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Post-Election 2020 - Health Care Preview

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Health Care Preview

With the presidential transition underway, we now look forward to what the Biden administration will seek to accomplish, particularly in the realm of health care policy. President-elect Biden has been clear that he wants to bolster the Affordable Care Act (ACA, commonly known as "Obamacare") and seek adding a "public option" – to purportedly inject more competition into insurance markets and to provide more coverage choices. This is essentially the opposite position of the Trump administration position, which is supportive of efforts to dismantle the popular health care law despite having presented no concrete alternatives beyond the promise of maintaining pre-existing conditions protections. Congress and the United States Supreme Court also have important roles in determining the direction of the nation's health care policy.

Supreme Court

Within the next year, the Supreme Court is poised to rule on several cases that could have major effects on the health care industry. Two we're watching closely are:

Rutledge v. Pharmaceutical Care Management Association, argued on October 6, 2020, could alter the way pharmacy benefit managers' negotiated rates are regulated by the states. The court could make a decision by the end of 2020 but it is more likely to be pushed to 2021.

California v. Texas, a hot topic in newly-confirmed Justice Amy Coney Barrett's confirmation hearing, was argued on November 10, 2020. At issue in this case is the question of severability surrounding the individual mandate, on which the fate of the Affordable Care Act rests. The Trump administration joined with Texas and other Republican attorneys general to argue against the law's constitutionality. A ruling that the law is unconstitutional would result in millions of people losing health insurance they obtained through the ACA, which would impact not just those patients but the entire health care industry.

Congress

House

The House is now officially projected to stay in Democratic control, but given the seats the Democrats lost in the 2020 election, passing legislation in the new Congress may be more challenging for Speaker Pelosi and Democratic leadership. Through the end of 2020, House leadership is expected to continue talks with Senate leadership for a COVID relief bill. It's possible that a bipartisan compromise is reached during the "Lame Duck" legislative session, but conventional wisdom with each passing day is that action in the first quarter of 2021 is more likely, when a new Congress and Administration are in place.

We expect health care priorities for the Democratic House to align with many of the priorities set by President-elect Biden. We expect the House to act on legislation bolstering the ACA, expanding Medicaid, eliminating surprise billing, and lowering drug costs. Whether these priorities become law depends in large part on the Senate.

Senate

Control of the Senate in the 117th Congress is currently unknown owing to two run-off elections in Georgia. If Democrats win both those races, the Senate would be split evenly between Democrats and Republicans, giving Vice President-elect Kamala Harris an outsize role in legislative activity in at least the first two years of the Biden administration (the vice president is the constitutional tiebreaker in an evenly split Senate).

Although we will not know the final makeup of the Senate until January, we are guaranteed new leaders for the Senate committees with jurisdiction over health policy. If the Senate stays Republican, Senator Richard Burr (R-NC) is next in line to take over for the retiring Senate HELP Committee Chairman Lamar Alexander (R-TN). However, Senator Burr stepped aside from his chairmanship of the Senate Intelligence Committee due to an ongoing investigation into alleged insider trading, so if he is unable to assume chairmanship of HELP, Senator Rand Paul (R-KY) is next in line in seniority on the GOP side. Due to GOP-imposed term limits on chairmanships, Senate Finance Committee Chairman Chuck Grassley (R-IA) is set to step down from the committee to take over as Senate Judiciary Committee Chairman and it is

reported that Senator Mike Crapo (R-ID) will be taking over in the Finance Committee. In a Democratic Senate, Senator Patty Murray (D-WA) would assume leadership of HELP and Senator Ron Wyden (D-OR) would assume leadership of the Senate Finance Committee.

Trump Administration – Lame Duck

As we move into his lame duck period, we are seeing President Trump take action to implement policies that have been on his agenda. On July 24, President Trump announced four executive orders that aimed to reduce drug prices. Of those, the **Increasing Drug Importation To Lower Prices for American Patients** is the only one to have an officially published **final rule** (the rule allows importation of certain prescription drugs shipped from Canada; for our prior coverage and analysis on that, see **here**). On Friday, November 20, 2020, President Trump announced two more final rules impacting the health care ecosystem. One of the more surprising actions was the release of a **final rule** which expressly removes safe harbor protection for rebates paid by drug manufacturers to Part D plan sponsors, Medicaid Managed Care entities, and their intermediaries. HHS had initially proposed such a rule in early 2019, received tens of thousands of comments, and then announced that it would withdraw the rule in July 2019. One of the President's July 24th executive orders revived the issue.

The Trump administration also delivered on one of the more controversial executive orders from July, **Lowering Drug Prices by Putting America First**, releasing an **interim final rule** to create a most favored nation pricing model for drugs covered by Medicare Parts B and D. This model has received criticism from the pharmaceutical industry and other stakeholders. It is expected that both rules will see legal challenges moving forward.

Along with the drug pricing final rules, the Trump administration also took action on November 20 to address the goal of coordinated and value based care through two finalized rules. The HHS Office of the Inspector General released a **final rule** addressing changes to safe harbors under the Anti-Kickback Statue and beneficiary inducements civil monetary penalty regulations, while CMS released a **final rule** updating the Stark Law. The final rules are effective January 19, 2021, except for one provision in the Stark Law rule which goes into effect January 1, 2022. Our Mintz colleagues' full analysis is **here**.

We are also closely monitoring the Trump administrations moves to alter the 340B drug pricing program. The Trump administration is proposing to finalize a rule on the 340B dispute resolution process and submitted it for OMB review on November 17. The rule was initially proposed by the Obama administration in 2016 but affirmatively withdrawn by the Trump administration in August 2017.

The Trump administration has also continued to push for more transparency in healthcare costs, including by publishing a **final rule** on November 12, 2020. This rule, among other things, sets up a framework for the disclosure of certain rates from group health plans and insurance issuers in the individual market when requested by an enrollee.

In terms of ending surprise billing, President Trump issued an executive order on September 24, 2020 that instructs the Secretary of Health and Human Services to work with Congress to reach a legislative solution by December 31, 2020. If no deal is reached, Secretary Azar is instructed to take administrative action, but it is unclear what action would be taken. The chance is small for Congress to come to any agreement as the Senate HELP, House Energy & Commerce, and the House Ways and Means Committees all remain far apart on how to solve this issue.

President-elect Joe Biden

President-elect Joe Biden made his health care agenda a central theme of his campaign. A top priority is to protect the ACA and add a public option. If the Supreme Court rules in California v. Texas to fully or partially strike down the ACA, the Biden administration alongside a possibly divided Congress will be back at square one.

The outcome of the Georgia Senate run-off elections may be crucial in determining the likelihood of many Biden health priorities becoming enacted law. In 2009, the ACA **passed** the Senate along party lines when the Democrats, along with 2 independents, controlled 60 seats (the minimum needed to avoid a filibuster). The House then passed the Senate version by a close margin of 219 to 212 votes with 34 democrats voting against the bill. Similar to the tactics used to pass much of the ACA, Speaker Nancy Pelosi (D-CA) has **said** that they would use reconciliation in order to bypass the Senate filibuster for any health care reform.

President-elect Biden's team, alongside Senator Bernie Sanders (I-VT), developed a plan for addressing high health care costs as part of their **Unity Task Force Recommendations**. In order to lower drug prices, a Biden administration would look to revoke the law preventing Medicare from negotiating drug prices, establish an independent review board to set caps on novel drugs that face no competition when entering the market using international price indexing, establish caps for price increases and tax penalties for non-compliance, allow drug importation when safe, and eliminate tax breaks for pharmaceutical advertising. In terms of surprise medical bills, the Biden administration will aim to increase transparency throughout the entire health care supply chain, reduce administrative burdens through uniform billing, and use existing anti-trust laws to prevent some mergers. Some of these policies are aligned with Trump administration and Republican actions or proposals, shedding light on possible bipartisan compromise even in a divided Congress.

Beyond what President-elect Biden intends to accomplish with Congress, we expect him to use executive powers to reverse many of Trump's health care initiatives and to address shortfalls in the current administration's handling of COVID-19. Biden intends to establish a Pandemic Testing Board, acting in a similar manner to the War Production Board created by President Franklin Roosevelt during WWII, and a US Public Health Jobs Corps, which would seek to mobilize 100,000 COVID-19 contact tracers. President-elect Biden has also expressed his intention to reverse President Trump's withdrawal from the World Health Organization, which would go into effect on July 6, 2021. It is also expected that President-elect Biden would rollback Trump era Medicaid policies. We expect to see CMS reverse course and abandon all attempts to allow individual states to impose Medicaid work requirements as a condition of Medicaid eligibility (none of these efforts to date have withstood court challenges, but some of those cases remain on appeal) and to abandon all demonstration projects/efforts that would allow states to transform Medicaid into block grant programs.

Food and Drug Administration

The FDA, an agency with regulatory oversight of 20-25 percent of products on which consumers spend, including food and medicines, was thrust into the public conscience during the COVID-19 pandemic. All eyes remain on FDA's progress towards authorizing a safe and effective vaccine for COVID-19 in addition to other treatments and diagnostic tests. Scrutiny of the agency in recent months has been intense and criticism has been leveled from members of both parties. To achieve the promise of deferring to science, the incoming Biden administration will need to lower the temperature and depoliticize FDA.

We expect FDA Commissioner Stephen Hahn to step down at or before the end of the Trump administration. FDA Commissioners are Senate-confirmed political appointees and they typically resign before a new administration takes control. In the past, it has sometimes taken more than a year for a new president's FDA Commissioner-nominee to be confirmed. Given the COVID-19 pandemic, we expect a swift confirmation because the agency will need strong and consistent leadership to see that safe and effective COVID-19 countermeasures are coming to market. Moreover, members of Congress from both parties will want someone to hold accountable.

Policy priorities at the FDA may shift depending on who is confirmed as Commissioner. While FDA policy is science- and data-driven, there are things a Commissioner and other senior officials can do to shift the balance between policies that seem to favor industry and policies that appear more aligned with patient advocacy aims. We will continue to watch, in particular, **diagnostic test reform** proposals as well as those related to **digital health**, in addition to **other** timely **topics**. Look for more thorough summaries and analyses of FDA law and policy matters from Mintz and ML Strategies in the coming weeks.

Authors



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