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National Health Advisors

# The First 100 Days: Projecting & Tracking Health Care Developments in the Biden Administration

**Updated: January 25, 2021**

# Key Personnel

## HEALTH LAW & REGULATIONS EMERGE FROM NEGOTIATION AMONG MULTIPLE STAKEHOLDERS

### Dep't of Health & Human Servs. (Nominees & Appointments)

- **Secretary of HHS**
  - **Nominated** | Cal. AG Xavier Becerra
  - **Acting** | Norris Cochran (until Becerra confirmed)
- **Deputy Secretary** | Andrea Palm
- **CMS Administrator** | ? (Liz Richter acting)
- **FDA Commissioner** | ? (Janet Woodcock acting)
- **CDC Director** | Dr. Rochelle Walensky
- **COVID-19 Equity Task Force Chair** | Dr. Marcella Nunez-Smith
- **Surgeon General** | Dr. Vivek Murthy

### The White House (Appointments)

- **Chief of Staff** | Ron Klain
- **Director of OMB** | Neera Tanden (Nominee)
- **Director of the National Economic Council** | Brian Deese
- **Director of the Domestic Policy Council** | Susan Rice
- **Chief Medical Adviser on COVID-19 to the President** | Dr. Anthony Fauci

### Congressional Leadership

#### U.S. Senate

- **Senate Majority Leader** | Sen. Chuck Schumer (D-NY)
- **Senate Minority Leader** | Sen. Mitch McConnell (R-KY)
- **Key Committee Leadership**
  - **Finance**: Sen. Ron Wyden (D-OR)
  - **RM**: Sen. Mike Crapo (R-ID) (presumed)
  - **HELP**: Sen. Patty Murray (D-WA)
  - **RM**: Sen. Richard Burr (R-NC) (presumed)

#### U.S. House of Representatives

- **Speaker of the House**: Speaker Nancy Pelosi (D-CA-12)
- **Key Committee Leadership**
  - **Energy & Commerce** | Rep. Frank Pallone (D-NJ-06)
  - **RM**: Rep. Cathy McMorris Rodgers (R-WA-05)
  - **Ways & Means** | Rep. Richard Neal (D-MA-01)
  - **RM**: Rep. Kevin Brady (R-TX-08)

The Biden Administration must fill nearly 4,000 political appointee positions, 1,200 of which require Senate confirmation. This usually takes more than 1 year.

# “Midnight” Regulations & Last Minute Rulemaking

## BIDEN ADMINISTRATION RESPONSE TO LATE TRUMP RULEMAKING

**Jan. 20, 2021 Memo of WH Chief of Staff to Agencies, “Regulatory Freeze Pending Review”** – For final rules that are not yet effective, “consider postponing the rules’ effective dates for 60 days from the date of this memorandum, . . . for the purpose of reviewing any questions of fact, law, and policy the rules may raise. For rules postponed in this manner . . . consider opening a 30-day comment period.”

- Finalized and effective regulations require new notice and comment rule-making to alter, including simply deferring effective date
  - Medicare Most Favored Nation Demo (Part B Drug International Pricing Index) finalized on No. 27, 2020. Currently blocked by preliminary injunction
- Congressional Review Act (CRA) – Through March 2021, a simple majority vote can rescind certain “midnight” regulations. However, after a successful CRA vote, an agency may never issue a similar regulation without new express Congressional authority

### Late Trump Administration Rulemaking Potentially Subject to Additional Review

Regulation	Summary	Finalized	Effective	Biden Administration Action
Clinic 340B Drug Discounts	Access to Affordable Life-saving Medications – Requires 340B program participating health clinics to pass 340B price discounts on insulin and injectable epinephrine on to low-income patients	Dec. 23, 2020	Jan. 22, 2021	Effective date deferred to Mar. 22, 2021
PBM Rebates	Removes anti-kickback safe harbor for rebates from pharma manufacturers to Medicare plans and PBMs unless 100% of value is passed to consumer at point of sale. PCMA suit challenges as arbitrary and capricious	Nov. 30, 2020	Jan. 29, 2021	
Medicaid Drug Rebate Program	Facilitates value-based purchasing arrangements. Requires inclusion in the calculation of best price and AMP any pharma manufacturer financial assistance not directly benefitting the patient	Dec. 28, 2020	Mar. 1, 2021	
SUNSET Rule	All regulations expire after 10 years unless reviewed to confirm ongoing need and appropriate impact	Jan. 8, 2021	Mar. 8, 2021	
MCIT Pathway	Medicare Coverage of Innovative Technology Pathway allows for expedited coverage of “breakthrough” devices. Also creates new definition of “reasonable and necessary” for coverage to be informed by commercial payer policies	Jan. 14, 2021	Mar. 15, 2021	
2022 Medicare Advantage Rates	Final rate announcement of CMS methodology or setting 2022 payment rates for MA plans to inform plan development and submission of bids due in June. Normally finalized in April, the Trump administration finalized in January	Jan. 15, 2021	Due Apr. 5, 2021	
Notice of Benefit and Payment Parameters (2022)	Allows states to drop reliance on healthcare.gov Exchanges and instead rely on direct enrollment entities like web-based brokers to extend coverage. Codifies guidance allowing states to use ACA subsidies for short-term limited-duration health plans and association health plans. Other provisions to be finalized in later rulemaking	Jan. 14, 2021	Jan. 1, 2022	
Prior Authorization Rule	Medicaid & QHP plans required in 2023 to implement application programming interfaces (APIs) to tell providers in advance what documentation would be needed by each payer. Facilitates electronic exchange of requests and documentation	Jan. 15, 2021	Mar. 16, 2022	

# Immediate HHS Regulatory To-Do List Based on New Law

## CONSOLIDATED APPROPRIATIONS ACT OF 2021 (ENACTED DEC. 27, 2020) REQUIRED RULEMAKING

### COVID Relief

- New HHS Provider Relief Fund (PRF) general distribution of approx. \$30 billion (\$3 billion in new funds)
- Update PRF reporting standards
- \$22 billion for purchase of vaccines, therapeutics, diagnostics, and necessary medical supplies
- Approx. \$8 billion vaccine distribution and related planning and tracking initiative
- \$22 billion initiative to monitor and suppress COVID through testing, contact tracing, surveillance, containment, and mitigation

### Medicare Reimbursement and Compliance

- Allow Medicare beneficiaries to receive mental health services via telehealth, including in the beneficiary's home
- Permitting occupational therapists to conduct the initial assessment visit and complete the comprehensive assessment with respect to certain rehabilitation services for home health agencies under the Medicare program
- Requires all manufacturers of Medicare Part B drugs to report ASP information in 2022 even if they lack a rebate agreement under the Medicaid Drug Rebate Program
- Create Medicare payment designation to allow a CAH or rural hospital with fewer than 50 beds to convert to a Rural Emergency Hospital
- Permitting direct Medicare reimbursement to physician assistants beginning in 2022

### Surprise Billing Regulations

- The "No Surprises Act," enacted through the Consolidated Appropriations Act, requires rulemaking to be performed within 1 year, such as establishing:
  - The independent dispute resolution process for surprise bills
  - Audit requirements and regulations regarding establishing "qualifying amount" methodologies
  - A patient-provider dispute resolution process for uninsured individuals

# COVID Presidential Actions

## EXECUTIVE ORDERS & ACTIONS ON JAN. 21, 2021 (DAY 2 OF BIDEN'S "10 DAYS OF PRESIDENTIAL ACTIONS")

	Executive Action <small>(with Links)</small>	Details
1	<a href="#">EO</a>   "Improving and Expanding Access to Care and Treatments for COVID-19"	<ul style="list-style-type: none"><li>• Directs the Defense, HHS, VA Secretaries to establish targets for the production, allocation, &amp; distribution of COVID treatments</li><li>• Directs the HHS Secretary to evaluate and take any available steps to promote insurance coverage for safe and effective COVID-19 treatments and clinical care in Medicare, Medicaid, group health plans, and health insurance issuers</li><li>• Directs the HHS Secretary with NIH to develop plans to support studies for promising COVID treatments &amp; future public health threats, to support research in rural locations &amp; to study long-term impacts of COVID on health</li><li>• Directs relevant agency heads to provide targeted surge assistance to critical care and long-term care facilities</li><li>• Directs the HHS Secretary to issue recommendations to states &amp; healthcare providers to increase the capacity of their healthcare workforce capacity</li></ul>
2	<a href="#">EO</a>   Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats	<ul style="list-style-type: none"><li>• Establishes the "COVID-19 Pandemic Testing Board" comprised of representatives from dep'ts &amp; agencies to coordinate efforts</li><li>• Directs the Treasury, HHS &amp; Labor Secretaries to facilitate provision of free COVID testing for those that lack comprehensive coverage &amp; clarify insurers' obligations to cover testing</li><li>• Directs HHS, Ed. &amp; Homeland Sec. Secretaries FEMA to support surveillance tests in certain settings &amp; expand access to testing</li><li>• Establishes a Public Health Workforce Program &amp; requires planning for public health threats</li></ul>
3	<a href="#">EO</a>   Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats	<ul style="list-style-type: none"><li>• Directs various agency and executive leaders (including HHS, Labor Dep't, Ed. Dep't, OMB, OSTP) to designate a senior official to lead their agency's work on COVID and pandemic-related data issues</li><li>• Directs agencies to review current public health data systems to advance innovation in public health data &amp; analytics</li></ul>
4	<a href="#">EO</a>   Sustainable Public Health Supply Chain	<ul style="list-style-type: none"><li>• Directs the State Dep't, Defense, HHS &amp; Homeland Sec. Secretaries to evaluate inventory of emergency response supplies , including PPE and the resources to effectively produce &amp; distribute tests &amp; vaccines at scale &amp; to use all available legal authorities, including the Defense Production Act, to fill shortfalls</li><li>• Directs these Secretaries to identify &amp; analyze each agency's needs &amp; capacity to produce/provide/distribute supplies</li><li>• Directs HHS, Defense, &amp; Homeland Sec. Secretaries to recommend how to address the pricing of pandemic response supplies (including whether to use GSA schedules for State, local &amp; tribal govt.)</li></ul>

**Note:** On Jan. 20, 2021, Pres. Biden [established](#) the position of the "Coordinator of the COVID-19 Response and Counselor to the President" (COVID-19 Response Coordinator) to assist the President and executive departments & agencies coordinate on the pandemic response

# COVID Presidential Actions

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	Executive Action <small>(with Links)</small>	Details
5	<a href="#">EO</a>   Protecting Worker Health and Safety	<ul style="list-style-type: none"><li>• Directs OSHA to issue revised science-based guidance on COVID workplace safety within 2 weeks to reduce workers' exposure to COVID and considering emergency temporary standards such as mask-wearing</li><li>• Directs OSHA to launch a national program to focus OSHA enforcement efforts related to COVID violations</li></ul>
6	<a href="#">EO</a>   Ensuring an Equitable Pandemic Response and Recovery	<ul style="list-style-type: none"><li>• Establish COVID-19 Health Equity Task Force</li><li>• Directs agency heads to work with the Task Force to strength equity in pandemic response</li></ul>
7	<a href="#">EO</a>   Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Providers	<ul style="list-style-type: none"><li>• Directs the Ed. Secretary to develop evidence-based guidance for reopening and for remaining open for in-person learning</li></ul>
8	<a href="#">EO</a>   Promoting COVID-19 Safety in Domestic and International Travel	<ul style="list-style-type: none"><li>• Requires travelers will have to wear masks in airports and in certain public transportation</li><li>• Requires international travelers to show proof of a negative COVID test &amp; imposes self-isolation &amp; quarantine guidelines</li></ul>
9	National Security <a href="#">Directive</a> on U.S. Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness	<ul style="list-style-type: none"><li>• Focuses on increasing the United States' role in the global pandemic response</li><li>• Follows the Jan. 20, 2021, reversal of the previous administration's decision to withdraw from the World Health Organization</li></ul>
10	<a href="#">Memorandum</a> to Extend Federal Support to Governors' Use of the National Guard to Respond to COVID-19 and to Increase Reimbursement and Other Assistance Provided to States	<ul style="list-style-type: none"><li>• Increases FEMA reimbursement to 100% of the costs states and tribal governments incur for deploying the National Guard or buying emergency supplies used to set up vaccination centers</li></ul>

**Executive Orders** | Exercising authority that Congress has given to the president alone or statements of administration policy that direct agencies to develop regulations or substantive law

[Reported](#) upcoming orders:  
Jan. 28<sup>th</sup> – Health Care Day



# President Biden's "American Rescue" COVID Relief Legislative Plan\*

OVERVIEW AND HEALTHCARE PRIORITIES RELEASED JANUARY 14, 2021

## Additional \$20B for National Vaccine Program

- Encourage access for more priority groups (65+, essential workers)
- Establish more vaccination sites through FEMA, Nat'l Guard, FQHCs, and pharmacies
- Increase vaccine supply using Defense Production Act
- Use PHS Commissioned Corps for vaccinations and hire a contact tracing workforce
- Public education campaign to encourage vaccination

## Additional \$50B Testing Initiative

- Purchase rapid tests & Expand lab capacity
- Implement regular testing protocols for schools and local governments

*\*Dec. 2020 Consolidated Appropriations Act provided \$30B for vaccination program and \$20B for testing program*

## Health Coverage Expansion

- Subsidize Continuation of COBRA coverage through Sept. 2021
- "Expand and increase the value of the Premium Tax Credit"
- Ensure ACA Exchange enrollees pay no more than 8.5 % of their income for coverage

## Other Provisions

- \$1,400 per person stimulus checks (in addition to \$600 previously enacted)
- Extend unemployment comp to Sept. 2021
- \$15 minimum wage
- Increase funding for long term care residents and workers and in prison settings
- \$30B into the Disaster Relief Fund + \$10B investment into domestic manufacturing for pandemic supplies

# Parameters of Democratic Control of Senate

## LEGISLATIVE OPPORTUNITIES AND RESTRAINTS IN 50-50 SENATE WITH VP BREAKING TIE VOTES

### 51 Votes for a Simple Majority

- Cabinet and judicial nominations may be easily confirmed
- Set agenda for Committees and Senate floor
- Pass low profile legislation
- Senate rules may be changed (eliminate filibuster; expedited impeachment for former POTUS)

### 60 Votes to Pass Cloture Motion

- Rules require supermajority of 60 votes to invoke “cloture” to end debate and move to final vote on passage of bill
- Failure to invoke cloture is considered a “filibuster”
- Effectively requires supermajority support to pass major legislation
- Use has more than doubled over 20 yrs

### 51 Votes for “Budget Reconciliation”

- Not subject to filibuster
- Legislation must be limited to changing either (1) taxes, (2) entitlement spending, or (3) debt limit
- Limited to only one bill addressing each topic per budget resolution
- Multi-stage process required: (1) include directives in budget resolution; (2) Committees draft corresponding changes to underlying law; (3) expedited final vote
- Used by Congress 25 times since 1980

## Eliminating the Senate Filibuster? Considerations for Democrats . . .

- Leadership likely to maintain perpetual threat of eliminating filibuster in order to enforce party discipline on other votes

Factors In Favor of Eliminating Filibuster	Factors In Favor of Maintaining Filibuster
Democratic base is owed substantive legislative wins (add seats to Supreme Court; create new states; single-payer; Green New Deal)	Democratic majority status in Congress is razor-thin. Threat of losing majority in electoral backlash against overreach (i.e., 1994, 2010)
Pressure on Majority Leader Schumer (NY) and other Dem incumbents to avoid primary challenge from left; 13 Dem Senate seats up in 2022	Swing state Democrats may face tight reelection race in 2022: Raphael Warnock (GA); Mark Kelly (AZ)
Once in generation opportunity to pass long-standing, major reforms	Expanded legislative power would be used by Republicans against Democrats when they next gain back 1 Senate seat



# Coverage & Access

LIKELY INCREMENTAL, WHILE ROLLING BACK TRUMP’S CHANGES IMPACTING THE ACA

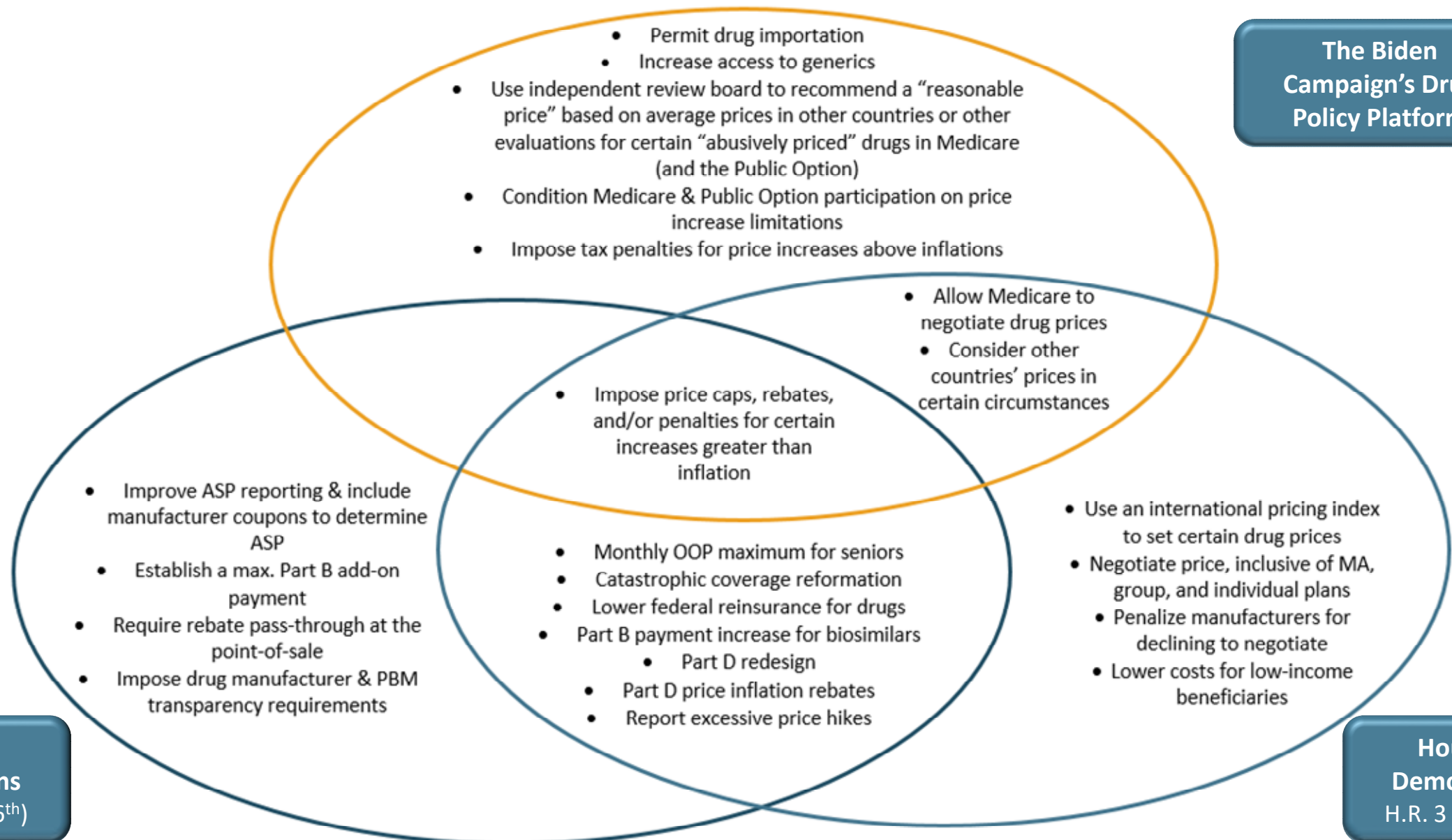
## Biden Campaign Plan: “Public Option That Would Build Off of the ACA”

- Increase the value of ACA tax credits, eliminate the 400% income cap for eligibility, and lower the limit on the cost of coverage
- Allow all states to move the Medicaid expansion population to the premium-free Public Option
- Lower Medicare age to 60

ACA-Related Actions During the Trump Administration	Biden’s Options & Possible Actions
Reduced the individual mandate penalty to \$0	Requires legislative action to increase the penalty above \$0
Reduced ACA outreach funding & shortened open enrollment	The Biden administration could reverse funding cuts
Final rule permitted enrollment in short-term limited duration plans for 364 days, with an option to renew for 36 months	The final rule was upheld. The Biden administration might seek to withdraw the rule
Policy announcement permitting states to test Medicaid work requirements	<p>The Biden administration would have the authority to reverse CMS’ policy change and withdraw approved waivers (which states can challenge) or decline to renew or renegotiate waivers</p> <p>The Supreme Court has agreed to hear a case, <i>Azar v. Gresham</i>, challenging HHS’s approval of work requirements for Arkansas and New Hampshire</p>

# Drug Pricing Legislation

## DRUG PRICING LEGISLATION & OVERLAPPING POLICY PRIORITIES



**Senate  
Republicans**  
S. 2543 (116<sup>th</sup>)

**The Biden  
Campaign's Drug  
Policy Platform**

**House  
Democrats**  
H.R. 3 (116<sup>th</sup>)