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Wolters Kluwer White Paper

Simply unpredictable: Health care under the Trump Administration and 115th Congress

Inside

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Executive Summary

Whoever said uncertainty is the only certainty there is must have been speaking of 2017. The Trump Administration coupled with a Republican majority in control of both chambers of the new 115th Congress has left the future of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) enormously uncertain. What's at risk?

- *Expanded access to health insurance through private health insurance, employer-provided health plans, and Medicaid.*
- *Premium support to individuals to health pay for insurance.*
- *Financial incentives to insurance companies and states to expand health insurance.*
- *Broader coverage of basic preventive health services.*
- *Various taxes and fees enacted to health pay for expanded coverage.*
- *The FDA's regulation of drugs, food, cosmetics, and medical devices.*

This White Paper compares Trump's campaign promises related to health care with the actions taken thus far by the executive branch and Congress. At the time this White Paper was drafted, there were close to 100 bills introduced before the 115th Congress that would affect the health care industry, from repealing and replacing the ACA to negotiating Medicare prescription drug prices, and many others impacting the ACA, Medicare, and Medicaid. The President has signed two Executive Orders (EOs) directly affecting the industry. The first, signed just hours after Trump took the oath of office, sets the course for repeal of the ACA. The second, signed on January 30, 2017, will have a wide-reaching effect on all government agencies. Trump's nominees for HHS Secretary (Rep. Tom Price, M.D. (R- Ga)), CMS Administrator (Seema Verma), and to fill the Supreme Court vacancy (Judge Neil Gorsuch) are proving contentious. But no real movement has been made to repeal the ACA, despite health care being labeled Trump's top priority, and Congress has certainly not offered any one viable replacement plan.

This White Paper will specifically discuss the varying options for dismantling the ACA and what that would mean for specific programs offered under the ACA, as well as what the Trump presidency and new Congress may mean for other areas of health care and life sciences. It was compiled with the assistance of the entire Wolters Kluwer Legal & Regulatory U.S. Health Law Editorial team.

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Setting the Stage

While little movement has been made on health care changes by the new Administration or Congress, it is useful to review Trump's health care campaign platform, examine his nominees to lead CMS and HHS and to fill the vacancy in the U.S. Supreme Court, and review some of the legislative proposals related to health care.

Campaign promises

In a position paper posted on his campaign website, Trump laid out his plan for health care, which included:

- complete repeal of the ACA;
- permitting the sale of health insurance across state lines;
- allowing individuals to fully deduct health insurance premium payments from tax returns;
- enabling all Americans to make tax-free contributions to health savings accounts (HSAs);
- requiring price transparency from all health care providers;
- changing the Medicaid structure from a federal-state partnership to a block-grant system;
- removing barriers to free-market entry for drug providers; and
- reforming mental health programs and institutions.

The plan also called for obtaining health care savings by enforcing immigration laws and increasing the employment rate to decrease enrollment in the Children's Health Insurance Program (CHIP). Most of these proposals were similar to House Speaker Paul Ryan's (R-Wis) plan for replacing the ACA.

Ryan's "better way"

Ryan unveiled the Republican health care agenda in June 2016 that would repeal much of the ACA but keep some of the health care law's more popular provisions (see *Ryan proposes 'A Better Way' to repeal Obamacare*, June 29, 2016). Ryan's proposal was part of his larger agenda, titled "A Better Way," to change what he considers America's "biggest challenges." Ryan's plan includes proposals, some similar to Trump's campaign platform, to:

- expand health savings accounts;
- offer refundable tax credits to subsidize the purchase of private health insurance and decrease dependence on employer-sponsored plans;
- cap the tax exclusion for employer-provided health insurance;
- allow people to purchase insurance across state lines;
- provide $25 billion in funding for high-risk pools over 10 years;
- devolve Medicaid to the states, either through a block grant or a per capita allotment;
- partially privatize Medicare beginning in 2024 through a "premium support" option; and
- slowly raise the age of eligibility for Medicare to 67.

Trump nominees

On November 29, 2016, Trump announced he would nominate Price as HHS Secretary and Verma as CMS Administrator. On January 31, 2017, Trump announced Gorsuch as his nominee to fill the vacancy left on the U.S. Supreme Court by the death of Justice Antonin Scalia. According to the Washington Post, Republicans hope Gorsuch will be confirmed before the Easter recess in April and seated on the High Court for the end of the Court's term.

Tom Price, M.D., a Congressman and private-practice orthopedic surgeon, served in the Georgia State Senate prior to his election to Georgia's 6th district in November 2004. Price serves on the House Committee on Ways and Means and was Chair of the House Committee on the Budget in the 114th Congress. On the topic of the ACA, Price introduced H.R. 2300, the Empowering Patients First Act of 2015, in May 2015, which would repeal the health reform law, replacing it, in part, with refundable tax credits for purchasing health coverage and for contributing to (higher annual limit) health savings accounts (HSAs) The top Democrat of the committee, Patty Murray (D-Wash), however, questioned him on policy, conflicts of interest, and some of his past statements, including one suggesting cost is not an issue for women buying birth control (see *Is HHS Secretary too high for Price?*, January 19, 2017).

Seema Verma, MPH, nominated as CMS Administrator, is the president, CEO, and founder of SVC, Inc., a national health policy consulting company. She helped to redesign or advise Medicaid programs in Indiana, Iowa, Ohio, Kentucky, Tennessee, and Michigan. Most notably, she was the "architect" of the Healthy Indiana Plan (HIP), "the nation's first consumer directed Medicaid program" under former Governor Mitch Daniels and the HIP 2.0 waiver proposal submitted by Vice President Mike Pence while he was governor. She also worked with state insurance agencies and public health agencies in preparing for ACA changes. Although her confirmation hearings have yet to take place, on January 12, Alexander announced that he met with Verma and that he "look[s] forward to working [with Verma] as she leads CMS…

[and believes that] she will have an opportunity to change the direction of the agency to be more responsive to state requests for flexibility and innovation as Congress and the president move more health care decisions out of Washington and back to states."

Judge Neil Gorsuch was seated on the U.S. Court of Appeals for the 10th Circuit in 2006 after being nominated by President George W. Bush. He is a graduate of Harvard Law School and served as a law clerk with the D.C. Court of Appeals and U.S. Supreme Court and was in private practice with the firm Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC, specializing in complex litigation. He is listed as adjunct faculty for the University of Colorado Law School, having taught Legal Ethics and Professionalism and Antitrust classes from Fall 2012 through Fall 2016. According to the *New York Times*, Gorsuch is a conservative who has "a strong record of favoring religious freedom over other values, built largely on two prominent cases in which he sided with employers who objected for religious reason to providing some forms of contraception coverage." In *Hobby Lobby Stores, Inc. v. Sebelius*, with Gorsuch concurring, the 10th Circuit held that the ACA's contraceptive mandate impermissibly infringed on the religious rights of business owners who refused, in Gorsuch's words, "to underwrite payments for drugs or devices that can have the effect of destroying a fertilized human egg." In his concurrence, Gorsuch wrote, "for some, religion provides an essential source of guidance both about what constitutes wrongful conduct and the degree to which those who assist others in committing wrongful conduct themselves bear moral culpability . . . Understanding that is the key to understanding this case" (see *Tenth Circuit rules in favor of Hobby Lobby regarding HHS contraceptive mandate in employer provided health plans*, June 28, 2013).

Backed against the wall

The contention currently present in Congress is perhaps best highlighted in the events surrounding the Gorsuch nomination and voting on other Trump nominees. In early February, media outlets described the bitterness Democrats still have over the treatment of Chief Judge Merrick Garland of the D.C. Circuit, who was nominated by President Barack Obama shortly after Scalia's death in early 2016, and whose nomination was effectively ignored by the GOP-controlled Senate, which refused to hold confirmation hearings. Democrats claim they will try to block Gorsuch's confirmation. Sixty votes are needed in the Senate for a Supreme Court nominee to be confirmed, and there are only 52 Republicans in the Chamber, so if fewer than eight Democrats or Independents support Gorsuch, he will not be confirmed. Reports also state that Republicans could invoke the "nuclear option" which was used in 2013 to change Senate rules to require only the bare majority rather than 60 votes to confirm most nominees. In 2013, however, Supreme Court picks were excluded from the rule change. Now the Republicans may change the rule to apply even to Supreme Court nominees.

On February 1, 2017, the Senate Finance Committee advanced Price's nomination for HHS Secretary in a 14 to 0 vote. Price was confirmed in a straight party-line 52 to 47 vote in the early morning hours of February 10, 2017.

Republicans could invoke the "nuclear option" allowing a bare majority of votes to confirm a Supreme Court nominee.

ACA: Repeal and Replace or Repair

Repeal and replace? Repair? It seems like every other day the Congressional undercurrent changes direction or Trump is quoted as giving a different timeframe for acting on the ACA.

Slowly but surely

The repeal and replacement of the ACA will take place at the same time, according to Ryan on January 12, 2017. Ryan's announcement was made the day after then-President-elect Trump announced the repeal and replacement of the ACA would be done "essentially simultaneously." Later, at a Republican congressional retreat on January 26, 2017, Ryan reportedly stated that the "goal is to get these laws done in 2017." The expectation is that the GOP will have repeal/replacement legislation on the House floor by the end of March. However, as of February 5, 2017, Trump reportedly swayed from that previous estimate, saying in an interview that a replacement plan would not likely be ready until late 2017 or in 2018.

Colin Roskey, partner at Alston & Bird, LLP, and member of the Wolters Kluwer Health Law Advisory Board, opined that repealing and replacing the ACA would not happen immediately upon Trump taking office. Speaking at the American Health Lawyers Association (AHLA) Institute for Health Plan Counsel in Chicago on December 8, 2016, Roskey said major changes will not occur quickly and Republicans will build in a transition period when replacing ACA provisions. He predicted that any replacement will be delayed to protect both individuals who will be impacted as well as health plans and other businesses (see *Health care in 2017: Insights into repealing and replacing the ACA*, December 13, 2016).

Roskey added that, although there is pressure to replace the ACA quickly, Congressional committee chairs will moderate the rush for change, allowing the transition to new laws and regulations to occur over an extended period. He believes that the relationship between moderate Republicans, Price, Pence, and Ryan will help win over those in the Republican Party who want to see a faster repeal and replace.

Much ado about the ACA

Whatever the timeframe, changes to the ACA as well as to other health care and life sciences matters could come through a variety of methods. In January 2017, lawmakers began paving the way for repeal of the health law. With the passage of resolutions in the House and Senate, lawmakers set the groundwork for use of the reconciliation process, and Trump executed the EO aimed at ACA repeal. However, despite these actions, along with Trump's regulatory freeze and the EO aimed at reducing the number of, and costs pertaining to, regulations, as of mid-February the ACA was still intact.

Concurrent resolutions

Republicans in both houses of Congress are relying on unorthodox measures to affect repeal and replacement of the ACA. The concurrent resolution (S. Con. Res. 3), which passed 51 to 48 without amendment (but not without objection by Democrats), authorizes repeal through the budget resolution process—a mechanism requiring only a simple majority vote for success. The budget resolution also allows Republican senators to avoid the threat of a filibuster. The resolution instructs House and Senate committees to develop repeal legislation by January 27, 2017 (see *House and Senate pull out all the stops to halt ACA*, January 18, 2017).

The House passed the concurrent resolution on January 13, 2017, by a vote of 227 to 198. Concurrent resolutions are non-binding and do not require the approval of the president; therefore, the concurrent resolutions are in effect and were not presented to either Obama or Trump for signature. Another House resolution (H.R. 5), which passed 234 to 193, instructs the Congressional Budget Office (CBO) to analyze all bills that will cause a net increase in direct spending except for bills pertaining to the repeal or replacement of the ACA—a limitation that lies in conflict with the CBO's declaration that its "work reflects the agency's objective, impartial, and nonpartisan analytical judgment." Title II of the resolution seeks to further upend the status quo with a proposal to repeal the Chevron and Auer doctrines to "end judicial deference to bureaucrats' statutory and regulatory interpretations." Limitation on those doctrines would significantly impact the rulemaking and interpretive powers of HHS, CMS, and the FDA.

Reconciliation

In January, the Senate released a budget containing reconciliation instructions, which could serve as the foundation for the passage of future health reform legislation. The technique is designed to allow Senate Republicans to "fast track legislation"—to pass legislation with a simple majority, preventing the bill from being filibustered. Although the instructions are vague, the 52-Republican majority is sufficient to effectuate at least a partial repeal. The debate over the budget resolution could take several days, as Democrats may propose numerous amendments to slow down the process.

The reconciliation process was developed to allow Congress an easier means to maintain a budget for complex federal spending programs like Medicare and Medicaid. Thus, a repeal effort through the budget reconciliation process will not repeal all of the ACA because the process can only be used to pass legislation affecting spending and revenue. However, previous reconciliation repeal efforts suggest that the reconciliation process could be used to repeal the ACA's tax credits, Medicaid expansion, and insurance mandates—a repeal wide-reaching enough to strip 22 million individuals of health insurance coverage. Early in 2016, Restoring Americans' Healthcare Freedom Reconciliation Act of 2015 (H.R. 3762), a bill repealing the ACA's coverage subsidies, tax credits, Medicaid expansion provisions, individual and employer mandate penalties, and the medical device and health insurance taxes, made it to Obama's desk before being vetoed (see *What will a Trump presidency mean for*

health care?, November 9, 2016; *Bill to repeal portions of the ACA heads to the President's desk, Obama veto imminent*, January 13, 2016; *Message in a veto: President says ACA stays put*, January 13, 2016). Enactment of H.R. 3762 would repeal portions of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) and cause the number of uninsured Americans and the insurance premiums in the non-group market to rise immediately. With a new Congress and presidential administration, the previously rejected legislation will likely be revisited.

According to a CBO report issued on January 17, 2017, in collaboration with the Joint Committee on Taxation (JCT) and by request from Senate minority leaders, the number of uninsured Americans would increase by 18 million in the first new plan year following enactment and premiums in the non-group market would increase by 20 to 25 percent in that same year. The legislation would repeal portions of the ACA related to penalties and subsidies, but leave the ACA's insurance market reforms intact.

Regulatory freeze

In a January 20, 2017, memorandum to the heads of executive departments and agencies, White House Chief of Staff Reince Priebus communicated Trump's plan to manage the federal regulatory process while the Administration is in its early days. With exceptions for regulations subject to statutory or judicial deadlines, and for emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters, an immediate regulatory freeze pending review is in effect.

Regulations that have not yet been sent to the Office of the Federal Register (OFR) should not be sent until Trump's appointed or designated department or agency head, or his or her designee, reviews and approves the regulation. Regulations that have been sent to the OFR but not yet published should be immediately withdrawn from the OFR consistent with OFR procedures, and then similarly reviewed and approved before being resubmitted for publication.

Regulations that have been published in the Federal Register but have not yet taken effect will have, as permitted by law, a temporary 60-day postponement of the effective date—the earliest effective date for such regulations will now be March 21, 2017. The purpose of the postponement is to review questions of fact, law, and policy raised by each regulation. Agency and department heads are further directed to consider proposing further notice-and-comment rulemaking for regulations that have been delayed to review questions of fact, law, or policy. According to the memorandum, regulations that do raise substantial questions of law or policy after review require notifying the Office of Management and Budget (OMB) and taking further appropriate action in consultation with the OMB Director (see *Trump Administration previews health care plans with Executive Order, regulatory freeze*, January 23, 2017).

Executive orders

One of Trump's first official acts was signing the EO titled "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal." The EO states it is the Trump Administration's policy to seek the prompt repeal of the ACA. It further gives executive agencies and departments the authority and discretion to waive, defer, grant exemptions from, or delay the implementation of many ACA provisions and requirements. The EO, which has the full force of law but is subject to judicial review, states that while the Trump Administration is seeking the prompt repeal of the ACA, the Executive Branch must ensure that the law is being implemented efficiently and take steps to minimize its economic and regulatory burdens. It also previews the Administration's view of what an ACA replacement may look like, directing executive agencies and departments to make preparations to give states more flexibility and control of the health insurance market, including encouraging health insurers to provide policies across state lines.

As of January 20, 2017, and with some exceptions, an immediate regulatory freeze pending review is in effect.

Under the EO, the HHS Secretary and the heads of all other executive departments and agencies with authorities and responsibilities under the ACA—that is, the Departments of Labor and the Treasury—are directed to use all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the ACA that would impose (1) a fiscal burden on any state; or (2) a cost, fee, tax, penalty, or regulatory

burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. Therefore, the Secretaries of HHS, Labor, and the Treasury are effectively required to do everything in their power to end implementation of the ACA, including provisions covering the individual and employer mandates, Medicaid expansion, contraception coverage, changes to Medicare payments, the medical device tax, and more. However, the EO does not repeal the ACA, which must be done by Congress, and any changes to regulations require the standard notice-and-comment procedures (see *Trump Administration previews health care plans with Executive Order, regulatory freeze*, January 23, 2017).

On January 30, 2017, Trump signed an EO titled "Reducing Regulation and Controlling Regulatory Costs," as the first step in fulfilling his campaign promise to repeal two federal regulations for every one that is issued. The EO affects all agencies except functions pertaining to the military, national security, and foreign affairs. For fiscal year (FY) 2017, the EO requires any executive department or federal agency that proposes a new regulation to identify at least two regulations to be repealed. In addition, the order effectively creates a regulatory budget of $0 for FY 2017, by requiring that the total incremental cost of all new regulations, including repealed regulations, to be no greater than $0.

Under the order, the Director of the OMB must provide federal agency guidance addressing:

- processes for standardizing the measurement and estimation of regulatory costs;
- standards for determining what qualifies as new and offsetting regulations;
- standards for determining the costs of existing regulations that are considered for elimination;
- processes for accounting for costs in different fiscal years;
- methods to oversee the issuance of rules with costs offset by savings at different times or different agencies; and
- emergencies and other circumstances that might justify individual waivers of the requirements.

The order also requires that, beginning in FY 2018 and going forward, each agency identify to the OMB each regulation that increases incremental costs, the offsetting regulations, and the best approximation of the total costs or savings associated with each new regulation or repealed regulation (see *Trump orders two regulations repealed for each one issued*, January 30, 2017).

Bills, Bills, and More Bills in Response to the ACA

Numerous bills have been proposed by members of Congress to address the ACA, either in whole or in part. For a full, up-to-date list of bills, please refer to the Legislative Status link available on this page. Just a few of the proposed bills are highlighted below:

- The Plan Verification and Fairness Act of 2017 (H.R. 706) would require HHS verification of an individual's eligibility for a special enrollment period (SEP) before an insurer would be permitted to make coverage effective for that individual. Although HHS has already developed a pilot program for some SEP eligibility verifications, the bill would require HHS to create a verification process, through interim final rulemaking, for plan years beginning on or after January 1, 2018.
- The State Age Rating Flexibility Act of 2017 (H.R. 708) would give insurers more authority to vary the premium rates charged to older enrollees, as compared to younger enrollees, in the individual and small group markets. The bill would permit insurers to raise the current ratio of three-to-one to a ratio of five-to-one, or, to any other ratio established by a state. The greater variation addresses insurer complaints that the three-to-one ratio is not actuarially appropriate.
- The Health Coverage State Flexibility Act of 2017 (H.R. 710) would reduce the length of the current 90-day grace period afforded to premium tax credit recipients who miss their premium payments. The bill would shorten the grace period to one "provided by law" or one month. Although premium tax credit recipients are, by definition, experiencing financial difficulty, the bill is designed to assuage insurers' contentions that premium tax credit recipients are using the grace period to skip the last three months of premium payments, catching up only when or if they develop a need for health care. However, HHS noted in the preface of its Notice of Benefit and Payment Parameters for 2018 (81 FR 94058) that such grace period "gaming" claims are unsubstantiated.
- The Preexisting Conditions Protection and Continuous Coverage Incentive Act of 2017 (not formally introduced), which does not promise a change in policy, is a statement of policy. In essence, the bill is a promise, in the event Congress decides to repeal the ACA, that the health reform replacement will include a provision with an absolute ban on preexisting conditions clauses. The bill establishes Congress' position that it will not allow a return to a health insurance market where coverage decisions are based upon the status of an enrollee's

health. The bill makes a curious exception, however, for genetic conditions which have not already led to a diagnosis (see *House Republicans narrow aim to specific provisions in health reform battle*, January 31, 2017).

- The Patient Freedom Act of 2017 (S. 191), introduced January 23 by Sens. Bill Cassidy (R-La) and Susan Collins (R-Me), would allow states to continue to use the infrastructure of the ACA state or federal Marketplaces, or to create new marketplace portals. Under the bill, states would have three options: first, continuing the implementation of the ACA, and generally continuing the premium and cost-sharing subsidies; second, creating their own state marketplace, with a new Roth health savings accounts (HSA)-based deposit system for people who do not qualify for health coverage subsidies; and third, rejecting, to the extent permitted by the new plan, Title 1 of the ACA and replacing it with nothing. States that fail to opt for any of these three will be deemed to have chosen option two (see *Patient Freedom Act introduced to repeal and replace ACA*, February 1, 2017).
- The Protect Medical Innovation Act of 2017 (H.R. 184), reintroduced by Rep. Erik Paulsen (R-Minn.), would permanently repeal the ACA's 2.3 percent excise tax on medical devices. Similar legislation was proposed in the 114th Congress, where the permanent repeal of the tax failed. However, the 114th Congress did pass, with bipartisan support, a two-year suspension of the medical device tax, which was signed into law by Obama. The California Life Sciences Association (CLSA) praised the reintroduction of the tax, noting that without permanent repeal, the tax will hamper innovation and investment in medical technology research and development.
- The To bar Supreme Court decisions in certain Patient Protection and Affordable Care Act cases from citation bill (H.R. 177), was introduced by Rep. Steve King (R-Iowa) to bar ACA-related precedent in what he *called* "an effort to look ahead and bar the Supreme Court from citing Obamacare in forthcoming decisions as binding precedent." The proposed legislation is designed to override the Supreme Court's ACA decisions, including *King v. Burwell* and *Burwell v. Hobby Lobby Stores, Inc.* In addition to furthering his goal of passing laws to make it seem as though the health reform law "had not been enacted," King's also stated that the bill was important to protect Congress' authority under Article I of the Constitution, so that "Congress is the only entity of our government making or changing laws" (see *Beyond repeal: Congress tries additional tactics to undermine ACA*, January 11, 2017).

Effect of Repeal

Health care was the third most important issue that American voters wanted Trump and the new Congress to tackle in 2017, according to a January 2017 Kaiser Family Foundation (KFF) poll. The poll posed a number of questions regarding health care, but results were notably split on whether Americans wanted the ACA repealed. The poll found that 47 percent believed that lawmakers should not vote to repeal the ACA, 28 percent were in favor of waiting to vote on repeal until details have been announced on a replacement plan and 20 percent were in favor or voting to repeal now and working out the details of the replacement plan later. [See Table 1.] This was similar to Americans' views on the ACA when it was passed in 2010 when 46 percent saw it unfavorably, 43 percent favorably.

Under the ACA, the uninsurance rate in the U.S. has dropped to 8.6 percent, the lowest level on record.

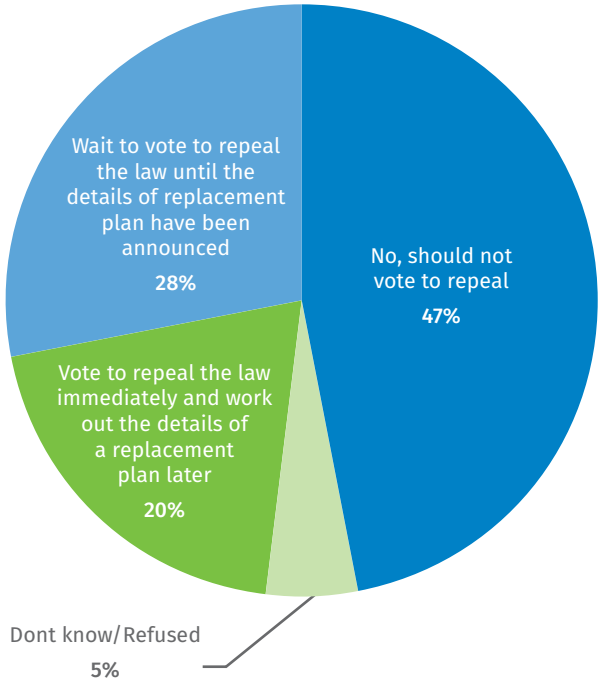
Cost of repeal. Repeal would not only increase Medicare spending but also lead to higher beneficiary costs, a less-solvent Part A trust fund, and the return of the Part D drug benefit "doughnut hole," according to a KFF issue brief. KFF noted that the CBO estimated an increase in Medicare spending of $802 billion from 2016 to 2025 if the ACA were repealed in full (see *Repealing the Affordable Care Act—an unaffordable idea?*, June 24, 2015). This increase would primarily be attributed to higher payments to health care providers and Medicare Advantage (MA) plans, which the ACA reduced based on the expectation that due to coverage increases, hospitals would have fewer uninsured patients.

Uninsured numbers and other effects. Under the ACA, the uninsurance rate in the U.S. has dropped to 8.6 percent, the lowest level on record (see *White House celebrates ACA, Republicans refuse to join party*, October 26, 2016). The CBO estimated that 22 million people would lose health insurance if H.R. 3762, discussed above, became law (see *Senate's ACA repeal would reduce deficits by $474B*, December 16, 2015).

TABLE 1

Most Americans Want Lawmakers To Either Not Repeal ACA or Wait to Repeal Until Replacement Details Are Known

Percent who say they would like to see lawmakers do each of the following with the 2010 health care law:



SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted December 13-19, 2016)

In a different report, the CBO found that repealing the ACA would first increase the federal deficit, but later begin to reduce the deficit while leaving individuals with higher premium costs (see *Can health care spending be reduced while improving effectiveness?*, September 28, 2016).

The nonpartisan Committee for a Responsible Federal Budget analyzed Trump's campaign plan and determined that if it were implemented, the number of uninsured would increase to 48 million (compared to a projected 27 million in 2018 under current system); it also found that the Medicaid block-grant proposal lacked sufficient detail to estimate whether it would maintain current spending levels or save hundreds of billions of dollars.

Not all is bad. If the ACA is repealed, Roskey expects some provisions of the ACA—such as pre-existing condition protection, required coverage of dependent children through age 26, and the continuous coverage provision—will remain part of health care reform. Recent bipartisan legislation that grew out of the ACA, including the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (P.L. 114-10), also will likely continue. A core theme of the Republicans, Roskey noted, is to bring certain provisions that were governed by the federal government back to the states, but he added this may not be doable for some of the Republicans' plans. For example, allowing insurance companies to sell across state lines to increase competition may need more time to put in place. Although he expected an immediate call to repeal the contraception mandate by churches and other individuals, Roskey did not believe it would be a top priority of the new Administration (see *Health care in 2017: Insights into repealing and replacing the ACA*, December 13, 2016).

Big Headlines on the ACA

Three likely contentious reforms of the ACA include providing states with block grants to fund Medicaid, whether people with preexisting conditions will still be able to get insurance, and the differences between universal access to insurance versus universal coverage.

Block grants for Medicaid. Trump supports the use of Medicaid block grants, which would give states a set amount of money instead of matching funds, aimed at limiting federal spending by making it predictable and giving more power back to the states. Just how much money would be provided per state through the grant is not known. However, limits on funding could eliminate guaranteed coverage for eligible beneficiaries while shifting costs and risk onto beneficiaries, states, and providers and eliminating Medicaid benefits. It is also unknown how such Medicaid changes would affect the ACA expansion of Medicaid. (See also *Top 5 Medicaid litigation actions of 2016 and a look at 2017*, December 21, 2016).

Other changes to Medicaid could be made through waivers under Section 1115 of the Social Security Act. Section 1115 waivers are designed to provide states the opportunity to test demonstrations that advance program objectives but do not meet federal program rules. Several states—including Indiana—are using Section 1115 to expand their Medicaid programs. Indiana's waiver includes premiums on most Medicaid beneficiaries, a coverage lockout period for individuals with incomes above the poverty level who fail to pay premiums, health savings accounts, and healthy behavior incentives. The Obama Administration previously rejected proposals under Section 1115 to require work as a condition of Medicaid eligibility and impose premiums regardless of income. The Trump Administration will be able to renew existing waivers and approve a new set of waivers, likely on a new set of terms.

Trump and Ryan have both indicated a desire to replace traditional Medicaid with a block grant program. Under such a program, states would receive annual fixed amounts to spend on activities permitted under the terms of the program. As a result, federal funding would become disconnected from the number of Medicaid beneficiaries and the cost of providing care. Under such a program, entitlement to coverage could no longer be guaranteed and states would be obligated to substantially restructure eligibility, payment, and coverage rules.

The CBO estimated that recently proposed block grant legislation would reduce federal spending by $1 trillion over 10 years—saving which would result from the denial of coverage to about 14 million people.

Preexisting conditions. Although Trump claims he wants to maintain protections for people with preexisting conditions, the big question is how this would be accomplished. The ACA prevented those with preexisting conditions from being denied, or charged more for, coverage by an insurance company. Without the mandate for everyone to have health insurance coverage, an unbalanced number of "sick" people may sign up than "healthy" people, leading to skyrocketing premiums. Under Ryan's plan, on the other hand, preexisting condition protections are other offered when people are switching to a new plan and would shuffle people with preexisting conditions into high-risk pools that would be subsidized by the government. However, Democrats say that high-risk pools have failed in the past due to lack of funding.

Trump and Ryan have both indicated a desire to replace traditional Medicaid with a block-grant program, where states would receive annual fixed amounts.

Universal access versus universal coverage. Trump's claim that "we're going to have insurance for everybody" has left many, including fellow Republicans, scratching their heads. What this means, and what will ultimately be enacted, is unknown. Republicans seem to favor "universal access" to health insurance coverage. As Bernie Sanders (I-Vt) was quoted as saying during Price's confirmation hearing, "I have access to buying a $10 million home, I don't have the money to do that."

Other Affected Health Topics

Trump's proposals announced during his campaign did not include many details and did not mention certain health law topics. So what are experts watching for in the next four years?

Medicare spending

Trump pledged to "save Social Security and Medicare without cuts" in multiple advertisements and speeches. The GOP 2016 platform, however, calls for privatizing Medicare through a premium-support model. Trump also endorsed giving HHS the authority to negotiate prescription drug prices. As of January 31, 2017, Trump sidestepped the issue in a meeting with executives of drug companies, and did not follow through with his promise to allow the government to negotiate directly with drug companies to lower prices for Medicare drugs and instead claimed that streamlining the FDA and getting approvals faster will lower prices, according to the White House statement. At a press briefing on February 7, 2017, however, press secretary Sean Spicer was asked whether Trump is for or against negotiating Medicare drug prices to which he responded, "He's for it, yes."

Drug and food regulations

During the campaign, Trump's Health Care Reform Plan set the following goal: "Remove barriers to entry into free markets for drug providers that offer safe, reliable and cheaper products. … Though the pharmaceutical industry is in the private sector, drug companies provide a public service. Allowing consumers access to imported, safe, and dependable drugs from overseas will bring more options to consumers."

While the Trump campaign also criticized the FDA's food industry regulations, post-election there has been no additional information about the President-elect's plans for food regulations, and it is unknown whether Trump will follow through and direct the FDA to lower the bar when it comes to food safety. [In a fact sheet that was later removed from his website, Trump called for rolling back many FDA regulations related to food safety; later pages related to regulations did not mention the FDA.]

Health compliance officers

Roy Snell, CEO of the Health Care Compliance Association (HCCA) noted that regardless of changes to the ACA, the workload of compliance officers won't change much. "It would take years to change or eliminate enough regulations to make any material difference in the workload of compliance officers," Snell said. "Although there are many regulations, a vast majority of the compliance officers' risk and workload is connected to billing. Billing is complicated because patient care is complicated, therefore documenting patient care will be always complicated and questioned. That will never change because no administration can simplify patient care. Claims that changes to laws such as the ACA will materially reduce the average health care compliance officers' workload are [only] made by people who haven't studied the typical health care compliance officer's workload."

Medicaid and hospitals

The ACA allowed many states to expand their Medicaid enrollment, with the federal government paying for most of the cost of the expansion. Susan A. Benz, partner and co-chair of the Health Care & Human Service Practice Area at Barclay Damon LLP, noted, "Medicaid expansion has provided reimbursement for hospitals for care that was previously uncompensated. The potential loss of the Medicaid reimbursement to providers could result in a substantial increase in bad debt due to uncompensated care and cause financial stress on front-line providers."

Fraud provisions

Benz said, "It is unclear whether the anti-fraud provisions of the ACA will be repealed. One notable anti-fraud provision is the duty to repay Medicare and Medicaid overpayments within 60 days of identification of the overpayment or it is deemed a 'false claim.' This provision has caused considerable anxiety for providers due to the '60-day clock' and the risk of false claims liability which multiplies the damages and imposes substantial penalties on providers." Benz continued, "The repeal of some or all of the ACA is causing instability in the insurance marketplace, anxiety for the 20 million+ individuals who may lose health care coverage, and panic among health care providers who anticipate reduced government reimbursement."

Veterans' health

In his campaign policies on the U.S. Department of Veterans Affairs (VA), Trump laid out plans to allow veterans to choose between receiving health services at the VA or through a private provider of their own choice. He also shared plans to increase the number of available mental health care providers, and allow veterans to obtain mental health services outside of the VA. Trump nominated David Shulkin, current undersecretary for health at the VA, as Secretary of Veterans Affairs. Shulkin was nominated to his current position by President Obama and confirmed in June 2015.

Behavioral health

Gerald "Jud" E. DeLoss, an Officer in the Health Care Practice Group at Greensfelder, Hemker & Gale, P.C., Chicago office, believes that the new Administration may impact behavioral health care legislation and regulation. At the time of the interview, DeLoss was awaiting the Substance Abuse and Mental Health Services Administration's (SAMHSA) modifications to the confidentiality regulations for substance-use disorder (SUD) records, which were ultimately published on January 18, 2017 (82 FR 6052). DeLoss is "relatively optimistic" that behavioral health care will continue to be an important focus, and hopes the Trump Administration will continue the current move "toward improvement and integration of behavioral health into the full health care spectrum." He praised CMS' decision to "roll back the restriction on larger SUD treatment facilities prohibited by the institutions for mental disease (IMD) exclusion," saying it "should dramatically increase the number of beds available for treatment."

See also *Health and Life Sciences Implications of the Trump Administration*, December 28, 2016.

Conclusion

The ability of Trump and the new Congress to implement many of their ideas and campaign promises will unfold in the coming months, or perhaps years, but there has been no action to repeal or replace the ACA or to make any substantial changes to Medicare by Congress or the President. The Republican-controlled Congress will likely create a spiral of changes to the health law industry but which changes will win out, and which priorities are identified by the president, are yet to be seen. Until then, it is business as usual.