



To: KPM Group DC Colleagues
From: KPM Group DC
Date: February 1, 2021
Re: February Eye on Washington Policy Update



Fireworks over the White House following the inauguration of President Joe Biden

Overview

In terms of priorities for Congress and the Biden Administration, several will continue to dominate the policy agenda for the next few weeks: impeachment, the COVID-19 stimulus, vaccination distribution, and the confirmation of Presidential appointees. The net result is that key pharmaceutical policy priorities (e.g., drug pricing, rare disease legislation/regulation, the opioid epidemic, Medicare Part D, FDA reforms, etc.) have been temporarily placed on the backburner.

As nominees are confirmed at critical agencies, such as HHS, CMS, and FDA, we can expect more drug-specific policies to come out of the Biden Administration.

That said, we believe now is the time for companies to **plan** their policy agenda, **organize** themselves and their stakeholders, and begin to **introduce** the company priorities to policymakers.

As members of the Senate are busy working on the Administration's agenda and other issues, we will be doing a number of meetings with key members of committees and caucuses on the House side to make sure we are aligned when healthcare-specific legislation comes to the floor for a vote. In the meantime,

please enjoy our February Eye on Washington Report, which details key actions undertaken by the Administration and Congress.

Congressional Overview

In the Senate, Minority Leader McConnell (R-KY) agreed to a power-sharing pact with Majority Leader Chuck Schumer (D-NY). The hold-up was around an agreement on eliminating the use of a filibuster on legislative proposals - at the end of the day, Senator Joe Manchin (D-WV) and Senator Kyrsten Sinema (D-AZ) agreed that they would “under no circumstances would change course” on their complete opposition to eliminating the filibuster not giving Democrats the 50 votes they needed to change Senate rules.

- **A filibuster** is a political procedure where one or more Congress members debate over proposed legislation to delay or entirely prevent a decision on the proposal. In the US Senate - the filibuster process also requires a 60-vote margin for most legislation (not including federal judges and presidential political nominees .)

Senate Power-Sharing: the Senate power-sharing deal is expected to be codified and voted on later this week. Once adopted, committees can move forward and organize, with Democratic senators formally becoming committee chairs.

The deal would provide an equal number of members on Senate committees, with a process for discharging bills and nominations that deadlock, provide equal staffing levels, and office space - effectively giving the Democrats a narrow advantage on setting the agenda on contentious issues.

A word you will often hear this month - reconciliation.

Generally, a 60 vote majority is needed to pass legislation in the Senate. While the chamber can move routine measures without a formal vote, they are able to advance certain annual budget and tax-related measures with a simple majority of 50 senators through a process known as reconciliation.

Speaker Pelosi and Majority Leader Schumer are planning on using this process to push forward several more partisan measures, including a COVID relief bill, changes to Obamacare, and drug pricing measures (e.g., Medicare Part D negotiation).

So What:

- Although Democrats are in the majority, they will have to work with Republicans to get legislation out of committees for non-reconciliation-related measures.
- Reconciliation is something we will need to watch and actively engage in - including educational meetings on what makes your companies different. We anticipate that Democrats may look to reconciliation to move forward legislation related to:
 - Drug Pricing (e.g. International Pricing Index, Medicare Part D Negotiations, etc.)
 - Medicare Reimbursement Reform

- **Divided government makes partisan drug pricing legislation (e.g. Most Favored Nation, H.R. 3, international reference pricing, and Medicare Part D negotiation legislation) less likely - but still a possibility and something we should be prepared for.**

In the House, Speaker Nancy Pelosi indicated she would pass a budget resolution this week, the first step in setting up the reconciliation process that would allow Democrats to approve a coronavirus relief bill without Republican votes.

So What:

- Like the Senate, the Democrats hold a very slim majority in the House - bipartisanship will be key in getting legislation passed through both chambers.
 - Incoming Energy and Commerce Health Subcommittee Ranking Member Rep. Brett Guthrie was quoted saying, “There’s just a slim majority; let’s put some bills out there we can work on and move to the Senate that could pass” showing that his committee is interested in negotiating on major legislation.
- **Member education on bedrock pharmaceutical issues like Medicare Part D non-interference, etc. is going to be key - with new leadership in several posts, this is the time to get back to the basics, create/update the corporate policy one-pagers, and educate members and staff.**

Committee Assignments:

Democrats will finally take over as the majority party in the Senate - taking control of all committees’ chairmanships. In the House, subcommittee assignments will be made this week. See below for leadership assignments for committees of jurisdiction:

[*For a full breakdown of the committees, please click here for a link to our detailed committee breakdown.*](#)

The Biden Administration

President Biden has announced a majority of his Cabinet picks, including key healthcare roles. Two controversial nominations are healthcare-related, and we expect to see a fair amount of pushback from the GOP. For reference, President Barack Obama’s first HHS Secretary, Kathleen Sebelius, was not confirmed until the end of April 2009, so nominations are moving faster than in the past.

- **HHS Secretary Nominee Xavier Becerra** has been the [target](#) of many in the GOP who claim he lacks healthcare experience and who are opposed to the lawsuit he led as California Attorney General against the Little Sisters of the Poor.
- **OMB Director Nominee Neera Tanden** has been called Biden’s most controversial nomination receiving criticism from both Republicans and Democrats.

[*For a full breakdown of all of President Biden’s healthcare-related nominations, please click here for a link to our detailed background memo.*](#)

President Biden's Regulatory Freezes

On January 20, President Biden's Chief of Staff, Ronald Klain, shared a [memo](#) stating that all rules, guidances, or other agency actions that didn't take effect prior to noon of that day — time of the official transition from the Trump Administration to the Biden Administration— are subject to review by the new administration before they can take effect.

The regulatory freeze includes a number of HHS rules and regulations, including the State Drug Utilization Review (DUR)/Value-Based Purchasing (VBP) rule, Medicare Coverage of Innovative Technology (MCIT) rule, Part D Payment Modernization Model for Calendar Year (CY) 2022, and the Rebate Rule.

[***For a full breakdown of President Biden's regulatory freezes, please click here for a link to our detailed background memo.***](#)

Biden Administration Executive Order

On January 28, President Biden issued an [Executive Order on Strengthening Medicaid and the Affordable Care Act](#):

- The EO directs the Department of Health and Human Services (HHS) to consider establishing a broad special enrollment period for HealthCare.gov and reassess rules and policies that undermine access to ACA and Medicaid coverage.
- HHS [announced](#) the new special enrollment period, set to begin on February 15, and committed to spending \$50 million on outreach and education.
- This EO demonstrates the Biden Administration's commitment to bolstering the ACA and Medicaid coverage.

The Biden Administration has been aggressively issuing EO's, and we are expecting he will continue to do so - we will keep you updated on announcements from the White House that may impact your business.

Upcoming Firm Events

- Policymaker Event - Rare Disease Caucus Co-Chairs Staff Briefing - Tuesday, February 16 - 1 p.m. ET
 - We kick off 2021 with this client-only meeting with the health staff representing the four rare disease caucus co-chairs:
 - **Ashley Bykerk**, Office of Senator Amy Klobuchar (D-MN)
 - **Kirby Miller/Sally Farrington**, Office of Senator Roger Wicker (R-MS)
 - **Shayne Woods**, Office of Representative Gus Bilirakis (R-FL-12)
 - **Caitlin Van Sant**, Office of Representative G.K. Butterfield (D-NC-01)

- Meet the Winemaker Wine Tasting - Friday, February 12 - 5 p.m. ET
 - We are very pleased to invite you to another winemaker tasting with Kelly Fleming, owner of [Kelly Fleming Wines](#), and Rebecca George, one of their winemakers, on Friday, February 12th at 5 PM EST. Kelly and Rebecca recently joined us, Dr. Jeremy Levin, Dr. Michelle McMurry-Heath, and 40+ leaders in biotech for a spectacular wine tasting a couple of weeks ago.
 - For those wishing to purchase the wines in advance (totally optional) please send an email to Kelly at kelly@kellyflemingwines.com and CC Patroski. In order to ensure that your wine arrives on time, please make sure you **order TODAY, Monday, February 1st.** We will taste two reds: the ***2017 Big Pour and the 2017 Estate Cabernet.***
 - [Link to join the wine tasting via Zoom](#)
 - Meeting ID: 826 1957 5450
 - Passcode: 964339

Monthly Trivia

We wanted to make this interactive and fun, the first person to correctly guess the trivia question gets a mention in the next Eye on Washington. Don't Google it!

This Month's Question: *Which United States President and his wife had a pet raccoon named Rebecca that they kept in the White House?*

As always, we are here to answer any questions that you have as Congress and the Biden Administration get to work, please let us know how we can help.

Best,

Joe, Taylor, Katie, and Patroski