

What's Next for Health Care Policy Under a Biden Administration

hen President-elect Joseph R. Biden Jr. is sworn into office in January 2021, he will bring an ambitious health care agenda in the face of a thinly divided Congress. While control of the US Senate remains uncertain, we can begin to draw some conclusions about how President-elect Biden will prioritize the various aspects of his platform, the means by which he may pursue them, and their probability of enactment.

President-elect Biden's extensive plans to advance the nation's COVID-19 pandemic response are likely to be his highest health care-related priority. He has called for a major expansion of the federal role in testing, contact tracing, and resource deployment, as well as increased funding for states, localities, and individuals, which will require the cooperation of the US Congress. If and when the aggressive federal response efforts and the arrival of an effective vaccine can begin to turn the tide on the pandemic, the Biden administration can then turn to the longer-term and more complex proposals for health reform.

Biden's health plan is largely organized around restoring, strengthening, and expanding the system in place under the Affordable Care Act (ACA). Through rulemaking, the US Department of Health and Human Services (HHS) under the Biden administration might be expected initially to roll back much of the deregulation and regulatory changes made during the President Donald J. Trump era, restoring programs and policies to the way they were interpreted or implemented based on ACA statute. Even if he is working with a cooperative Congress, the larger and more ambitious features of President-elect Biden's health care plan — such as lowering the Medicare eligibility age and implementing a federal public option insurance plan — may prove more difficult to achieve. Looming over the health care agenda, ultimately, is the uncertain future of the ACA. Whether the US Supreme Court upholds or overturns the landmark health care law will determine the scope of reform that may be necessary, that is, whether it entails a collection of "fixes" and expansions on the existing system or necessitates a wholesale replacement.

The incoming Biden administration may focus on moving much of its health care policy agenda via the reconciliation process, which requires only 50 Senate votes to pass legislation (plus the vice president as the 51st vote). Top Biden advisors also are openly discussing the possibility of eliminating the filibuster, though it remains to be seen whether President-elect Biden and congressional leaders will ultimately do away with that long-standing Senate tradition completely. It should be noted that there is also a possibility that the Biden administration will prioritize issues on which there has been broader bipartisan support, such as prescription drug pricing, price transparency, telehealth, and mental and behavioral health.

This issue brief examines the authorities and processes available to President-elect Biden to pursue and implement his policy agenda, whether regulatory or legislative; the policies that are likely to define the Biden health care agenda; and how the potential fate of these initiatives will unfold during his first term.

Legislative and Regulatory Policy Implementation

The Legislative Process

Regardless of the outcome of the election, the reigning party in the Senate is expected to hold a fairly narrow, yet pivotal, majority. As the traditional gatekeeper of the chamber, the Senate majority leader carries out the party's policy agenda by deciding, for the most part, what bills, resolutions, and nominees are considered and when. The minority party, though not completely powerless, has less influence on shaping legislative priorities.

Still, the narrow party divide in the Senate, along with its standing rules, precedents, and practices, generally requires some bipartisanship among senators to pass substantial legislation in a timely manner. These factors often make the Senate the deciding body on major legislative initiatives.

Senate rules require a simple majority to pass a bill, but a supermajority of 60 votes is required to end debate and vote on final passage of a bill, though there are some exceptions.¹ The few limitations on debate make it possible for senators to filibuster a bill or amendment. A filibuster refers to "any attempt to block or delay Senate action on a bill or other matter by debating it at length, by offering numerous procedural motions or by any other delaying or obstructive actions."² Reaching the 60-vote threshold to break a filibuster incentivizes senators to negotiate a compromise, but political polarization, as has been repeatedly demonstrated in the current 116th US Congress, often leads to deadlocks. Even the threat of a filibuster can be enough to prevent consideration of a bill.

The Senate has two options to circumvent a filibuster and vote on a bill:

Unanimous consent. Any senator can request unanimous consent — asking if anyone objects to a measure — to expedite consideration of a bill. A unanimous consent agreement limits time for debate and specifies the amendments for debate, therefore clearing the way for a timely final vote. Cloture. The Senate can invoke cloture with a supermajority (with 60 votes in favor of doing so) to end debate and proceed to a final vote after up to an additional 30 hours of debate. This motion is customarily filed by the Senate majority leader.³

The Senate allows some important exceptions to the cloture rule, which would forgo the 60-vote procedural hurdle:

- Executive and judicial nominations. The Senate can invoke cloture with a simple majority to end debate on executive and judicial nominees (including Supreme Court nominees) and proceed to a final vote. Therefore, the Senate only requires a simple majority to avoid a filibuster and to confirm executive and judicial appointments, providing the minority party with seemingly no recourse to block appointments. Notably, this exception was accomplished through new precedents established by Democrats in 2013 and Republicans in 2017, respectively.⁴
- Budget reconciliation. The Senate can use budget reconciliation to pass legislation related to spending, revenue, or debt limits with only a simple majority. This process limits debate to 20 hours, which eliminates the need to invoke cloture to end debate, and prohibits nongermane amendments.⁵

The mechanisms for eliminating the filibuster vary, though the ultimate approach will likely depend on the level of support among senators and the extent to which they want to eliminate, or modify, the filibuster.⁶ Presidentelect Biden — a long-time former senator — has not committed to whether he would support the elimination of this Senate tradition nor is it clear that there would be sufficient votes in the Senate to do so.

Budget Reconciliation

Due in large part to the filibuster, the budget reconciliation process in the Senate has become an essential legislative maneuver to enact substantial legislation for the majority party. For example, Senate Republicans accomplished tax reform, which eliminated the ACA individual mandate, via budget reconciliation after failing to repeal the ACA through the same procedure.⁷ The purpose of budget reconciliation is to bring existing spending, revenue, and debt limits in line with fiscal priorities codified in the budget resolution. Accordingly, the budget reconciliation process has several restrictions regarding when and how it can be deployed.

Congress must first pass a budget resolution that includes "reconciliation directives," which instruct a congressional committee or committees to produce reconciliation legislation and detail their deadlines and the budgetary change that should result from the legislation (i.e., dollar amounts over specified time period).⁸ Over the last decade, Congress has frequently failed to pass a budget resolution.⁹

While budget rules direct Congress to adopt a budget resolution prior to April 15 in the year before the fiscal year in which the budget would operate, Congress has repeatedly ignored that deadline. A budget resolution containing reconciliation instructions can be passed at any time, including immediately prior to adoption of budget reconciliation legislation, as was the case for the so-called "reconciliation sidecar" to the ACA that passed in March 2010. Congress has not adopted a budget resolution for the current 2021 fiscal year, which runs through September 30, 2021, so it could do so at any time after it reconvenes in 2021 to set the stage for a reconciliation process.

Another key feature of the budget reconciliation parameters is the Byrd Rule, which prohibits the inclusion of "extraneous matters" in a budget reconciliation bill. Specifically, a provision is considered extraneous if it meets one of the following definitions:¹⁰

- Does not change overall spending or revenue levels or their terms or conditions
- Increases spending or reduces revenue when the committee that submits that provision is not instructed to do so
- Falls outside of the jurisdiction of the committee that submitted the provision
- Makes an "incidental" change to spending or revenue
- Increases the deficit outside the "budget window" covered by the budget resolution (typically 10 years)

Changes Social Security

Lastly, the number of budget reconciliation bills that can be considered in a single year is limited. Under Senate interpretations of the Congressional Budget Act, "the Senate can consider the three basic subjects of reconciliation — spending, revenues, and debt limit — in a single bill or multiple bills, but it can consider each of these three in only one bill per year (unless Congress passes a second budget resolution)."¹¹ In other words, because the Biden administration and Congress would likely combine revenue (i.e., tax) changes in the same bill as new spending initiatives for health care or other areas, current rules suggest that they can only pass one reconciliation bill per fiscal year.

Regulatory and Executive Powers

As derived from Article II, Section 1 of the Constitution, the president has the authority and responsibility to implement and enforce laws as they are written by Congress. A president may veto a bill with which he disagrees; however, Congress can override a veto with a two-thirds majority of members in both the Senate and the House. Otherwise, much of the work of the president and their administration is to carry out the law, often through directives to agency heads to whom rulemaking authority is delegated, such as the Secretary of HHS. Prior to regulatory promulgation, these agencies submit to a review and clearance process of regulatory decisions, which is conducted by the White House Office of Management and Budget.¹²

Executive Orders

Two ways exist in which presidents may enact initiatives without congressional approval: (1) They may issue a proclamation, which is often ceremonial in nature, or (2) they may issue an executive order, which typically contains mandatory requirements or directives for the Executive Branch and has the effect of law. However, executive orders are typically issued in relation to a law passed by Congress or are based on powers granted in the Constitution and must be consistent with those authorities. Therefore, executive orders are subject to judicial review and may be overturned if lacking support in statute or the Constitution. Congress cannot directly vote to override an executive order in the way they can a veto. Instead, Congress must pass a bill canceling or changing the order.

Questions have been raised about President Trump's frequent reliance on executive orders as a tool of policymaking. For example, stakeholders have questioned the validity of the president's executive order intended to guarantee health coverage for people with preexisting conditions. This order neglects to address the fact that the basis for legal protection of preexisting conditions lies in the ACA. Were the Supreme Court to strike down the ACA next year under *California v. Texas*, this executive order would not be a replacement for the ACA's provision guaranteeing protections for people with these conditions. President-elect Biden is likely to be more restrained and traditional in his use of executive orders, likely limiting his executive orders to those that have broader support in current law.

Congressional Review Act

The Congressional Review Act (CRA) governs the federal rulemaking process and gives Congress the ability to overturn rules issued by federal agencies within a limited period following their finalization. As of January 2020, Congress has used this procedure to overturn a total of 17 rules, 16 of which were President Barack Obama-era rules overturned in the 115th Congress (2017-2018), during the Trump Administration.¹³ Given that a president's signature is required to enact any such action by Congress, this procedure is most effective after the inauguration of a president of a different party and election of a Congress controlled by a different party than the outgoing administration. Depending on the majority in the Senate, this could provide one pathway for the Biden administration and Congress to address regulations finalized in the final months of President Trump's term.

Under the CRA, a federal rulemaking agency must send each new final rule in a report to Congress and the Government Accountability Office for review before it can take effect. After receiving the report, Congress has a window of 60 session days to submit and act on a joint resolution of disapproval.¹⁴ This timeframe applies to final rules, interim final rules, and in some cases, guidance documents and other agency actions.¹⁵ A disapproval resolution on a rule can originate in either chamber of Congress and its passage requires only a simple majority in each chamber. Enacting a joint resolution of disapproval will stop a final rule from taking effect — or from continuing to be in effect — and prohibits a federal agency from promulgating a "new rule that is substantially the same" as the disapproved final rule.

As stated earlier, Congress has a 60-day window following the submission of a final rule to act on a joint resolution of disapproval. However, if a final rule is submitted to Congress with fewer than 60 days remaining in the Senate's or the House's annual session, a "look-back" period may be implemented to ensure the new session of Congress has the full intended period to disapprove a final rule. In other words, the 60-day clock for Congress to take action on a particular rule is reset, and, according to the CRA, the reset period begins on the 15th day of session in the Senate and the 15th legislative day in the House.¹⁶

Based on the remaining legislative calendar for 2020, a 60-legislative day look-back period that begins 15 legislative days into the 117th Congress likely will encompass final rules issued by the Trump administration after mid-May 2020, as depicted in Table 1.

Table 1. Projected Timeline for Outgoing Administration

May 2020	Regulations finalized later than mid-month are likely subject to CRA.	
January 3, 2021	Scheduled first day of the 117th Congress	
TBD (15 legislative days later)	CRA "look-back" period begins.	
April 2021	Likely new CRA deadline for Congress to act.	

The uncertainty introduced to the legislative calendar by the COVID-19 pandemic makes the exact calculation of this period subject to change. However, even in a normal year, the determination of this timeline is complex. As noted by the Congressional Research Service, "The House and Senate Parliamentarians are the sole definitive arbiters of the CRA parliamentary mechanism, including time periods involved, and should be consulted for authoritative guidance on its operation."¹⁷

Pathways to Implementing the Biden Health Care Agenda

Table 2 identifies whether regulatory or legislative action would be required to effectuate key planks of the Biden administration platform, as reflected in the Biden-Sanders Unity Task Force series of recommendations.¹⁸

REGULATORY RESPONSE LEGISLATIVE RESPONSE Pandemic > Through regulation, a Biden administration Legislation would be required to implement plans to: response could: Guarantee coverage without cost sharing for COVID-19 Improve nursing home staffing and quality testing, vaccines, and treatment standards, strengthen accreditation, and Fully subsidize COBRA insurance combat corporate abuses > Expand Affordable Care Act (ACA) subsidies and offer a > Work with the private sector to shore up platinum-level plan that is federally administered until the the strategic national stockpile of medical pandemic ends supplies and equipment during public health Fund local public health department contact tracing efforts emergencies (e.g., through grant funding) Increase Centers for Disease Control and Prevention (CDC) > Open a 90-day special enrollment period fundina > Establish automatic triggers to increase federal medical assistance percentages (FMAP) funding to states during economic crises ACA fixes > A Biden administration could strengthen the > Legislation would be required to implement a portion of the Affordable Care Act (ACA) Exchange market Biden administration's proposed solutions to stabilize the by reinstituting funding for ACA enrollment ACA Exchanges, which include tying premium subsidies to gold-level plans, capping premiums at 8.5% of an individual's outreach. income and removing the 400% federal poverty level (FPL) limit for receiving premium subsidies. President-elect Biden with Congressional approval also could ≻ try to preempt the Supreme Court's potential striking of the ACA, or some of its key provisions, by reinstituting a small individual mandate penalty. This strategy could bring the law back in compliance with the legal principles that underpinned the Court's initial finding that the mandate, and thus the rest of the law, is constitutional. Public option > A Biden administration could defer to states > Legislation would be required to implement a singular, to develop their own, respective public option nationwide public option program, as proposed by the Biden programs and could support states in doing so campaign. In brief, the plan would: by coordinating various federal waiver authori-Offer at least one plan on the ACA Exchanges without ties, potentially including: 1332, 1115, and the deductibles, which would be administered by Medicare Center for Medicare & Medicaid Innovation and would cover all primary care services without copays (CMMI). > Encourage states to use ACA Section 1332 waiver authorities to test universal coverage programs at the state level > Automatically enroll lower-income Americans not eligible for Medicaid Make the plan available without premiums to individuals in > states that have not expanded Medicaid Medicare > A Biden administration could conceivably test Legislation would be required to lower Medicare eligibility the changes noted in the legislative column of to age 60, allow Medicare to negotiate drug prices directly this table through a series of CMMI demonstrawith drug manufacturers, and expand Medicare coverage for tion models. dental, vision, and hearing services.

Table 2. Proposed Biden Policies and the Required Regulatory and Legislative Responses

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REGULATORY RESPONSE	LEGISLATIVE RESPONSE
While the Biden platform does not speak to this directly, substantial changes are expected to Trump-era rules regarding work requirements and other barriers to Medicaid enrollment.	 Legislation would be required to make additional funding available to state Medicaid agencies for enrolling eligible adults, incentivize Medicaid expansion if states have not yet done so, and increase the federal Medicaid match to 12% during the COVID-19 pandemic. In addition, for states that have not expanded Medicaid, a Biden administration could try to automatically enroll qualify-
	ing individuals into the respective state's public option plan.
 A Biden administration could use the drug importation framework finalized by the Trump administration to establish state importation programs. A Biden administration also could potentially test certain Medicare-focused initiatives in the legislative column of this table through a CMMI demonstration. 	A Biden administration's drug pricing platform would require legislation to permit HHS to negotiate drug prices directly with manufacturers. His administration also would seek to impose inflation caps on drug price increases, cap Medicare Part D out-of-pocket spending, enact reforms to address anticompeti- tive practices, and end "pay for delay" arrangements.
 A Biden administration could continue the work on hospital and insurer transparency already initiated by the Trump administration. 	 Comprehensive solutions to end surprise billing would require legislative action.
Strategies to improve health care delivery and payment can largely be tested through existing CMMI demonstration authority. This could include, for example, innovations in primary care, accountable care organizations, global budgeting, and expansion of access to telehealth, among other services.	A Biden administration could seek more comprehensive legis- lative reforms to health care payment — especially with regard to Medicare costs — as concerns around Medicare insolvency rise. This could include comprehensive drug pricing reform, expansion of pricing transparency rules, or reimbursement cuts for some services.
A Biden administration could test the effects of Medicare telehealth flexibility through exist- ing and new CMMI demonstrations and could add certain telehealth services to the Medicare telehealth list via existing regulatory authority.	To accomplish more sweeping reform — namely, lifting the statutory geographic and originating site restrictions on the Medicare telehealth reimbursement — would require legisla- tive action.
 Strategies to address the social determinants of health through health care delivery and payment reform can be tested via CMMI demonstrations. A Biden administration could direct all federal agencies to develop data-driven policies to 	Increased funding to improve public health efforts and health equity research would require legislative action.
 advance health equity. A Biden administration could assess the recommendations included in the Agency for Healthcare Research and Quality's (AHRQ) National Healthcare Quality and Disparities Report¹⁹ to identify funding gaps for health equity research and to prioritize funding specific projects to close these gaps. A new administration also could roll back Trump administration reforms that allow providers to discriminate against LGBTQ+ patients. 	
	 While the Biden platform does not speak to this directly, substantial changes are expected to Trump-era rules regarding work requirements and other barriers to Medicaid enrollment. A Biden administration could use the drug importation framework finalized by the Trump administration to establish state importation programs. A Biden administration also could potentially test certain Medicare-focused initiatives in the legislative column of this table through a CMMI demonstration. A Biden administration could continue the work on hospital and insurer transparency already initiated by the Trump administration. Strategies to improve health care delivery and payment can largely be tested through existing CMMI demonstration authority. This could include, for example, innovations in primary care, accountable care organizations, global budgeting, and expansion of access to telehealth, among other services. A Biden administration could test the effects of Medicare telehealth flexibility through exist- ing and new CMMI demonstrations and could add certain telehealth services to the Medicare telehealth list via existing regulatory authority. Strategies to address the social determinants of health through health care delivery and payment reform can be tested via CMMI demonstrations. A Biden administration could direct all federal agencies to develop data-driven policies to advance health equity. A Biden administration could direct all federal agencies to develop data-driven policies to advance health equity. A Biden administration could assess the recommendations included in the Agency for Healthcare Research and Quality's (AHRQ) National Healthcare Quality and Disparities Report¹⁹ to identify funding gaps for health equity research and to prioritize funding specific projects to close these gaps. A new administration reforms that allow provid-

Table 2. Proposed Biden Policies and the Required Regulatory and Legislative Responses, continued

	REGULATORY RESPONSE	LEGISLATIVE RESPONSE
lmmigrant health	 A Biden administration could reverse the Trump administration's public charge rules. States also could apply 1332 waiver authority to expand ACA Exchange coverage and subsidy eligibility to undocumented immigrants, though such waivers would require administra- tion approval. 	Legislative action could explicitly expand immigrants' access to ACA Exchange coverage, make young immigrant "Dreamers" eligible for premium and cost-sharing subsi- dies, and repeal the current waiting period for Medicaid and Children's Health Insurance Program (CHIP) eligibility.
Reproductive and maternal health	 A Biden administration could reverse Trump administration rules that defunded Planned Parenthood. 	Legislation would be required to repeal the Hyde Amendment and reauthorize the Violence Against Women Act.
Rural health and workforce	 Ongoing CMMI demonstrations would continue to support rural health care transformation. A Biden administration also could establish an Office of Primary Care within the AHRQ. 	Legislation would be required to increase funding for commu- nity health centers (as part of Biden's "doubling America's investment in community health centers") and the National Health Service Corps, as well as align Medicare and Medicaid graduate medical education (GME) funding rules.
		Legislation would be required to expand Certified Community Behavioral Health Clinics and Federally Qualified Health Centers, especially in rural areas. Legislation would also be required to double the number of community health workers through expanded training, credentialing, and reimbursement.
		 Legislative efforts to expand telehealth/broadband also would support rural health.
Mental health and substance use	A Biden administration could enforce existing mental health parity laws under current author- ity. Biden's platform describes how states vary in how they define essential mental health benefits that are subject to federal parity and that his administration will set clearer	Legislation would be required to direct additional funding to hiring more mental health providers.

Table 2. Proposed Biden Policies and the Required Regulatory and Legislative Responses, continued

Conclusion

As stated earlier, the first priority of the Biden administration is likely to be an aggressive ramping up of the federal COVID-19 pandemic response. Shelf-ready plans that the incoming Cabinet has in place will likely focus on aligning federal agency policy and guidance with scientific and public health standards to provide clearer recommendations for state management of the virus. President-elect Biden also has committed to a full mobilization of his authorities under the Defense Production Act to provide health care systems, schools, and businesses with the required supplies.²⁰ Many of the administration's bolder plans on providing economic aid and coverage of testing and treatment will require legislation from Congress. Additional emergency provider relief funds as well as

standards for coverage.

longer-term investments in public health workforce and infrastructure might be anticipated as well.

The pending Affordable Care Act (ACA) US Supreme Court (*California v. Texas*) case and the confirmation of Associate Justice Amy Coney Barrett to the Supreme Court highlight the complexity of the other major focus of the Biden administration's health care agenda. If the Court were to strike down the ACA or some of its core provisions, that would thrust the law and broader health care reform to the top of the Biden administration's agenda. As noted above, this may depend on whether Congress works with President-elect Biden to mitigate this possibility by preemptively resolving the question of the individual mandate's constitutionality by, for example, reenacting a tax penalty for noncompliance. That potentiality aside, President-elect Biden's health care agenda would prioritize ACA improvements and an effort to enact a federal public option program. The House-passed Protecting Pre-Existing Conditions and Making Health Care More Affordable Act of 2019 (HR 1884) — sometimes referred to as "ACA 2.0" — is a strong signal of the starting point for congressional action on ACA improvements, such as expanding premium tax credit eligibility, resolving the "family glitch," expanding outreach and education, and adding funding for state innovation, among others.²¹

Whether it be legislation in pursuit of President-elect Biden's public option and Medicare reforms, or a larger ACA replacement bill, the majority party in the Senate may consider employing the budget reconciliation process to overcome opposition or may even contemplate the formal elimination of the filibuster. Doing either would likely expend a great deal of political will and intensify party divides. President-elect Biden will likely face great pressure to eliminate the filibuster, but ultimately, it is the Senate that must alter its own procedures. As has been done in the past with votes on judicial nominees, the majority could implement "reform by ruling" to create a new Senate precedent banning the filibuster on certain types of motions. This pathway - sometimes referred to as "the nuclear option" — can be accomplished by a simple majority.

Short of those efforts, there may be appetite to engage in additional health care reform depending on the degree of bipartisanship. Primary among these additional health reform topics would likely include reviving legislative action on drug pricing and surprise medical billing. For drug pricing, the reintroduction of House bill HR 3, The Lower Drug Costs Now Act, may closely align with President-elect Biden's stated platform, as it contains provisions that would allow the federal government to negotiate drug prices directly with manufacturers, impose inflation caps on drug prices, and cap beneficiary out-of-pocket spending in Medicare Part D.²² Legislative action on surprise medical billing too will depend on the party lines in Congress, although this will include the added dimension of balancing the interests of insurers and hospitals. Still, a unified Congress will likely improve the odds of aligning around an approach (i.e., arbitration versus set rates).

In addition to predominantly legislative priorities, a Biden administration also would likely pursue in parallel a series of regulatory actions to further its health care agenda. Primary among these would likely include reversal of certain Trump administration changes, including those that have limited access to care and benefits for undocumented immigrants, the LGBTQ+ community, and women. A Biden administration also could continue work on delivery system reform across a multitude of areas, leveraging existing CMMI authority and promoting the use of innovative waiver authorities by states. For example, a Biden administration could explore the use of waiver authority to support states in testing their own public option programs.

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