HORIZON
GOVERNMENT AFFAIRS

Health Policy Outlook; Predictions for the Key Legislative, Regulatory and Political Developments in 2016

Those anticipating a quiet year in health policy could be in for a surprise. While many analysts contend that election-year headwinds will prevent legislative progress on a broad range of issues, this year's HGA Health Policy Outlook offers a contrarian view. We believe the first half of 2016 could be the most productive legislative session since 1996, when several major laws were enacted just months before a presidential election.

Behind the harsh rhetoric of the primary season, lawmakers have quietly been working toward consensus on a range of key issues. At the same time, presidential election years typically feature a blizzard of bills designed to set the table for the next Administration and Congress.

In addition, we expect a steady stream of regulations throughout the year—a prospect summed up by the recent *Politico* headline, "Obama pushing thousands of new regulations in Year 8." The last year of a presidency often is marked by aggressive rulemaking on controversial issues, as the exiting Administration attempts to accomplish through fiat what they were unable to realize through legislation. This year is no exception.

Political Themes

1. **The elections will lend urgency to both the legislative and regulatory processes, driving most activity to earlier in the year—likely before the conventions in July.** As the election approaches, partisanship in Congress is bound to rise. Yet, this trend does not by itself translate to a dearth of legislative activity. Meanwhile, serious legislative work is being done on bills designed to tee up issues for 2017.

2. **Despite recent polling setbacks, Hillary Clinton remains the odds-on favorite to receive the Democrat presidential nomination.** All bets are off, however, should an ongoing FBI probe lead to charges that the former Secretary of State mishandled national security secrets.

3. **On the Republican side, the path to nomination is the murkiest in modern times.** Some insiders are raising the specter of a 19th century-style brokered convention that throws out the primary results to produce a consensus candidate from outside the current crop of contenders. This is by no means an assured conclusion, but the process used last November to select a House speaker provides an intriguing template.

4. **Whoever wins the White House this November is likely to change the Affordable Care Act in 2017.** A Democrat would likely seek incremental changes, while a Republican will seek to repeal and replace current law and at the same time use the regulatory process to address its most controversial aspects.

5. **More Senate Republicans are in cycle than Democrats, with several running in states that Obama carried in 2012.** Even so, we are not necessarily predicting Democrats will take over the Senate. While Republicans are likely to lose seats, Democrats have had some difficulty recruiting competitive candidates and there are also number of Democratic seats that are vulnerable in 2016, including Senator Harry Reid's. Republicans are almost guaranteed to retain the House comfortably, thanks in part to gerrymandering that has reduced the number of competitive seats to a precious few.

Budget and Appropriations

The Administration is expected to release its Fiscal Year (FY) 2017 budget earlier than usual this year—with an expected release on February 9th. Budgets submitted by lame duck presidents typically receive only cursory attention on Capitol Hill, but this one may be an exception as we expect a document that is rich with health care savings. Proposals will focus, in particular, on the price of breakthrough prescription drugs—a message the White House is expected to hammer on throughout 2016.

For institutional and political reasons, Republican leaders in both houses plan to pursue a budget resolution. FY2017 spending levels were set in last December's budget deal, but Republican leaders believe sound legislative practice requires a formal process. A resolution also would set up votes on issues that can then be used in campaigns. For the Senate, this means a time-limited debate, but with an open amendment process—leading to a "vote-a-rama" where any Senator may demand a floor vote on any amendment. Health issues likely to come up include ACA repeal and prescription drug pricing.

Many congressional Republicans—both the leaders and rank and file—feel burned by the December Omnibus, which increased spending while, in their view, producing few real policy wins. The leadership will address this discontent in 2016 by aggressively pursuing "regular" order— attempts to introduce, mark-up, and pass each appropriations bill. A stated goal is to pass all spending bills before July in both Chambers in order to wrap up funding issues by the end of September.

Major Legislation

HGA expects additional legislation to move in 2016, including:

1. **Innovation Package.** The Senate companion to the House-passed "21st Century Cures Act" has started to roll out publicly. Rather than pursuing a big package similar to the House-passed bill, the Senate HELP Committee plans to mark up discrete bills. This is partially due to the fact that the HELP Committee's jurisdiction is more limited that that of Energy and Commerce. Starting in February, the Committee will move legislation designed to revamp federal health IT programs, promote interoperability, clearly define how and by whom health IT is regulated, modify HIPAA, and expand incentives for biopharmaceutical companies and researchers to identify and produce new drugs. Interestingly, the Committee wants to put parameters around the President's cancer "moon shot" and precision medicine initiatives. The process currently is hamstrung by Democrat demands for automatic (mandatory) funding for the National Institutes of Health and proposals to control the

cost of prescription drugs. Republicans plan to dare Democrats to vote against a series of bipartisan bills designed to expand cures for patients.

2. **Chronic Care Initiative.** The Senate Finance Committee is working on a bipartisan package of reforms focused on improving outcomes for Medicare beneficiaries who require chronic care. Among other things, the bill would reform incentives structures under Medicare Advantage, Accountable Care Organizations, and medication adherence. Powerful stakeholders affected by these reforms include provider groups, Medicare Advantage plans, beneficiary groups, and organizations invested in health IT. While the most recent proposals are relatively limited in scope—and hence more likely to pass than a meatier approach—we believe it is unlikely to gain traction in 2016. Nonetheless, the Committee has been focused on gaining buy-in from Finance Members on both sides of the aisle, and stakeholders, which increases the chances of movement for aspects of the package post-election.

3. **Hospital Package.** The Ways & Means Committee plans to move forward with Medicare reforms, portions of which were introduced in mid to late 2015. There are significant political and logistical hurtles to passing such an ambitious package this year, but the initiative enjoys support from both Speaker Paul Ryan and Chairman Kevin Brady, who were heavily involved in its development. In particular, the Committee wants to reform financing of graduate medical education—which would have a major impact on teaching hospitals. Other components delve further into site neutral payments, including a potential fix for hospital outpatient departments that were under construction when the "Bipartisan Budget Act of 2015" was passed. The bill would also create relief for hospitals in states that chose not to expand Medicaid. Other areas being explored by the Committee include reforms to the recovery audit contracting system, Medicare Part B drugs, and rural health care.

4. **Prescription Drug and Opioid Abuse Prevention and Treatment Legislation.** Included in the Omnibus funding measure for the remainder of 2016 (P.L. 114-113) are increased funding and policy directives aimed at combating the prescription drug abuse and heroin epidemic. The Centers for Disease Control and Prevention has declared prescription drug abuse an epidemic, with 100 unintentional overdose deaths per day—four times as many as in 2010. (Drug overdose deaths now surpass homicides and car crash deaths in America at a cost of more than $193 billion annually.) We expect the Senate to act first on a bill to address prevention and treatment, including making state databases interoperable with real time information. We expect a second bill to also ease Drug Enforcement Administration crackdown on legitimate pharmacy efforts. Both are likely to reach the President's desk this year.

5. **Mental Health Legislation.** We believe there is sufficient—and growing—momentum for the House and Senate to pass the Murphy-Johnson mental health reform bill. The legislation addresses a shortage of inpatient beds for psychiatric patients, provides for faster intervention for people with schizophrenia; creates a grant program for school services for children with emotional disturbances; reauthorizes a suicide-prevention program; and improves coordination between government agencies that serve the mentally ill. Democrats are currently holding up the bill because of concerns over patient privacy and their belief that it does not go far enough to control gun violence, but we believe the obstacles are surmountable. Democrats on the Energy and Commerce Committee are slated to release an

alternate mental health reform bill shortly, but it is unlikely to go anywhere. The Energy and Commerce Committee plans to mark up the Murphy-Johnson legislation later this spring.

6. **Tax Reform.** Members are still searching for a long-shot deal on corporate tax reform that would rationalize the U.S. Code and bring back home profits currently stranded in overseas tax havens. Pharmaceutical manufactures would be particularly affected. Given the degree of public angst over corporate inversions, any deal will have to be bipartisan. A deal may be in the works between Senator Schumer (D-NY), Speaker Ryan and Ways and Means Chairman Brady. The fact that Ways and Means recently hired Barbara Angus, former International Tax Counsel for the Treasury Department, to lead the Tax Subcommittee can be viewed as a strong indication that the Committee plans to act in this space in the near future.

7. **ACA Reform.** High on the House Republican Leadership's election year agenda is the introduction of a bill designed to repeal and replace the Affordable Care Act (ACA). Speaker Ryan wants to address both coverage and (importantly) costs—the latter in explicit recognition that private coverage costs have ballooned by more than one-third since 2010, when the ACA was signed into law. It is not clear whether the Leadership will move it through the House this year, however. At a minimum, the bill provides talking-points for 2016 candidates and a starting point for 2017 lawmakers. We also expect several tightly focused ACA bills to move in 2016, including bills to relax restrictions on employers' use of HRAs and modest changes to the Obamacare health exchanges.

Congressional Hearings and Oversight

Control of the hearings agenda will continue to provide congressional Republicans with their main platform for challenging the Administration on a host of issues. In particular, we expect:

1. **Affordable Care Act.** Republicans (primarily in the House) will continue to criticize the Administration on implementation of the ACA, with a primary focus on exchanges and subsidies. Other issues will include affordability (costs) and CO-OPs. They will have plenty to work with: average exchange premiums are up by nine percent in 2016, and the average deductible for a self-only Silver plan stands at $4,000. Employer plan costs are again growing three times faster than wages. In response, Democrats will point to the roughly 10 million who have enrolled through the exchanges and CBO's estimate that the ACA has brought down the number of uninsured by 25 million.

2. **Prescription Drugs.** Partly in response to significant regulatory action (see next section), we expect a flurry of hearings and oversight letters from Congress related to everything from drug prices and costs, to 340B, best price, drug coverage under the ACA, and the Administration's haphazard release of data around drug prices. House Republicans will call out the "bad actors," such as Turing and Valeant Pharmaceuticals, for opportunistic price increases on life-saving drugs. Democrats will call for tighter regulation of Big Pharma. In the Senate, the action will be more bipartisan. On the Finance Committee, Senators Wyden and Grassley have asked for input on how to rein in drug costs. The Aging Committee will continue to investigate issues of access, cost and pricing. The HELP Committee has indicated

that they will be closely following the Aging Committee's investigation, which may inform legislative action in the future. We expect little legislative action, if anything, to come from these exercises, outside of amendments offered during the vote-a-rama – at least in the near-term. The hearings and letters will contribute to the atmosphere driving action in 2017 and on the regulatory front.

3. **Insurance Mergers.** More hearings are likely concerning the merger of four major insurers. Aetna has applied to acquire Humana while Anthem is seeking to acquire Cigna. Both mergers will likely be approved by the Justice Department. This consolidation will have sweeping effects, with varying impacts on different communities and sectors. On the one hand, insurer consolidation could serve as a counterweight to the growing consolidation of health providers. The evidence suggests that private medical costs are higher in markets where providers enjoy greater market-dominance than insurers. Insurer consolidation may also help to contain drug prices, particularly where there are competing drugs on the market. On the other hand, diminished competition among insurers reduces market pressures to push back against medical cost increases by making it easier to pass them on to ratepayers in the form of higher premiums, copayments, and deductibles. MedPAC is currently undertaking initial assessments of the indirect effect the mergers may have on spending in the Medicare program, particularly Part C.

Regulatory Issues

The last year of a Presidency often is marked by an uptick in rulemaking—and this year should be no exception. Several prominent regulatory initiatives are underway:

1. **MACRA Implementation.** Last year saw the enactment of the most sweeping reforms to Medicare physician payment policies in a generation, including changes to the Meaningful Use (MU) electronic health record program. Although the new payment framework starts in 2019, the first reporting year on which those payments will be based is 2017. CMS will have just 11 months to gather input and produce proposed and final rules to effectuate the program. Congress will be paying close attention, with oversight hearings and letters to the Administration throughout the year.

2. **Medicare Payment Rules.** CMS will continue to issue its normal payment rules throughout the year, including changes for hospitals, End-Stage Renal Disease, long-term and post-acute care providers, and Durable Medical Equipment. With Medicare margins and marginal profits high—running in the double digits on average for many—we expect payment updates for most providers, especially Skilled Nursing Facilities, Home Health, and long-term care hospitals, to be minimal.

3. **Drug Pricing.** The Administration continues to probe the limits of its regulatory and enforcement authority with respect to drug pricing and costs. Recent efforts to improve transparency around payments to providers and the drug cost dashboard are two examples. The coming year could see a more fundamental push to address costs via the Part D call letter and in a yet-to-be-released Center for Medicare and Medicaid Innovation demo (or demos) to test payments for drugs based on their value or patient outcomes. A very hard push on this front—for example, should the Department of Health and Human Services (HHS) attempt to eliminate the Part D non-interference policy—would generate a vigorous pushback. Meanwhile, the

Health Research and Services Administration's forthcoming final 340B program rule appears likely to increase the documentation and reporting requirements for 340B participants. The Medicaid Average Manufacturer Price rule is out for comment, after years of delay. The major open issue is what products will be subject to line-extension rebates. Finally, it is possible (though unlikely) that CMS could use its limited statutory authority to release more information about Part D claims, and to propose changes to Average Sales Price methodology. Several states have pending ballot initiatives on the issue of transparency on research and development costs. We expect states to explore price caps on high cost drugs, particularly for exchange plans. Additionally, Massachusetts has launched an investigation into the pricing of Hepatitis C drugs from Gilead to determine whether they have conducted unfair trade practices. Other states will likely follow.

4. **Parts C and D Call Letter**. We expect this year's call letter to include program changes that were floated in 2014 but ultimately abandoned. These could include changes to six protected classes, non-interference, network adequacy, LIS co-pays, and possible auto-enrollment and pharmacy and prescriber lock-in. We also expect changes to quality standards and adherence measures that match the Administration's call for more payments tied to value over time.

5. **Meaningful Use.** As Congress considers legislative changes to MU (see item 1 in this section), CMS Administrator Slavitt declared the MU program "dead." In a clarifying blog post, Slavitt and HHS Assistant Secretary Karen DeSalvo said the program will change to reflect the new statutory demands of MACRA and pledged to reward technology-driven outcomes, focus on interoperability and open APIs, and allow more flexibility to customize technology based on provider needs. The intersection of Congressional desire to legislatively change the program and CMS' need to accommodate MACRA means the rules governing MU are (as they have always been) uncertain.

6. **CMS QE program.** As part of MACRA, Congress expanded the CMS data sharing program for Qualified Entities, leaving CMS with broad discretion on the implementation parameters. The proposed rule effectuating the changes is out. The program could provide more granular insights into cost and quality problems by sharing Medicare and Medicaid claims data with researchers, academics, employers, and insurers. How widely HHS ultimately decides to share the data will help determine how useful the program is to big data analytics firms and number crunchers across the country.

Emerging Issues in 2017

Issues setting the table for legislative action in 2017 include:

1. **User Fees.** Negotiations are already underway between the Administration and drug and device industry groups over the next round of FDA modernizations. The Prescription Drug User Fee Act and other user fee programs are set to expire in September 2017, creating a "must-pass" challenge for Congress. Without such resources, Food and Drug Administration (FDA) drug and device approvals will slow to a crawl. High on industry's agenda are fast track reviews of devices, combination products, and priority review vouchers. Left undone is how FDA may (or may not)

regulate next-generation devices, data and analytics platforms (health IT), and whether Congress will address the issue.

2. **HIPAA/Data Sharing.** After years of pushing hyper-privacy, Democrats are coming to realize that many models of care coordination and teamwork depend on fundamental changes to how information is shared and protected. For their part, Republicans see decades old regulations as inhibiting economic growth and innovation. A number of emerging tech start-ups would like to expand their foothold in health care—arguably, our least productive sector. But many are hesitating due to the Health Insurance Portability and Accountability Act (HIPAA) rules, the lack of clarity around FDA regulatory authority, and the absence of a coherent framework for federal data policy generally. The technology life cycle is driven by data, which puts it fundamentally at odds with health privacy rules and the concomitant regulatory life cycle. Both parties want to address HIPAA and data sharing issues on Capitol Hill and in the Administration. Past efforts have been stymied by privacy advocates on the right and left, but cultural and societal norms have shifted, particularly with the emergence of Millennials and their data consumption habits. A perfect storm of technology, data, and cultural changes could pave the way for a legislative and regulatory rewrite of federal data and privacy rules that breaks open a new cycle of innovation and creativity.

3. **Technology Applications and Regulatory Science**. An emerging issue is the deteriorating state of what might be called regulatory science. Rapid advances in computing and software are creating opportunities to solve many challenges once thought to be intractable, such as patient identifiers, interoperability, and security breaches. But advances in the tech sector have already outstripped the government's ability to absorb them—as reflected, for example, in the confusion over how health IT apps on iPhones are regulated. The resulting opportunity costs will only grow worse over time.

4. **Transparency.** As data and technology increasingly pervade all aspects of everyday life (think self-driving cars, online banking, Fitbit) the data generated by online activity and "wearables" will further refine consumer options and product design. Transparency around prices and quality in health care and also around how and by whom information is collected, consumed, and used will increasingly become a major policy issue.

5. **Budget Reconciliation.** We expect that, regardless of who occupies the White House, the next president is likely to see a big budget bill designed both to move policy and address the ballooning deficit and entitlement burden. (For example, interest on the debt will add more to spending over the next decade than Social Security.) In other words, 2017 could be the year when sacred cows are finally herded onto the menu.