

HEALTH POLICY OUTLOOK FOR THE 117TH CONGRESS



A look at the policy landscape for the new Democratic government

January 22, 2021

THORN RUN PARTNERS



GOVERNMENT RELATIONS

CONGRESSIONAL OUTLOOK

- Following the Inauguration and victories in the Georgia Senate runoffs, Democrats hold a slim Senate majority.
- With a bare Senate majority including Vice President Kamala Harris' vote, Democrats have toyed with the idea of ending the filibuster to be able to advance ambitious legislation. However, centrist Democrats, notably Sen. Joe Manchin (WV), have ruled out eliminating the filibuster.
- A rule change is reportedly under consideration in the Senate to require bills that attain a specified number of bipartisan cosponsors to be considered on the floor, with each side guaranteed a certain number of amendments. This change could be presented as a compromise alternative to eliminating the filibuster.
- Senate Democrats have a tool available to them – budget reconciliation – to pass certain items with a bare majority.
- With Democratic majorities in both chambers, Congress can invalidate certain rules finalized late in former President Trump's administration using the Congressional Review Act. It is expected that this will be used to roll back certain Trump-era regulatory priorities.

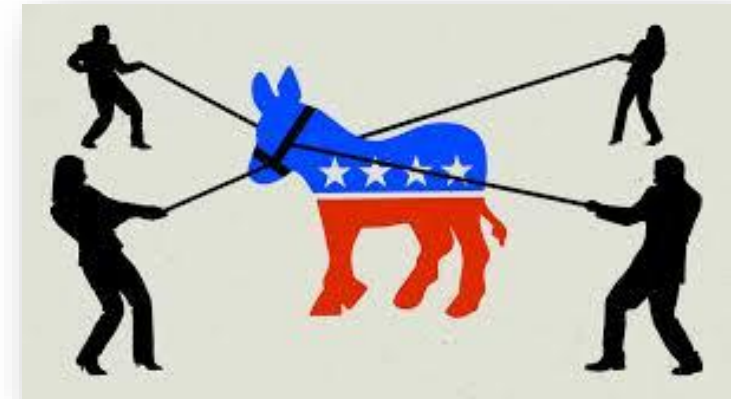
UNIFIED GOVERNMENT IN 2021

- President Biden will inherit a unified legislature in what could shape up to be a busy first 100 days for the Democratic House and Senate.
 - The President has emphasized that tackling the COVID-19 pandemic will be his top priority after getting sworn in.
- A key challenge for the President and Congressional Democratic leadership will be balancing the priorities of the progressive and moderate wings of the party.
 - This factor will be especially important as the new Congress looks to take up health-related legislation.
- Tight margins in both chambers means that the Biden administration will need to strive for bipartisan cooperation in order to clinch significant policy wins.



PROGRESSIVES VS. MODERATES

- **The State of Play:** House Speaker Nancy Pelosi (D-CA) and Senate Democratic Leader Chuck Schumer (D-NY) will be tasked with bridging policy divides between progressive and moderate lawmakers in the next Congress.
 - This involves coalescing the priorities of more liberal Members in the Progressive Caucus with the moderates in the New Democrat and Blue Dog Coalitions.
- **What This Means:** Lawmakers will need to navigate sensitive political landmines (e.g. Medicare for All) in order to clinch policy wins.



THE FUTURE OF THE FILIBUSTER

- There have been loud calls among Democrats to eliminate the legislative filibuster in the Senate.
 - Many Democrats see this as a necessary step in order to clinch legislative reforms sans bipartisan cooperation from the minority party.
- However, several Democratic Senators remain concerned with the long-term repercussions of abolishing the legislative filibuster altogether.
- Senators on both sides of the aisle have offered support for filibuster reform instead of abolishment.
- A rule change has been floated to require floor consideration of any bill that receives a given number of bipartisan cosponsors.

Key Options for Filibuster Reform

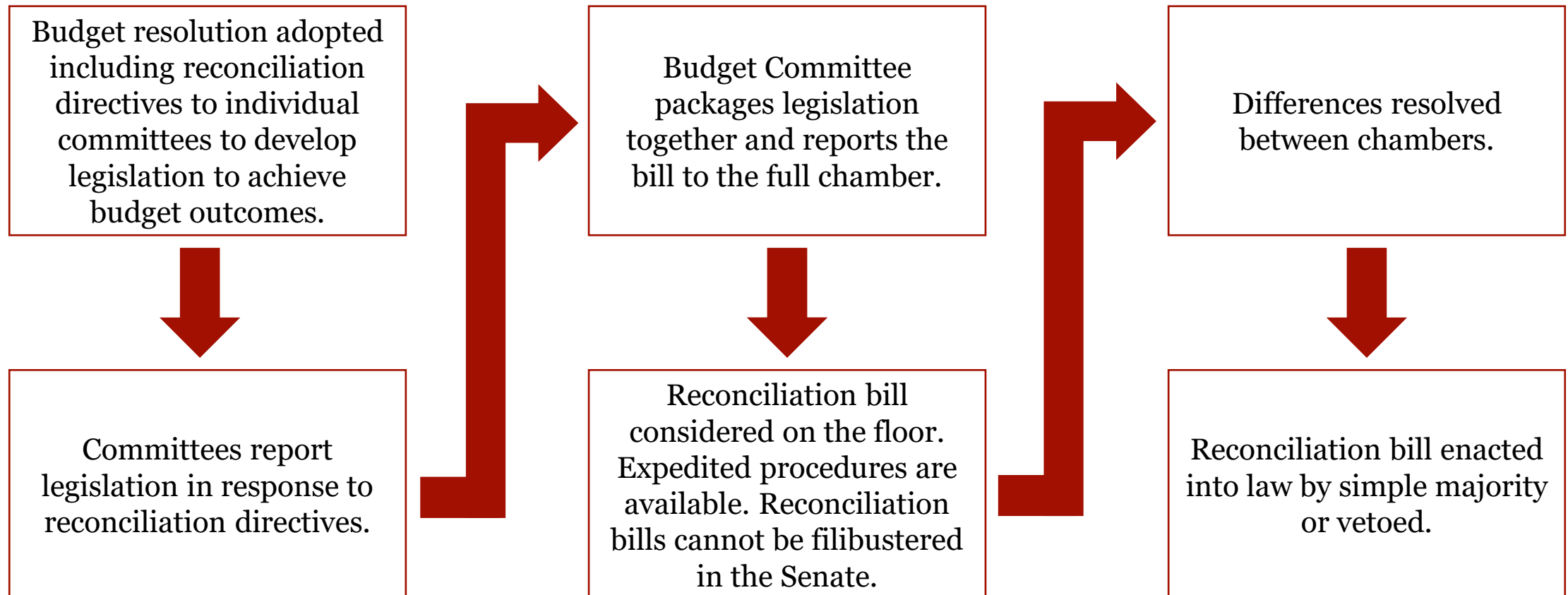
- ✓ Eliminate the filibuster in its entirety.
- ✓ Eliminate the filibuster on motions to proceed.
- ✓ Lower the cloture vote threshold from 60 to 55 votes.
- ✓ Reduce the time allotted (currently 30 hours) for post-cloture debate.

RECONCILIATION

- With the Georgia runoff election results confirming a Democratic-controlled Senate, House, and administration, the budget reconciliation process in Congress presents Democrats with a significant opportunity to pass sweeping legislation with a simple majority.
- Certain limitations, delineated by the so-called “Byrd Rule,” apply. Legislation considered under reconciliation must not:
 - Worsen the deficit when a committee has not achieved its reconciliation target.
 - Have no budgetary effect (i.e., no change in outlays or revenues).
 - Be outside the jurisdiction of the committee that submitted the title or provision.
 - Produce a budgetary effect that is merely incidental to the non-budgetary policy change.
 - Increase deficits for any fiscal year (FY) outside the reconciliation window.
 - Recommend changes in Social Security.
- The boundaries of the Byrd Rule could be reinterpreted through a similar process as eliminating the filibuster.

RECONCILIATION PROCESS

The annual budget process, through which reconciliation instructions may be provided, generally kicks off when the president submits a budget to Congress. However, there is no requirement that the president submit a budget for the congressional process to move forward.



‘FIRST 100 DAYS’

- The “First Hundred Days” is a term first used by FDR in 1933 to describe his initial policy priorities, but within those first days, the President must also take certain steps to launch the new administration.
- During this time, President Biden will:
 - Nominate a Cabinet and senior non-cabinet officials
 - Submit a Budget to Congress.
 - Suspend pending regulations.
 - Issue Executive Orders and rescind Trump-era EOs.
 - Begin the process of filling positions for over 4,000 political appointees.
- The bills numbered 1-10 from the 116th Congress may indicate top priorities for the 117th.
- Congress is likely to take up COVID-19 relief during this time as well. Reports indicate that Congress will aim for quick wins and then take up a more comprehensive package later.



EXECUTIVE ORDERS

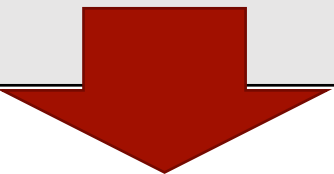
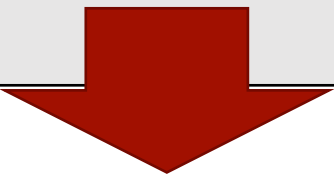
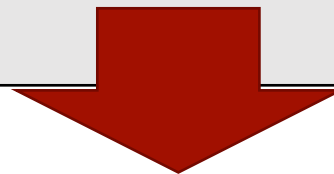
Selected Announced EOs

Health Care	Biden will sign an EO that will take “steps to strengthen Medicaid and initiate an open enrollment period under the ACA.” He will also sign an EO to rescind the Mexico City Policy and review the Title X domestic gag rule.
COVID	Require social distancing and masks on federal lands, in federal buildings, for federal employees and contractors, and in interstate travel on airplanes, busses, and trains. Encourage therapeutic development, expand testing, bolster the public health supply chain, and emphasize equity in the COVID-19 response.
Equity	Rescind Trump federal workforce EO, repeal Muslim travel ban, “pause” construction on the border wall while cutting off money, rescind the Trump ban on transgender military service and deferred enforced departure for Liberians, move forward on DACA, issue racial equality EO, rescind Trump Census EO
Economy	Direct “agency action on Medicaid; Pell grants; SNAP; and unemployment insurance,” and restore “collective bargaining rights to federal employees.”
Buy America	Strengthen agency requirements to procure goods and services from sources that support U.S. businesses and workers. There will be a “Buy American EO” aimed at directing “agencies to strengthen requirements for procuring goods and services from sources that will support U.S. businesses and workers.”

REGULATORY MORATORIUM

Shortly after the Inauguration, White House Chief of Staff Ron Klain issued a regulatory moratorium to halt regulations in process.

Regulatory Freeze covers all rules not yet in effect so that a Biden appointee may review them for “questions of fact, law, or policy.” The process is run through OMB.

Rules not yet sent to the <i>Federal Register</i>	Rules sent to the <i>Federal Register</i> but not yet published	Rules published in the <i>Federal Register</i> or issued in any other manner but not yet taken effect
		
Hold the rule until reviewed by a Biden-appointed department or agency head	Withdraw the rule from the <i>Federal Register</i> and hold until reviewed by a Biden-appointed department or agency head	Consider postponing the rule’s effective date by 60 days and consider opening a new 30-day comment period.

CONGRESSIONAL REVIEW ACT

- Congressional Democratic leadership will likely prioritize the use of the Congressional Review Act (CRA) to invalidate certain regulations promulgated by the Trump administration.
- The CRA enables Congress to disapprove of, and thereby invalidate, the entirety of ‘major’ final rules within a 60-day window.
- Since the CRA was enacted in 1996, Congress has overturned 17 rules, 16 of which were Obama-era regulations.
- Rules finalized since August 21, 2020 are eligible for a CRA resolution of disapproval.

Subtitle E—Congressional Review

SEC. 251. CONGRESSIONAL REVIEW OF AGENCY RULEMAKING.

Title 5, United States Code, is amended by inserting immediately after chapter 7 the following new chapter:

“CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

“Sec.
“801. Congressional review.
“802. Congressional disapproval procedure.
“803. Special rule on statutory, regulatory, and judicial deadlines.
“804. Definitions.
“805. Judicial review.
“806. Applicability; severability.
“807. Exemption for monetary policy.
“808. Effective date of certain rules.

CRA: WHICH RULES COULD BE TARGETED?

Finalized Within Lookback Period

**Importation of Prescription
Drugs**

Medicaid VBP Rule

**Medicare Coverage of Innovative
Technology/“Reasonable and
Necessary”**

PBM Rebate Rule

Most Favored Nations Model

**340B Pass-Through Insulin and
Epi-Pen Pricing for FQHCs**

HHS Term Limits Rule

Regulatory SUNSET Rule

DRUG PRICING REFORM

- President Biden aims to encourage more **drug importation**, enable Medicare to **negotiate prescription drug prices**, and **limit drug price increases** beyond inflation.
- **Part D benefit redesign** to establish an out-of-pocket cap.
 - The House passed a drug pricing reform package ([H.R.3](#)) in December of 2019 that would cap out-of-pocket Part D costs at \$2,000 after \$6,545 in total drug costs. Senate Finance Chair Ron Wyden and outgoing Chair Chuck Grassley co-authored similar legislation.
 - MedPAC's June 2020 [report](#) recommended restructuring the Part D benefit to give plans stronger incentives to manage enrollees' drug costs.
- CMS finalized its **Medicaid VBP rule** on December 21, 2020 to encourage value-based payment arrangements in Medicaid and in commercial insurance. The rule protects certain VBP prices from inclusion in "best price."

What Might Happen?

President Biden could use his regulatory moratorium to modify or scrap the MFN rule. While his campaign platform did call for external reference pricing for newly-launched drugs, the later developed DNC platform did not. Current litigation regarding MFN could also allow for a reset on reference pricing.

Democrats may look to drug pricing reforms to offset spending in a reconciliation package, as the rules governing that process require budgetary savings. However, it will be challenge to construct such a package without losing any of the 50 Democratic senators.

A revamped Grassley-Wyden package or H.R. 3 could be considered by a fully Democratic Congress. However, the more ambitious drug pricing measures are likely to be stymied by Senate Republicans.

Part D redesign is a bipartisan priority that likely represents the most probable reform to be accomplished through regular order in the 117th Congress.

The Biden administration could revisit the VBP rule through its regulatory moratorium.

DRUG PRICING REFORM, CONT'D

➤ **Most Favored Nation Model and International Pricing Index Policies**

- In late November, CMS issued an interim final rule creating the seven-year Most-Favored Nation (MFN) model to peg reimbursements for certain drugs in Medicare Part B to prices paid in other countries. The demonstration was scheduled to phase in on January 1, 2021 before it was blocked by two federal judges. Industry groups sued to stop the rule and while the rulings were temporary, both included findings that the industry groups were likely to ultimately succeed in their challenges.
- Biden could push for Congress to pursue action on international reference pricing, and House Democrats' signature drug pricing legislation, H.R. 3, would allow for mandatory price negotiations on drugs in Parts B and D with an upper limit of 120 percent of the drug's price in a basket of peer countries.

➤ **Medicare Part B Reforms**

- Sen. Ron Wyden (D-OR), Finance Committee Chairman, said he plans to build off a package of drug pricing measures he and the previous Committee Chairman, Chuck Grassley (R-IA), created. That package would cap drug costs for Medicare beneficiaries and force drug manufacturers to provide Medicare inflation rebates, paying back the government for price increases. The Grassley-Wyden drug pricing bill would:
 - Require the value of coupons to be included in the calculation of ASP.
 - Change payment for new biosimilars.
 - Require manufacturers to pay a rebate for drugs and biologicals for which the ASP increases faster than inflation.
 - Require manufacturers of certain single-dose or single-use package drugs to provide refunds to HHS for discarded amounts of drugs.
 - Establish a maximum add-on payment for drugs and biologicals.

BIOSIMILARS

- Bipartisan legislation introduced in the House ([H.R.4455](#)) and Senate ([S.2543](#)) in the 116th Congress would eliminate a beneficiary's out-of-pocket cost for a biosimilar under Medicare Part B, regardless of the type of coverage and without any other changes to the underlying coverage.
 - Bipartisan legislation in the House would direct CMS to implement a “shared savings” model whereby Medicare savings associated with prescribing a biosimilar is shared with providers.
 - A second reimbursement bill would increase the add-on payment for a biosimilar biological product from ASP+6 of the reference product to ASP+8 of the reference product for a period of five years.
- Legislative efforts to redesign the Part D benefit could impact utilization of biosimilars.
 - Bipartisan legislation in the House and Senate would require new measure to support biosimilar utilization in the Medicare Advantage (MA) and Part D Star Rating programs.
- CMS finalized a rule in mid-January 2021 that would allow Part D plans to create a second specialty tier – which could include biosimilars.
- Already in the 117th Congress, bipartisan legislation ([H.R.153](#)) has been introduced that would prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market and prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers in order to delay entry of biosimilar and interchangeable products.

MEDICARE ELIGIBILITY

➤ Medicare Age

- Democrats have proposed lowering the Medicare eligibility age to 60.
- This is projected to increase enrollment by 32 percent in 2030, 33 percent in 2040, and 34 percent in 2050.

How Could this Policy be Enacted?

Items related to the Medicare age could be addressed through reconciliation. It has been posited that a Medicare-based public option could be accomplished through reconciliation as well.

340B REFORMS

- Upon confirmation, Xavier Becerra is projected to step up enforcement of 340B provisions that he believes pharmaceutical companies are violating. A group of lawmakers concurred in a letter sent on September 17, 2020 to HHS, calling for swift action to restrict companies from refusing to provide 340B discounts to contract pharmacies. These lawmakers may find an ally in Becerra.
- Drug manufacturers sued HHS in mid December over its general counsel advisory requiring drug manufacturers to provide 340B discounts to providers in the program via contract pharmacies. If allowed to stand, the opinion would doom any administrative disputes over contract pharmacy restrictions.
- President Trump's HHS finalized a rule requiring FQHCs to charge their patients 340B prices for insulin and epinephrine. The effective date of this rule has been delayed by President Biden's HHS until March 22, 2021.
- Administrative Dispute Resolution (ADR) process – what's next?
 - The Health Resources and Services Administration (HRSA) published a final rule on December 14, 2020, which outlined the requirements and procedures for the 340B pharmacy program's ADR process. Effective January 13, 2021, the rule replaces the 340B Program's current guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers.

What Might Happen?

The ADR process may be subject to the regulatory freeze, thereby allowing stakeholders to further weigh in.

The Biden administration may reopen the comment period or otherwise pursue changes to the rule that requires certain providers to pass through 340B prices to patients.

MEDICAID REFORMS

➤ **Medicaid Expansion**

- Biden has expressed interest in encouraging Medicaid expansion.
- The House passed a bill (H.R. 1425) in the 116th Congress encourages non-expansion states to expand through a combination of carrots and sticks. It would provide enhanced FMAP for new expansion states and require 12-month continuous eligibility while cutting administrative FMAP and imposing new reporting requirements on non-expansion states.

➤ **Waivers**

- CMS approved a 1115 waiver for Tennessee on January 8, 2021 that would cap federal funding and allow the creation of a closed prescription drug formulary, though it requires the state to preserve coverage in accordance with Medicare's protected classes policy.
- Biden is expected to withdraw guidance that permits and encourages 1115 waivers to impose work requirements on certain beneficiaries or to create caps on federal funding.
- The Trump administration announced a new, nine-month process for waiver withdrawals.

➤ **State-Level Reforms**

- Many state Medicaid programs have begun to leverage DUR boards to assess value and reimbursement for drugs. Several states – notably Massachusetts and New York – rely on ICER for value assessments.
- Tennessee's recently-approved 1115 waiver opens the door to using cost-effectiveness analysis in Medicaid formularies.

➤ **Medicaid Eligibility during the PHE**

- An Interim Final Rule from CMS allows states to decrease benefits, increase cost-sharing, and in some cases, terminate enrollment for people considered not "validly enrolled" or change eligibility groups while still receiving increased federal matching funds.

➤ **Social Determinants of Health**

- The new administration has indicated that it will accelerate policies focusing on social determinants of health.

What Might Happen?

Certain Medicaid expansion reforms could be enacted through reconciliation, while others would not qualify under current rules.

As for waivers, the incoming administration may seek to withdraw waivers with which it disagrees, with or without the new process instituted by CMS.

COVID-19 ACCESS AND REIMBURSEMENT

Biden's \$1.9 trillion COVID-19 plan includes...

\$50 Billion to
Expand Testing

\$10 Billion
to Expand
Domestic
Production
Capacity

\$30 Billion to
Purchase
Supplies and
Protective Gear

\$20 Billion
for Vaccine
Procurement
and
Distribution

- The Biden team has said they are confident the manufacturers can produce enough additional vaccines to deliver second doses in a timely manner. President Biden announced that he will use the Defense Production Act to boost supply.
- Senate Finance Chairman Wyden has indicated the Committee's first order of business will be a COVID-19 relief bill that will include a \$2,000 check (compared to Biden's suggested \$1,400), more unemployment aid, and **funding for vaccine distribution**. He also plans to reintroduce a measure to stop drug makers from raising the price of COVID-19 vaccines.
- President Biden's COVID-19 plan includes providing 100 percent federal funding for vaccine coverage under Medicaid.

TELEHEALTH

➤ Repeal of Geographic and Originating Site Restrictions

- Certain requirements for Medicare reimbursement of telehealth services, including restrictions on originating site and geography, were waived for the COVID-19 pandemic.
- Bipartisan legislation was introduced last Congress to permanently end geographic and originating site restrictions. A bipartisan group in the House is also seeking to extend data collection on telehealth three months beyond the conclusion of the public health emergency.
- Democrats have expressed concern that telehealth may exacerbate geographical and racial disparities. Given this, they have been more cautious in aggressive expansions, instead offering legislation to lift the restrictions for a more limited set of services like mental health and evaluation & management (E/M) services.

➤ Additional Practitioners

- Republican lawmakers have offered legislation to permanently expand the universe of providers eligible to receive payment from Medicare for telehealth services, such as physical therapists, occupational therapists, and speech-language pathologists.
- It also seeks to make it easier to designate new provider types eligible to provide telehealth services.

➤ FQHC and RHC Telehealth Payments

- Both Democrats and Republicans have offered legislation to allow FQHCs and RHCs to serve as distant sites and receive payment for telehealth services under Medicare.

What Might Happen?

Measures to maintain certain pandemic-era telehealth flexibilities are broadly popular. It is likely that Energy & Commerce in the House and HELP in the Senate will consider such measures as the pandemic draws to a close.

INSURANCE REFORMS

➤ Public Option

- Biden and other Democrats have called for enacting a public option for health care coverage but this faces a steep uphill battle even in the Democratically controlled Congress.
- Biden's health care plan calls for an independent review board to determine acceptable launch prices for drugs. Launch prices would be determined based on external reference pricing for and evaluation by the board's independent members.
- Biden plans to enact a series of measures to **strengthen the ACA marketplace**, lowering costs for people who buy insurance on the exchanges.
- Passed by the House last year, the **Patient Protection and Affordable Care Enhancement Act (H.R. 1425)** would strengthen the ACA pillars and reverse Trump Administration's actions. It is possible that the House will take up similar legislation this year.
- Expands premium tax credits beyond 400% of FPL and tightens up short-term plans that limit coverage of pre-existing conditions.
- HHS will need to issue implementing regulations for **surprise billing** legislation, which was passed in the year-end omnibus package.

What Might Happen?

The future of the ACA is currently uncertain due to litigation surrounding its constitutionality. While most observers expect the law to stand, the outcome could provide a vehicle for addressing coverage and other priorities. In addition, the new administration may change the government's position in the suit.

Certain reforms, such as premium tax cut expansions and possibly going as far as a Medicare-based public option, could be enacted through reconciliation.

INTELLECTUAL PROPERTY

- While CA Attorney General, HHS Secretary nominee Xavier Becerra asked the federal government to use “march-in rights” to lower the cost of the COVID-19 drug remdesivir, and attorneys generals from both parties have encouraged the Biden administration to consider using march-in rights in the future.
 - The Commerce Department recently proposed that “march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention,” potentially hobbling future action.
- Democrats – and Republicans as well – have long taken aim at so-called “patent thickets” to block generic competition and “evergreening” to extend exclusivity periods.
 - A September 2020 report from the Center for American Progress, whose head, Neera Tanden, will be nominated to lead OMB under Biden, heavily criticizes these practices.
- The same report from the Center for American Progress suggested using compulsory licensing to expand supply and lower prices for COVID-19 drugs.
 - However, Biden was one of the only 2020 Democratic candidates to run on a drug pricing platform that does *not* include a policy to let the government break patents when a drug is deemed unfairly priced.

What Might Happen?

Intellectual property reforms, like tackling “evergreening” and “patent thickets,” are most likely to be considered as part of a larger package and may be used as pay-fors for expensive programs.

SUPPLY CHAIN

- President Biden has proposed several policies related to the health care supply chain:
 - **Use BARDA to spur medical production.** Biden will use the Biomedical Advanced Research and Development Authority (BARDA) to ensure adequate production of vaccines and other medical countermeasures to address COVID-19.
 - **Leverage Federal health care purchases.** Biden will leverage the country's purchasers of health care – between Medicare, Medicaid, the Department of Veterans Affairs, and other health programs – to encourage pharmaceutical companies to make key drugs, drug inputs, and medical devices in the United States while ensuring fair and transparent pricing.
 - **Ensure the U.S. tax code encourages on-shoring of pharmaceutical supply chains.** Biden wants to eliminate tax incentives for offshoring and pursue other tax code changes that will encourage pharmaceutical production in the U.S.
 - **Require companies to develop plans to address potential supply chain disruptions for critical products.** Biden plans to work with Congress and direct regulatory agencies to require companies that manufacture, distribute, and use designated critical products in the U.S. to regularly identify potential supply chain vulnerabilities and develop plans for addressing them.
 - **Impose targeted restrictions on imports from Russia and China or any country that poses national security threats.**

KEY TAKEAWAYS

- COVID focus will dominate immediate Congressional and Administration actions.
- The Biden Administration has taken steps to expeditiously unwind or pave the way for more thorough review of recent regulatory actions.
- Close coordination between Congress and the Administration is expected, particularly to determine which policies will be considered under the CRA or through the regulatory process.
- Pending litigation on several topics, such as drug pricing, the role of pharmacy benefit managers, Medicaid work requirements, and the ACA, will influence the urgency and specific legislative and regulatory actions.