PUBLICATION

2019: What to Expect in Health Care Policy

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Health care issues will remain a central focus in Washington throughout 2019. Having gained control of the House following the 2018 mid-term elections, Democrats now have the ability to block President Trump's legislative agenda, taking items such as Affordable Care Act (ACA) repeal and replace and Medicaid block grant reforms off the table. Although a significant bipartisan breakthrough on insurance coverage or entitlement reforms remains unlikely, Congress may reach agreement on incremental reforms to address surprise medical billing and prescription drug prices. The Trump Administration will also continue moving forward with new regulatory reforms affecting Medicare payment policies, Medicaid waivers, and prescription drug costs.

Below, we provide an outline of the major legislative, regulatory, and state policy areas to watch for in health care in 2019.

Continued Debate, but Limited Action on the Affordable Care Act

The divided Congress means that lawmakers will continue to have heated debates over the ACA, and the potential for passing bipartisan legislation remains narrow.

House Democrats will seek to use congressional hearings and legislation to position themselves as defending the ACA against the Trump Administration's regulatory changes. The House Ways and Means and Education and Labor Committees held hearings on protections for pre-existing conditions on January 29 and February 6, respectively. The House Energy and Commerce, Health Subcommittee held a markup hearing to consider legislative changes to the Trump Administration's regulations affecting protections for pre-existing conditions and short-term plans on February 13. House Democrats will also respond to the *Texas v. United States* lawsuit, which has created fresh uncertainty regarding the ACA's coverage expansions, consumer protections, and payment and delivery system reform policies. In the first week of the 116th Congress, House Democrats passed a rules package and a resolution authorizing the House Counsel to intervene as a defendant in the lawsuit. The House Energy and Commerce, Health Subcommittee also held a hearing on February 6 to discuss the lawsuit's potential impacts. Expect these types of hearings to continue throughout 2019.

Democrats and Republicans may find common ground on bipartisan legislation to address surprise medical billing, particularly after President Trump recently hosted a White House round-table discussion on the issue. Nearing the end of the last Congress, Senators Michael Bennet (D-CO), Tom Carper (D-DE), Bill Cassidy (R-LA), Chuck Grassley (R-IA), Todd Young (R-IN), and former Senator Claire McCaskill (D-MO) introduced draft legislation to protect patients from surprise out-of-network medical bills. Although there is support in both parties for addressing surprise billing, lawmakers must navigate conflicts among health care industry stakeholders to achieve consensus on a solution. Other potential areas for bipartisanship include a delay or repeal of the ACA's taxes on health insurance, medical devices, and high-cost employer plans (Cadillac tax). In addition, lawmakers may have interest in reviving a stabilization package for the ACA's insurance exchanges. Senate Health, Labor, Education and Pensions Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) have indicated a willingness to reconsider a package to address the stability of

the individual insurance market, but the prospects of resolving the abortion politics that prevented an agreement in 2018 remain uncertain.

What to Watch: How will the federal courts rule on the appeal of Texas v. United States?

Both Parties Seek Action on Drug Prices, but Solutions Differ

There may be substantial action on prescription drug prices in 2019. Republicans and Democrats have identified drug pricing as a key focus for the 116th Congress, against the backdrop of the Trump Administration's ongoing regulatory efforts in this area. However, while both parties share the goal of bringing down rising drug prices, they differ in their approaches to potential solutions.

Congressional Republicans, led by Senate Finance Committee Chairman Chuck Grassley (R-IA), seek to strengthen private sector negotiation mechanisms and eliminate anti-competitive practices that may increase drug prices. Chairman Grassley has introduced bills to allow importation of lower-cost drugs (S. 61) and to deter patent settlements that delay competition (S. 64). Congressional Democrats, led by House Oversight and Reform Committee Chairman Elijah Cummings (D-MD), Energy and Commerce Committee Chairman Frank Pallone Jr. (D-NJ), and Ways and Means Committee Chairman Richard Neal (D-MA), favor increasing government oversight and negotiating power in the drug industry in an attempt to bring down prices. Chairman Cummings has introduced bills to allow drug importation (H.R. 447) and to require direct government negotiation in Medicare Part D (H.R. 448). House Ways and Means, Subcommittee on Health Chairman Lloyd Doggett (D-TX) introduced his own Medicare drug price negotiation bill (H.R. 1046) on February 7, as well.

Both House and Senate Committees held hearings on January 29 examining high drug prices and potential congressional actions to address them. Chairman Grassley expressed frustration that major drug companies declined to participate in the first hearing and indicated he would hold a subsequent hearing on February 26 featuring testimony from drug company CEOs. Chairman Cummings attacked drug company pricing practices. Both committee hearings examined the role of rebates in drug pricing and the lack of transparency among pharmacy benefit managers (PBMs). The House Ways and Means Committee followed with its own hearing examining rising prescription drug prices on February 12. Committee Chairman Neal and Ranking Member Kevin Brady (R-TX) issued a statement at the start of the hearing calling for bipartisan "meaningful action" on unsustainable price increases, lack of transparency, and incentives in government programs that reward high prices.

On January 31, the Department of Health and Human Services (HHS) issued a long-awaited proposed rule to overhaul the drug rebate system, the latest in the Administration's regulatory efforts to address drug prices. Currently, drug manufacturers pay rebates to PBMs, but those rebates are not typically passed on to patients. Under the proposed rule, those rebates would be prohibited. Instead, drug manufacturers would be encouraged to provide direct discounts to patients accessible when they pay for drugs at the pharmacy counter.

Specifically, starting in 2020, the proposed rule would remove the existing safe harbor to anti-kickback scrutiny that exists for rebates that drug manufacturers pay to PBMs in the Medicare Part D and Medicaid managed care markets. In its place, the rule would create two new safe harbors. The first new safe harbor would protect direct discounts that manufacturers provide to patients at the pharmacy counter, and the second would protect certain PBM service fees. The Administration argues that these reforms will significantly lower out-of-pocket retail drug costs for seniors. However, there are concerns that the proposal would result in increased premiums for all Medicare beneficiaries to offset the loss of the drug rebates.

What to Watch: Can Senate Finance Chairman Grassley, House Ways and Means Chairman Neal, and House Energy and Commerce Chairman Pallone find common ground to advance incremental prescription drug pricing reforms? Will legal challenges by PBMs delay or change implementation of the Administration's overhaul of drug rebates?

House Democratic Majority Aims to Increase Congressional Oversight in Health Care

House Democrats plan to use their majority throughout 2019 to conduct aggressive oversight hearings and investigations into the Trump Administration's regulatory changes to the ACA, the drug industry's price increases, and increasing payer/provider consolidation.

House Democrats have signaled that key ACA priorities for investigation include the Administration's cuts to outreach and marketing funding, limits to the duration of open enrollment, and the expansion of short-term and association health plans that operate outside the law's coverage requirements. Democrats will also likely examine whether the Administration's guidance changes for Section 1332 and 1115 waivers – including allowing states to institute Medicaid work requirements – have undercut access to coverage.

Chairman Cummings has emphasized that Democrats will conduct broad investigations into the prescription drug industry's price increases. The House Oversight and Reform Committee held a hearing on January 29, featuring testimony from academics, patients, and pharma executives.

Health care industry consolidation is another key target for scrutiny. House Judiciary Committee Chairman Jerrold Nadler (D-NY) has indicated that mergers are one of his top concerns, citing the recent CVS Health and Aetna merger. House Judiciary Committee, Subcommittee on Reform, Commercial and Antitrust Law Chairman David Cicilline (D-RI) stated that examining health care price hikes driven by increasing hospital consolidation is one of his top priorities.

What to Watch: How will the prescription drug industry respond to increased oversight? Will this oversight drive further legislative action in Congress?

States Take Divergent Paths on Medicaid Access

States are increasingly moving in different directions on policies affecting Medicaid, which will accelerate variations in access to care across the country.

Idaho, Nebraska, and Utah are expected to expand Medicaid following passage of ballot initiatives in the 2018 mid-term elections, covering more than 300,000 new beneficiaries collectively. Maine is also set to expand Medicaid after the new Democratic governor signed an executive order to begin implementation. The previous governor had delayed implementation of the Medicaid expansion following the state's ballot initiative in November 2017. Virginia implemented the Medicaid expansion in January that the state approved last year. In addition, new Democratic governors in Kansas and Wisconsin ran on expanding Medicaid, but they must still gain approval in the state legislatures to enact such policies. Kansas Governor Laura Kelly sent her plan for the Medicaid expansion to the state legislature on January 29. Finally, at least ten states, including Nevada, New Mexico, California, and Washington, are exploring various options to allow residents to pay premiums to "buy in" to Medicaid coverage.

In contrast, several Republican-led states are pursuing and enacting work requirements tied to eligibility in the Medicaid program. Last year, the Centers for Medicare and Medicaid Services (CMS) approved work-

requirement waivers for seven states: Arkansas, Indiana, Kentucky, Maine, Michigan, New Hampshire, and Wisconsin. Arkansas implemented its waiver in 2018, and Indiana, Kentucky, and New Hampshire are set to do so in 2019. Another eight states have pending work-requirement waivers with CMS, including Alabama, Mississippi, Ohio, Oklahoma, South Dakota, Tennessee, Utah, and Virginia. In addition, Utah and Georgia are considering proposals that would require CMS approval for a partial Medicaid expansion covering individuals only up until 100 percent of the federal poverty level (instead of the full 138 percent under current guidance), while still receiving the enhanced 90 percent federal funding match. CMS has not approved such a waiver thus far.

Initial reports also suggest that CMS is considering avenues to grant states the option, likely through the existing Section 1115 waiver program, to trade a cap on federal Medicaid dollars for additional flexibility in program administration (similar to previous legislative proposals for a Medicaid block grant program). The legal authority for new flexibilities in this direction under a Section 1115 waiver is unclear. However, if CMS does issue such a policy, we may see further significant variation across state Medicaid programs.

What to Watch: Will additional states adopt the Medicaid expansion? Will CMS approve additional Medicaid waivers, including work requirements, a partial expansion, or a block grant option? How will litigation in Arkansas and Kentucky affect Medicaid work-requirement waivers?

New Medicare Payment Regulations and Delivery Innovations

Over the last two years, the Trump Administration has issued numerous Medicare payment regulations aimed at increasing patient choice, reducing health care costs, and promoting delivery system innovation. We expect such actions to continue on several fronts in 2019.

In late 2018, CMS finalized regulations to implement site-neutral payments, phased in over two years, between physician offices and hospital outpatient departments for certain clinical visits. Hospital groups quickly sued HHS to stop the new payment policies from going into effect on January 1. The debate over site-neutral payments and the push to expand these policies to other facilities will likely continue throughout the year.

HHS is also examining changes to the physician self-referral law, known as the Stark Law, to promote valuebased care. The Stark Law prevents physicians from referring patients for certain services payable by Medicare and Medicaid to an entity where the physician or their immediate family members have financial interests. The Administration believes that these laws and regulations may serve as a barrier to providers, payers, and patients seeking to coordinate care through innovative and alternative payment models. HHS intends to issue regulatory changes this year that would provide greater flexibility for providers while maintaining the guardrails against fraud and abuse.

The CMS Center for Medicare and Medicaid Innovation (CMMI) will likely continue to establish new payment and delivery model demonstrations in 2019. Potential demonstrations may address end-stage renal disease, radiation oncology, and other chronic illnesses. Models may also address direct provider contracting and certain social determinants of health, with a particular focus on rural areas. CMS has indicated it will offer new opportunities for providers to accept higher levels of risk and new financial models that ease providers into value-based agreements.

What to Watch: What new demonstrations and regulatory actions will the Administration issue related to Medicare payment policies?

House Democrats Lay Groundwork for "Medicare for All"

As the 2020 presidential campaign heats up, progressive House Democrats are seeking to use 2019 to lay the groundwork for consideration of a Medicare for All single-payer proposal in Congress. Support from key 2020 Democratic presidential candidates, such as Senators Kamala Harris (D-CA), Kirsten Gillibrand (D-NY), Cory Booker (D-NJ), and Elizabeth Warren (D-MA), may provide further momentum.

Rep. Pramila Jayapal (D-WA), Chair of the Medicare for All Caucus, plans to unveil draft legislation in early February. House Democrats will likely consider the proposal in preliminary hearings this year, including in the House Budget Committee, chaired by John Yarmuth (D-KY). Rep. Jayapal is pushing for a vote on Medicare for All in 2019, but the prospects of it reaching the floor remain uncertain without commitments from the House Ways and Means and Energy and Commerce Committees. Of course, even in the unlikely scenario that the House passes a Medicare for All proposal, such legislation would not advance in the GOP Senate.

Democrats are divided over whether to focus on defending and fortifying the ACA or pursuing ambitious reforms for a Medicare for All single-payer proposal in 2019. Moderate Democrats worry that Republicans will likely ramp up attacks on Medicare for All as more details come out on the costs and trade-offs of the proposals. House Energy and Commerce Committee Republicans have already called for a hearing to examine the impacts of Medicare for All. Progressive Democrats argue that the party must show what they stand for beyond defending the status quo and that preliminary work now will make passage of a broader proposal easier, should Democrats win the White House in 2020. Reflecting these tensions, Democratic presidential candidates who have indicated support for Medicare for All have also stressed that they are open to a variety of approaches for expanding health coverage. For example, on February 13, Senators Debbie Stabenow (D-MI) and Tammy Baldwin (D-WI), and Representatives Brian Higgins (D-NY) and Joe Courtney (D-CO) introduced a bill to allow individuals over age 50 to buy into Medicare as a more incremental alternative to the progressive push for Medicare for All.

January polling from the Kaiser Family Foundation finds majority support for a Medicare for All plan, but notes that this support is highly malleable as the public learns more information. Specifically, Medicare for All starts with a net favorability rating of +14 percentage points (56 percent favor, 42 percent oppose). The net favorability jumps to +45 percentage points when people hear the argument that this plan would guarantee health insurance as a right for all Americans. However, net favorability falls to -21 percentage points when people hear it would eliminate private health insurance companies and further to -44 percentage points when people hear it would lead to delays in some patients getting medical tests and treatments.

What to Watch: How will congressional hearings shape public perception of Medicare for All? What role will these proposals play in the 2020 presidential campaign?