.
Changing Landscape

FDA initially applied “enforcement discretion” on LDTs because clinical genetic testing was not widespread.

What has changed?

- Genetic testing becoming more pervasive in clinical care
- Growth of direct-to-consumer (DTC) genomic testing
- Rapid advances in complex technology like next-generation sequencing (NGS) tests

What steps has FDA taken?

- Announced plans to move away from “enforcement discretion” in 2010
- 2014 draft regulatory framework for LDT oversight (updated in 2017)
- 2017 released guidance on regulation of NGS test to verify analytical and clinical validity
Current Legislative Efforts

Diagnostics Accuracy and Innovation Act (DAIA)

- Proposed by Representative Diana DeGette (D-CO) and Larry Bucshon (R-IN) in March of 2017
  - Proposes to modernize regulations by creating a new category — in vitro clinical tests — encompassing laboratory developed tests (LDTs) and kits
  - The draft legislation clarifies the aspects of IVCT development, performance, and interpretation that the FDA and CMS would be responsible for overseeing
  - Draft bill evolved out of industry-led efforts to advance a regulatory proposal that was a more favorable alternative to the draft guidelines issued by the FDA in 2014
Current Legislative Efforts (Cont.)

FDA Technical Assistance on DAIA

• Proposed in August of 2018
  o Entirely new framework from DAIA positioning LDTs squarely in a medical device paradigm
  o Includes provisions related to premarket approval, provisional approval, and a precertification program
  o Makes some exceptions to exempt some test for use in public health emergencies and small populations for rare diseases
  o Gives FDA explicit authority for FDA to revoke approval, request raw data, and take corrective action against test developers
Current Status of Legislation

- Request for comment on FDA’s proposal from Congress in August
- Stakeholder listening session with FDA, HHS, congressional champions and relevant committee staff
- One-on-one stakeholder meetings with staff of Reps. DeGette Bucshon, as well as Sens. Bennet and Hatch staff (August-September)
- House and Senate staff draft new legislation (October-November)
- House Energy and Commerce Health Subcommittee hearing on new draft bill before end of 115th
- Priority for Congress, FDA and stakeholder community to get a compromise bill across the finish line in 2019
Thank you for your attention. Questions?

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