

Emerging Policy Environment and Implications for Publicly-Funded Health Care

January 2021

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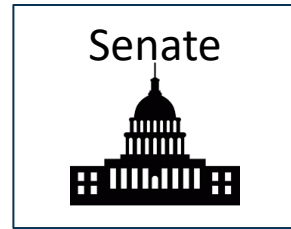
2021 Health Care Agenda Will Be Shaped by Narrow Democrat-Controlled Government and Exogenous Factors

2020 Election Results



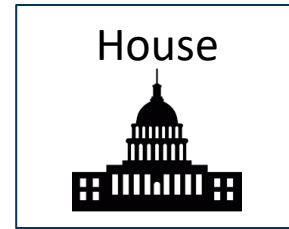
306 – 232

Joseph
Biden
Elected



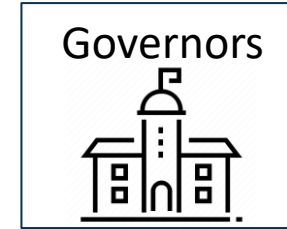
48 – 2 – 50

Democrat
control (w/ VP
tiebreaker)

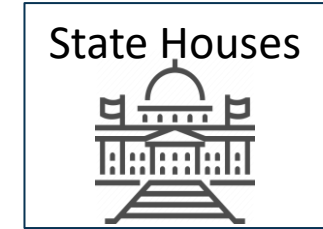


222 – 2 – 211

Democrat
Control



Republicans will
control 28 governorships;
Democrats 22



Republicans control 29
legislatures; Democrats 19
(1 split and 1 non-
partisan)







Exogenous Factors Will Shape Health Care Agenda

- COVID-19 pandemic at highest peak levels
- Economy has yet to rebound, and may be further falling
- State and local government fiscal crisis deepening
- Congressional fallout following Capitol Hill riot – timing of legislative priorities is unclear
- Supreme Court ACA actions still pending

Political Implications of Democrat Federal Government

- Elements of Biden's platform (including American Rescue Plan) and other budget related actions can pass Senate on simple majority through budget reconciliation process
 - Other elements may be stripped or could pass if bipartisan support
- Senate may become the starting point for future legislation and negotiation
- Democrat-controlled Senate should allow for Biden appointees to be confirmed quickly

Significant Pending Nominations and Appointments To Date: Health Care Team

	HHS Secretary Xavier Becerra 	General Surgeon Dr. Vivek Murthy 	Chief Medical Advisor Dr. Anthony Fauci 	COVID-19 Equity Task Force Chair Dr. Marcella Nunez-Smith 	COVID-19 Czar Jeffrey Zients 	CDC Director Dr. Rochelle Walensky 
Duties	Administer and oversee the Department of Health and Human Services' 11 agencies; Advise president on issues relating to health, welfare, and income security programs	Provide Americans with the best scientific information available on how to improve their health and reduce the risk of illness and injury; Oversee the U.S. Public Health Service (USPHS) Commissioned Corps	Advise president on public health policy	Ensure response, care, and treatment for COVID-19 is distributed equitably	Coordinate Biden administration COVID-19 response; Oversee testing, mobilization of economic aid and vaccine rollout, among other top priorities	Execute CDC's mission to protect public health and safety through the control and prevention of disease, injury, and disability in the US and internationally; Lead management of vaccine distribution across U.S., including COVID-19
Current Role	Attorney General of CA (2017-Present)	Health adviser on Biden campaign; Co-chair of President-Elect Covid-19 advisory board	Director of NIAID (1984-Present); White House COVID-19 Task Force member (Jan 2020-Present)	Associate professor of medicine and epidemiology at the Yale School of Medicine; Associate Dean for Health Equity Research	Co-chair of Biden transition team	Associate professor of medicine and epidemiology at the Yale School of Medicine; Associate Dean for Health Equity Research
Relevant Experience	Member of the House of Representatives (1993 – 2017); Served on Health Subcommittee and Social Security Subcommittee in Committee on Ways & Means as congressman	Surgeon General (2014-2017); Key leader in addressing Ebola and Zika outbreaks and Opioid crisis	Infectious disease expert, including COVID-19 and HIV/AIDS; HIV/AIDS Researcher	Founding director of the Equity Research and Innovation Center	Addressed mismanaged rollout of Healthcare.gov; Director of National Economic Council (2014-2017); Acting Director of Office of Management and Budget (2010 & 2013)	Infectious disease expert, primarily HIV/AIDS; Advisor to WHO and UNAIDS
Requires Senate Confirmation	Yes	Yes	No	No	No	No

Biden Actions/Policies on COVID Response- American Rescue Plan

Biden's "American Rescue Plan": \$1.9 trillion economic recovery and coronavirus plan (L)

1. National vaccination program: \$20 billion (L)
2. Expanded testing: \$50 billion cover the purchase of rapid tests, expand lab capacity and assist schools with testing protocols (L)
3. School funding: \$130 billion to help schools reopen; can include modifying spaces for social distancing or improving, improving ventilation, or providing PPE (L)
4. Significant funding for new health care workers (100,000 community health workers) and community clinics and tribal clinics (L)
5. Financial support for congregate settings to deal with outbreaks (L)
6. Extension of 15% increase in monthly SNAP benefits and other direct relief to families (E/L)
7. Increase subsidies for insurance to increase coverage and reduce out of pocket costs (L)
8. Reinstate paid leave supports and cost protections for COVID-19 infected people (L)

Policies to Watch:

- Future distributions and guidance of the Provider Relief Fund
- Extensions/additions of Medicaid waivers and Medicare payment flexibilities
- Federal standards that may override state vaccine distribution and response, testing, and staffing requirements
- Funding distribution and usage rules for states and local stimulus

Potential Disruptors/Influencers:

- Vaccine and vaccinator availability as well as the distribution infrastructure are already stretched, need to fill the gap. Data systems and vaccination tracking are disorganized and underfunded.
- Vaccine uptake still problematic—slowing progress towards herd immunity even if supply/distribution path is smoothed

Note: E= Likely can be done through executive action/L= May require legislation. Some policies/elements of policies noted as requiring legislation may be able to be implemented through executive action, particularly if federal or state waiver authority is used

Potential Biden Administration Actions/Policies to Restore the ACA

Biden Campaign Proposals:

1. Provide new choices of ACA coverage through a public option plan (L)
2. Expand tax credit eligibility and limit the cost of coverage to make ACA coverage more affordable (L)

Policies to Watch:

- Expansion of Marketplace enrollment, extension of open enrollment, restoration of Navigator program and renewed education and marketing, updated guidance on Section 1332 waivers
- Reversal of “market stabilization” regulations and Section 1557 (discrimination in health programs) changes that limited scope of protections
- Rescinding prior executive orders such as interstate insurance sales, short-term limited-duration health plans, and religious exceptions to coverage for LGBTQ and women’s reproductive health
- Expansion of Essential Health Benefits to cover pandemic-related services, require standardized plans, limit surprise medical billing

Potential Disrupters/Influences:

- Supreme Court Outcome in April-June 2021; Senate’s interest in legislative fixes after Supreme Court decision
- Roll back of Trump Administration’s 2019 guidance on 1332 waivers; implementation of new paradigm for 1332 waivers
- Shift in Senate balance could open new doors for ACA policy, but unlikely dramatic changes on legislative front

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Potential Biden Administration Actions/Policies for Medicaid

Biden Campaign Proposals:

1. Provide premium-free coverage through a public option for eligible individuals in states that have not expanded Medicaid coverage; provide states that have expanded Medicaid the choice to move expansion populations to the public option **(L)**
2. Ensure that people making less than 138% of federal poverty level (FPL) are automatically enrolled for coverage through public schools or by eligibility for other federal programs. **(L)**
3. Expand access to home and community based services (HCBS) by eliminating the current waitlist and providing states with option to convert current HCBS waivers into a new state plan option with an enhanced federal match **(L)**

Policies to Watch:

- Suspension of all actions to promote or approve work requirements and implement block grants, including recent waiver approvals
- Review recent and pending regulations and promulgate changes
- Continuation of flexibilities provided to states in response to COVID
- Incentives and dollars for non-expansions states to expand coverage
- Promotion of health disparities initiatives and greater state accountability to address them
- Reform of long-term services and supports to ensure safer living environments

Potential Disrupters/Influences:

- Supreme Court Outcome in April-June 2021
- State fiscal crisis may inhibit or drive uptake of different options, including COVID flexibilities
- Response of Republican-led states receiving Trump era waivers (GA, TN, FL, etc.)

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Potential Biden Administration Actions/Policies for Medicare

Biden Campaign Proposals:

1. Expand Medicare to individuals 60-65 **(L)**
 - The Biden Campaign proposed to lower Medicare eligibility to those age 60 and to permit individuals age 60-65 to “buy-into” the program on a voluntary basis. The Campaign stated that any new Medicare costs associated with the policy would be paid from sources outside of the Medicare trust fund
2. Reduce prices of pharmaceuticals (see slide 9) **(L, though additional regulatory proposals may be considered)**

Policies to Watch:

- Potential changes to Medicare Advantage payment rates
- Extensions of COVID-19 waivers and flexibilities including telehealth
- Promotion of value-based payments and Center for Medicare and Medicaid Innovation (CMMI) agenda

Potential Disruptors/Influencers:

- Medicare Trust Fund is projected to go insolvent in 2024 which may accelerate Congressional and Administration actions to reduce Medicare costs

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Potential Biden Administration Actions/Policies on Commercial Market

Biden Campaign Proposals

- 1) Promote public option to put greater pressure on provider reimbursements and private insurance premiums **(L)**
- 2) Address market concentration across the health care system by implementing more aggressive anti-trust enforcement of health care mergers **(E)**
- 3) Create limitations on practices that drive medical debt **(can be done through E but strongest protections require L)**
- 4) Reduce prices of pharmaceuticals (see following slide)
- 5) Increase wages and benefits for low-wage direct care workers (e.g., home health workers) **(L)**
- 6) Double federal investment in community health centers **(L)**

Policies to Watch:

- Reinstatement of limitations on short-term health insurance; rollback of Trump administration 12 months limit to Obama-era 90 days
- Acceleration of testing and deployment of innovations that target higher quality across the health care system
- Implementation of the recent "surprise billing" prohibition passed in December

Potential Disruptors/Influencers:

- State-level commercial market reforms

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Potential Biden Administration Prescription Drug Pricing Priorities

Biden Campaign Proposals

1. Lower Medicare prescription drug costs by: 1) repealing the statutory prohibition on Medicare negotiating drug prices with manufacturers **(E)**; 2) establishing an independent review board to assess the value of “specialized biotech drugs that will have little to no competition **(E)**; and 3) limiting the increase of brand, biotech and “abusively priced” generic drugs **(L)**
2. Leverage International Reference Pricing by creating a Review Board that will use International Reference Pricing to help set drug prices for newly launched specialty (Part B) drugs **(L)**
3. Allow drug reimportation **(L)**
4. Limit drug price increases to inflation, including Medicaid and Public Option (if implemented) and all brands, biologics, and some generics **(L)**
5. Eliminate the tax break for advertising drugs **(L)**

Policies to Watch:

- Biden Administration actions to repeal or modify pending Trump Administration regulations and Executive Orders to control drug prices
- Action on the Grassley-Wyden introduced legislation (S. 4199)
- Actions to further regulate pharmacy benefit managers in the post Rutledge v. PCMA decision that favors independent pharmacies
- Joint legislative and FDA policy making on removing/amending patent barriers and drug exclusivity periods to bring lower cost generics to market faster
- State waiver authority to allow states to maneuver around Section 1927 of the SSA (closed formulary provisions in TN Waiver) and pool drug purchasing

Potential Disruptors/Influencers:

- COVID-19 vaccine successes could mean manufacturers enjoy a hiatus in criticism over drug pricing, which could ameliorate Executive administrative actions
- Drug shortages for COVID-19 treatments could raise drug prices/rationing
- Supply chain issues with getting approved COVID-19 vaccines to communities quickly will continue to be a focus in the first term

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Potential Biden Administration Actions/Policies to Address Behavioral Health

Biden Campaign Proposals

1. Appropriate \$4 billion to SAMHSA and HRSA to expand access to mental health and substance use disorder services (L) (this funding is included in Biden's recent American Rescue Plan)
2. Provide flexible grants to states and localities for prevention, treatment, and recovery efforts (L)
3. Ensure that Medication Assisted Treatment (MAT) is universally available (L if new funding is needed)
4. Support development and expand coverage for alternative pain medications and treatments (E)
5. Enforce mental health parity laws (E)

Policies to Watch:

- Federal opioid settlements
- Promotion of new Medicare/Medicaid models to better integrate behavior health services
- Expansion of telehealth services

Potential Disruptors/Influencers:

- COVID-19 pandemic overshadowing opioid epidemic as priority public health crisis
- State-level settlements will differ state by state in their use and oversight models

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Trump Administration Actions Likely to be Reviewed by Biden Administration

■ ACA related:

- Length of open enrollment period (returning to 90 days)
- "Market stabilization" rule changes that increased access to short term plans, supported grandfathered plans
- 2019 guidance on Section 1332 waivers
- Women's health related policies, including payment for abortion, Section 1557 (discrimination in health programs), "provider conscience" protections, exemptions to the contraceptive mandate

■ Medicare/Prescription Drugs

- Review of recent drug pricing proposals issued through rulemaking (e.g., Most Favored Nation, Rebate Rule)
- Medicare Advantage payment rates
- Review of/modifications to recent CMMI demonstration models (e.g., Geographic Direct Contracting)

■ Medicaid

- Approval of TN waiver: 10-year demonstration providing fixed Medicaid funding on a per-capita cap basis. Provides enhanced state discretion on services offered; and includes implementation of prescription drug formulary. The Operational Plan requires approval by TN state legislature
- SCOTUS agrees to hear Trump admin appeal on Medicaid work requirement pilot programs in Arkansas (*Azar v. Gresham*) and New Hampshire (*Azar v. Philbrick*)
- Managed care regulations
- CMS [guidance](#) to help state Medicaid and CHIP programs transition back to normal operations when COVID-19 PHE ends (Addresses pending eligibility and enrollment actions developed during the COVID-19 PHE and other planning considerations, including steps needed to be taken should states make any of the temporary flexibilities permanent)

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QUESTIONS? CONTACT US



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