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Elephants in the Room: What Is Next for Health Policy?

Health policy in the US is a problem in search of a solution and, despite a current pause in actions, reform efforts will continue this year.

No different than several chief executives before him, President Donald Trump began his four-year term with the ambitious goal of overhauling domestic health policy – this time, to repeal and replace the Affordable Care Act (ACA). Working with US Department of Health and Human Services (HHS) Secretary Tom Price and US House of Representatives Speaker Paul Ryan (R-WI), he agreed to a three-phase approach to repeal and replace the ACA. Each phase was designed to utilize certain unique procedural processes to systematically change provisions of the ACA, though phases could be implemented concurrently.

The first phase of the approach was passage of H.R. 1628, the American Health Care Act (AHCA). Congressional Republicans intended to utilize the fast-track budget reconciliation procedure to make changes to the ACA, which would require only 50 votes for passage in the Senate. However, to take advantage of reconciliation, the Republican leadership needed to craft a bill that did not contain non-budgetary provisions that were subject to a procedural challenge by Senate Democrats. Moreover, the legislation needed to be completed before Congress could begin work on FY 2018 spending legislation, which Republicans hoped would make it possible to complete tax reform legislation using reconciliation as well.

To combat the narrowness and time-sensitive aspects of this legislation, in phase two of the strategy, Secretary Price was to utilize his administrative powers within the executive branch to "deregulate the marketplace to lower the cost and stabilize the market." In recognition that Congress, not the executive branch, is responsible for enacting certain changes to the ACA, phase three of the strategy was to pass legislation that would not fit within the budget reconciliation process and would thus require a 60-vote threshold in the Senate for passage. Since the bill was pulled from consideration on March 24, Congressional Republicans have already begun work on several pieces of legislation within phase three, including H.R. 372, the Competitive Health Insurance Reform Act of 2017, and H.R. 1101, the Small Business Health Fairness Act. Speaker Ryan has also stated that future legislation will focus on selling insurance across state lines, among other policies.

There is much commentary and speculation on why President Trump and Speaker Ryan decided to pull AHCA from consideration on the House floor on March 24, a move that signals delay or abandonment of the phase one strategy. Many observers blame intra-party conflict, stating that Republican leadership was unable to bridge the ideological divide between the conservative House Freedom Caucus and more moderate Republicans to pass the legislation without Democratic support. With the notion that "all politics is local," others note that the bill itself impacted congressional districts differently, and lawmakers weighed pleasing their constituencies over appeasing leadership. Some – including the President himself – iterate that health policy is complicated, and the 115th Congress and new administration needed more time to discuss and deliberate the details of how to reform a major, yet historically messy, domestic policy.

Analysis and intrigue aside, both political parties agree that the problems facing the healthcare sector will not disappear anytime soon. While Democrats argue that the lack of bipartisan support when passing the ACA led to issues now requiring modifications during implementation, some Republicans advocate that the ACA can never be successful and will ultimately collapse.

It remains unclear how the three-phase strategy will now be achieved and how the administration will negotiate with congressional Democrats and a fractious Republican conference to advance reforms. We anticipate several potential paths forward, including possible actions involving the AHCA, bipartisan opportunities in reauthorizations of current programs, potential appropriations activities and executive branch actions.

Possible Actions Involving the American Heath Care Act (AHCA)

Although the President and House Republican leadership have indicated that they do not plan to reconsider comprehensive health reform legislation immediately, other potential legislative routes, beyond or including reconciliation, exist for the legislation, either in whole or in part.

Those in the more conservative wing in the party have floated the possibility of a clean repeal of the ACA, which the House has passed 60 times before. Such a move would appease those in the Freedom Caucus who did not believe that the AHCA went far enough in its repeal provisions, but may repel more moderate Republicans, who argue that portions of the ACA – including guaranteed issue, allowing children to remain on their parents' insurance until age 26, and fraud and abuse provisions – are worth keeping.

Another school of thought would suggest taking a piecemeal approach wherein individual bills move through regular order. Such legislation would be restricted to policy items that received consensus among the Republican Party, such as repeal of the medical device excise tax and repeal of the Cadillac tax imposed on high cost employer-sponsored health coverage. However, it is unclear if, given all of the other agenda items competing for floor time, this would be a viable alternative. Further, such an approach runs the risk of opposition in the Republican base, who may argue that these changes in policy do not truly replace the ACA.

Conversely, it is possible to build a single comprehensive bill that would repeal ACA in its entirety, but concurrently include replacement provisions. If this process is utilized, thought must be given to a more deliberate, open and transparent process that engages the general public. It will also allow for a wider scope of changes that would not be stymied on the procedural rules of reconciliation.

In any scenario, Republicans want to have the ability to vote for the repeal and replacement of the ACA to fulfill their campaign promises.

Although it appears unlikely, the Senate could take the lead in the aftermath of the failed House reconciliation measure. The Senate has the ability to work under FY 2017 reconciliation instructions to reform healthcare policy or tax policy, including repeal of the ACA's taxes. Alternatively, senators could introduce legislation under regular order. Yet, due to the 60-vote threshold required for non-reconciliation measures, legislation would be a result of interparty compromise. Thus, if it moves to the House chamber, negotiations made in the Senate may create bipartisan House support.

Bipartisan Opportunities in Reauthorizations of Current Programs

The reauthorization of historically bipartisan legislation will give Congress the opportunity to work across the aisle on healthcare issues, potentially inserting some of President Trump's agenda items into must-pass legislation.

Both the House of Representatives and the Senate started the regular order process for the reauthorization of the US Food and Drug Administration (FDA) user fee agreements. The Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Amendments (MDUFA), Generic Drug User Fee Amendments (GDUFA) and Biosimilar User Fee Act (BsUFA) all expire in September 2017, and lawmakers hope to have the programs reauthorized before they leave for the August recess. PDUFA authorizes the FDA to collect fees from pharmaceutical companies to help fund the agency's drug review work. Stakeholders are satisfied with the progress PDUFA-V made, but hope that PDUFA-VI will include further efforts to involve the patient perspective in the drug development process, build on FDA's Sentinel System for active surveillance of safety issues and enhance regulatory science initiatives like patient-reported outcomes and biomarkers. In March, the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions (HELP) held hearings to examine the FDA user fee programs and they continue to move the process forward.

Separate from the repeal and replace efforts, the President has underscored the importance of removing bureaucratic roadblocks to drug development and innovation across the federal government, and he has discussed issues surrounding drug importation and the government's ability to negotiate drug prices in Medicare Part D. From the campaign trail to his February address to Congress, President Trump has routinely called for lawmakers to "work to bring down the artificially high price of drugs and bring them down immediately." Having nominated Scott Gottlieb, a physician and Resident Fellow at the American Enterprise Institute, as Commissioner of the Food and Drug Administration, it is clear the President has pharmaceutical policy in his sights. Given both President Trump's and Democrats' interest in tackling the high prices of prescription drugs, incorporating drug pricing into a user fee reauthorization conversation is a possibility and may be a chance for a bipartisan win. However, an initiative that seeks reforms in the often contentious worlds of drug pricing and innovation may be a tough road for a president focused on the big picture rather than details, especially if he has tired of the complexities of health reform.

The Children's Health Insurance Program (CHIP) was originally established in 1997 after President Clinton's failed efforts to pass comprehensive health reform at the beginning of his presidency. The program seeks to provide affordable health insurance to children from low-income families who had few insurance options besides Medicaid. Because funding for the program expires on September 30, 2017, and states are urging early action in hopes of incorporating funding into their budgets, Congress will work this spring on reauthorizing the program. Some observers have suggested that, like President Clinton, President Trump may utilize children's health as a vehicle for reform. This year's discussion over the extension will likely invoke an assessment of the current state of insurance markets for children.

The CHIP reauthorization debate in both chambers will center on how far into the future funding should be extended, as well as what programmatic changes should be placed in the reauthorization. However, the path for reauthorization remains uncertain. Republicans could work with Democrats and push for a clean reauthorization of CHIP or reauthorization could include a reduction in funding levels, a repeal of provisions related to state eligibility requirements and other Medicaid program reforms.

Medicare physician payments and value-based care are areas of common ground in Congress. With the 114th Congress' bipartisan passage of H.R. 2, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114-10), lawmakers on both sides of the aisle continued the support of a movement away from the fee-for-service system to paying providers for quality through value-based payments. The Medicare Payment Advisory Commission's (MedPAC) March Report to Congress provides recommendations for successfully implementing value-based payment policies, encouraging policymakers to further discuss expanding value-based payments and bundled payment programs to other care settings. The House Committee on Energy and Commerce, House Committee on Ways and Means and Senate Committee on Finance will work with Secretary Price to ensure a successful MACRA implementation process with proper oversight.

Potential Appropriations Activities

The appropriations process is the congressional mechanism to fund agencies and programs, and commentators have suggested that it may be used to advance President Trump's repeal and replace agenda, along with other reforms. Congress is currently wrapping up the FY 2017 process and it will soon consider the FY 2018 spending provisions.

Appropriations bills contain language to give the agencies direction on the purpose of the funds or program, but are limited in detail. A report accompanies each bill and is a tool each body of Congress uses to assert concerns or make specific directions regarding agency activities, prior policies and proposed policies, and to provide more details or instructions to the agency on how to spend the taxpayers' funds contained in the bill.

In general, the appropriations process is guarded against doing the work of the authorization process, where most policy changes, including ACA repeal and replace initiatives, would occur. Examples of authorization language can clearly be found in previous appropriations, but most are limited to technical changes in lieu of a pending authorization bill or limited "policy riders" and "limitation riders."

In theory, an appropriations bill, specifically an end of year omnibus-style bill, certainly could be used to carry policy reform language. However, it is unlikely that the appropriations process would carry a comprehensive reform. In part, some in the public would likely criticize the bill as having not passed via regular order or with full vetting. In the current environment, where members on both sides are looking for reasons not to support the bill, it would provide an easy way for lawmakers to vote "no."

The President's initial budget framework for FY 2018 was received by Congress on March 16, yet details are not expected until May. Within the so-called "skinny budget," the President requested US$69 billion for HHS, a US$15.1 billion, or 17.9%, decrease from the current level. The request includes increases for Health Care Fraud and Abuse Control, FDA medical product user fees and block grants to states to address public health challenges. Notably, the request proposes a reduction of US$5.8 billion for the National Institutes of Health (NIH) and the elimination of discretionary programs within the Office of Community Services, health professions and training programs, and NIH's Fogarty International Center. The budget reforms promote public health, emergency preparedness and prevention programs, and include a set of administrative actions within the FDA intended to achieve regulatory efficiency and speed the development of safe and effective medical products. The President also requested a major reorganization of NIH's Institutes and Centers and consolidation of the Agency for Healthcare Research and Quality into the NIH.

Congress is now reviewing the budget framework, holding hearings and listening to constituents and outside groups to dispose of the request in a manner it believes will support the best interests of the country. Each committee will then develop the initial response to the budget request with funding levels and a report that communicates additional information to the agency or administration.

Executive Branch Actions

On his first day in office, President Trump made it clear that he will use all powers available to him to repeal and replace the ACA. In signing his first executive order, he required the heads of executive departments and agencies, including HHS, to "exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [Affordable Care] Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden" on a variety of entities, including individuals, providers and insurers. He also ordered heads of executive departments and agencies to provide greater flexibility to states under the law, yet the order rightfully acknowledged that many executive changes would require notice-and-comment rulemaking and other procedures.

Last week, after agreeing with Speaker Ryan's decision to rescind the AHCA from a House floor vote, President Trump proclaimed that the ACA would fail on its own and Republicans would then initiate another replacement plan. While some may agree with this approach, others note that it is now in the administration's hands to either implement the ACA's provisions so that they work or risk being blamed for the law's failures.

It has yet to be determined whether President Trump will decide to continue federal payments to compensate insurers for lowering low-income enrollees' copayments, coinsurance and deductible responsibilities. While these subsidies have faced legal challenges by House Republicans, a loss of such payments would likely destabilize the insurance markets, potentially the death knell for much of the ACA and insurance coverage for many Americans.

Commentators have also suggested other actions President Trump could take to impact the insurance market, including not enforcing the individual mandate, expanding waivers and other administrative actions. However, the administration must address that such moves will face oversight – by members of Congress, the HHS Office of Inspector General (OIG) and the press. Most recently, HHS Inspector General Daniel Levinson informed Sens. Elizabeth Warren (D-MA) and Patty Murray (D-WA) that, in response to their letter, the HHS OIG will investigate "the decision to stop paid advertisements and temporarily suspend other outreach efforts directed at Marketplace enrollment in the final days of the 2016-17 open enrollment season."

In the Medicaid space, in a letter to governors earlier this month, Secretary Price and Centers for Medicare & Medicaid Services Administrator Seema Verma committed to "ushering in a new era for the federal and state Medicaid partnership where states have more freedom to design programs that meet the spectrum of diverse needs of their Medicaid population," suggesting such key areas as improving federal and state program management, supporting innovative approaches to increase employment and community engagement, aligning Medicaid and private insurance policies for non-disabled adults, providing additional timelines and processes for Home and Community-Based Services changes and providing states with more tools to address the opioid abuse epidemic.

We clearly live in exciting times, particularly in healthcare.

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