

Emerging Policy Environment and Implications for Publicly-Funded Health Care

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

2020 Election Results

Presidency



306 – 232

Joseph
Biden
Elected

Senate



48 – 2 – 50

Democrat
control (w/ VP
tiebreaker)

House



222 – 2 – 211

Democrat
Control

Governors



Republicans will
control 28 governorships;
Democrats 22

State Houses



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






Exogenous Factors Will Shape Health Care Agenda

- COVID-19 cases and hospitalizations are falling, but forecast to rebound soon
- Economy has yet to recover, and future trajectory and timeframes remain unclear
- State and local government fiscal situations highly variable with some facing significant deficits
- 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
- Senate may become the starting point for future legislation and negotiation
- Democrat-controlled Senate should allow for Biden appointees to be confirmed quickly, though more controversial appointees may be more challenging

Significant Pending Nominations and Appointments To Date: Health Care Team

	HHS Secretary Xavier Becerra 	Surgeon General Dr. Vivek Murthy 	Chief Medical Advisor Dr. Anthony Fauci 	COVID-19 Equity Task Force Chair Dr. Marcella Nunez-Smith 	COVID-19 Czar Jeffrey Zients 
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
Current/ Previous 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
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	Led turnaround of Healthcare.gov; Director of National Economic Council (2014-2017); Acting Director of Office of Management and Budget (2010 & 2013)
Requires Senate Confirmation	Yes	Yes	No	No	No

The nominees and appointments noted here do not represent all key positions and will be updated as official announcements are made

Nominations and Appointments: Select HHS Operating Divisions and OMB

	HHS Operating Divisions			Office of Management and Budget (OMB)
	CMS Administrator Chiquita Brooks-LaSure 	Center for Medicare and Medicaid Innovation (CMMI)* Director Elizabeth Fowler 	CDC Director Dr. Rochelle Walensky 	OMB Associate Director for Health Topher Spiro 
Duties	Administer and oversee Medicare, Medicaid, CHIP, and state and federal health insurance markets; Head the agency's mission to strengthen the healthcare system by improving quality, lowering costs, and eliminating instances of fraud and abuse	Oversee development and testing of new healthcare payment and service delivery models to improve patient care, lower costs, and better align payment systems to promote patient-centered practices	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	Oversee health programs at the White House's Office of Management and Budget
Current/Previous Role	Managing Director at Manatt Health (2016-Present)	Executive Vice President for Programs at Commonwealth Fund	Chief of Infectious Diseases at Massachusetts General Hospital; Professor of Medicine at Harvard Medical School	Senior Fellow and Vice President for Health Policy at the Center for American Progress (2011-Present)
Relevant Experience	Deputy director for policy at Center for Consumer Information and Insurance Oversight (2012-2014); Director of coverage policy at Department of Health & Human Services (2010-2012)	Vice President for Global Health Policy at Johnson & Johnson; Special assistant to President Barack Obama on health care and economic policy at the National Economic Council; Chief health counsel to former Senate Finance Committee Chairman Max Baucus	Infectious disease expert, primarily HIV/AIDS; Advisor to WHO and UNAIDS	Deputy staff director for health policy for the U.S. Senate Committee on Health, Education, Labor and Pensions (2009-2010)
Requires Senate Confirmation	Yes	No	No	No

The nominees and appointments noted here do not represent all key positions and will be updated as official announcements are made

*CMMI is managed by CMS

Photo Sources: Whitehouse.gov; LinkedIn Profiles

American Rescue Plan: Current Status of Congressional Efforts – Health Care

- The House recently passed their version of the American Rescue Plan
- Because the legislation is being advanced through reconciliation, the Senate only needs a simple majority (i.e., 51 votes) rather than a super majority (i.e., 60 votes) to pass it
- Legislation considered under reconciliation must satisfy the "Byrd Rule" to pass the Senate, which requires legislation to have a direct spending/revenue impact on the federal budget

Notable Provisions Included in House-passed Legislation

Medicaid

- 7.35% FMAP boost for HCBS (E&C)
- Medicaid coverage of COVID-19 vaccines and treatment w/o beneficiary cost sharing; vaccines matched at 100 percent (FMAP) through one year after the end of the PHE (E&C)
- Temporary 5 percentage point increase to state's base FMAP for newly expanded Medicaid states (E&C)
- Medicaid eligibility to incarcerated individuals for 5 years starting 30 days prior to release (E&C)
- Elimination of cap on Medicaid drug rebate (E&C)

Public Health

- \$7.5B activities to plan, prepare for, promote, distribute, administer, monitor, and track COVID-19 vaccines; led by CDC and in consultation with other agencies (E&C)
- \$1B for vaccine confidence activities (E&C)
- \$5.2B for expenses related to research, development, manufacturing, production, and the purchase of vaccines, therapeutics, and ancillary medical products for COVID-19 response (E&C)
- \$46B for funding for COVID-19 testing, contact tracing, surveillance, and mitigation (E&C)
- \$7.66B to establish a Public Health Workforce (E&C)

Other Relevant Provisions

- \$200M to HHS to carry out SNF infection control support through Quality Improvement Organizations (W&M)
- \$250M to HHS to allocate to states to establish strike teams to respond to COVID-19 outbreaks in SNFs (W&M)
- \$20M for State-Based Marketplaces (SBMs) to modernize information technology systems (E&C)
- \$7.6B for grants to Community Health Centers (E&C)
- \$3.5B for Substance Abuse Prevention/Treatment and Community Mental Health block grant programs (E&C)
- \$10M for SAMHSA's National Childhood Traumatic Stress Network (E&C)
- \$80M for mental and behavioral health training for health care professionals, para-professionals, and public safety officers (E&C)
- Significant supports for the purchase of individual coverage in the ACA Marketplaces

While stakeholders should monitor activity related to enactment of the American Rescue Plan, many of these provisions are likely to change or be eliminated before the Senate votes in early March

Current Status of Congressional Efforts – Federal Minimum Wage

- The federal minimum wage has remained unchanged at \$7.25/hour since 2009
- Most firms that employ 2 or more workers must pay them the higher of their state-enacted minimum wage or the federal minimum rate
- The House Bill included provisions similar to the Raise the Minimum Wage Act of 2021 (HR 603), which would have increased the federal minimum wage to \$15.00/hour over a five-year period



- The House legislation would also index future increases in the federal minimum wage (after 2025) to median wage growth to avoid the need for future federal legislation to increase the rate to keep pace with inflation

The Senate determined that the federal minimum wage requirement does not meet the requirements of the “Byrd Rule” and therefore not likely to be included in the American Rescue Plan, unless 60 Senators vote to approve. However, it is likely similar provisions may be proposed/enacted in future legislative efforts

Key Health Care-related Executive Orders

Executive Order	Issue Date	Topic Area(s)	Relevant Provision(s)	Implications/Open Questions
Restoring Faith in Our Legal Immigration Systems	February 2, 2021	Medicaid (Eligibility)	Reviews Public Charge Rule	<ul style="list-style-type: none"> TBD- May lead to growth in Medicaid enrollment among immigrant populations
Strengthening Medicaid and the Affordable Care Act (ACA)	January 28, 2021	ACA, Medicaid	ACA Exchange Special Enrollment Period (SEP)	<ul style="list-style-type: none"> Opened Feb. 15 – May 15, 2021 Only applies to Federally-Facilitated Exchanges, though states also opened enrollment periods \$2.3 million in funding recently provided by CMS for Navigator enrollment support
			Review and Potential Suspension or Rescission of Existing Regulations and Agency Actions	<ul style="list-style-type: none"> Work and community engagement requirements were specifically called out in the order Revokes two Trump executive orders that supported association health plans, short-term plans, and HRAs
			Consideration of Further Regulations and Actions to Improve Coverage	<ul style="list-style-type: none"> TBD – Will likely take time for agencies to develop regulations, and agencies are limited in the actions they can take
Protecting Women’s Health at Home and Abroad	January 28, 2021	ACA, Medicaid (Women’s Health)	Review of 2019 Title X Rule “Compliance With Statutory Program Integrity Requirements”	<ul style="list-style-type: none"> Likely to expand access and/or funding for abortion-related services and information
			Mexico City Policy is revoked (aka Global Gag Rule)	<ul style="list-style-type: none"> Likely to enhance ability for non-governmental organizations (NGOs) receiving federal funds to expand services and patient knowledge regarding abortion
Establishing the COVID-19 Pandemic Testing Board	January 21, 2021	Workforce	Establishes a national public health workforce program	<ul style="list-style-type: none"> TBD- Charges Secretaries of HHS and Labor to coordinate with State, tribal and local entities to establish the U.S. Public Health Job Corps
Sustainable Public Health Supply Chain	January 21, 2021	COVID-19	Assessment of supply and pricing for pandemic response supplies	<ul style="list-style-type: none"> May cause US government to reevaluate contracts with firms producing PPE
			Development of Pandemic Supply Chain Resilience Strategy	<ul style="list-style-type: none"> TBD- Likely to increase long-term inventory of PPE in national stockpile; alter US supply chains

Key Health Care-related Executive Orders: Continued

Executive Order	Issue Date	Topic Area(s)	Relevant Provision(s)	Implications/Open Questions
Improving and Expanding Access to Care and Treatments for COVID-19	January 21, 2021	COVID-19	Provide targeted surge assistance to critical care and LTC facilities	<ul style="list-style-type: none"> May reduce mortality rates during case spikes
			Support studies involving COVID-19 treatment and long-term impact; ensure underrepresented populations are present in such studies	<ul style="list-style-type: none"> Likely to further public knowledge regarding COVID-19 and variants, including testing and vaccination efforts
			Establish targets for the production, allocation, and distribution of COVID-19 treatments	<ul style="list-style-type: none"> May improve access and affordability of COVID-19 treatments
			Evaluate COVID-19 Uninsured Program	<ul style="list-style-type: none"> May increase access to treatments and clinical care for underinsured/uninsured; may support safety-net providers in delivering such treatments and clinical care
Ensuring an Equitable Pandemic Response and Recovery	January 21, 2021	COVID-19	Establishes COVID-19 Health Equity Task Force	<ul style="list-style-type: none"> Seeks to provide a coordinated approach to addressing nationwide health inequities during pandemic and beyond
			Evaluation of pandemic response	<ul style="list-style-type: none"> Seeks to address inequitable distribution of resources across nation, particularly among communities of color
			Vaccine trust outreach campaign	<ul style="list-style-type: none"> TBD- May improve trust in vaccine safety among American population, including communities of color
			Placement of contact tracers in hard hit communities	<ul style="list-style-type: none"> TBD- May improve federal tracking of COVID-19 spread
Protecting Worker Health and Safety	January 21, 2021	Workforce	Consideration of actions possible under Occupational Health and Safety Act (OSHA)	<ul style="list-style-type: none"> May improve oversight of employers pressuring employees to work, while at risk of infection May improve worker knowledge of rights regarding health in the workplace Will announce emergency temporary standards regarding mask-wearing in the workplace by March 15, 2021

Key Regulations Currently Under Review

Regulation	Date of Publication	Effective Date	Key Provisions	Biden Administration Actions
Medicare				
OIG Final Rule Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions	11/20/20	01/29/21	<ul style="list-style-type: none"> Eliminates safe harbor protection on rebates negotiated between plans/PBMs that are not passed through to patients Includes new safe harbor for rebates that are passed directly to the patient at the point of sale 	<ul style="list-style-type: none"> HHS delayed implementation to May 1, 2022 DC District Court delayed effective date to January 1, 2023
CMS Final Rule Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations	12/02/20	02/01/21	<ul style="list-style-type: none"> Changes to the Organ Procurement Organization (OPO) Conditions for Coverage 	<ul style="list-style-type: none"> Regulatory freeze pending review (60 days) CMS is also providing an additional 30-day public comment period
Proposed Rule (never published) Revisions to Medicare Part A Enrollment	N/A	N/A	<ul style="list-style-type: none"> Proposals to implement section 11 of Trump Administration Executive Order (EO) 13890 which directed HHS/SSA to “revise current rules or policies to preserve the Social Security retirement insurance benefits of seniors who choose not to receive benefits under Medicare Part A” 	<ul style="list-style-type: none"> Withdrawn on 1/25/21
Medicaid				
See “Other/Impacts Multiple Programs” Below				
Marketplace				
Proposed Rule (never published) Conditions for Coverage for End-Stage Renal Disease (ESRD) Facilities--Third Party Payments	N/A	N/A	<ul style="list-style-type: none"> Proposals to establish requirements for third parties that provide premium assistance to ESRD patients enrolled in individual market health plans 	<ul style="list-style-type: none"> Withdrawn on 1/25/21
Other/Impacts Multiple Programs				
HRSA Final Rule (Impacts Medicare and Medicaid) Implementation of Executive Order on Access to Affordable Life-Saving Medications	12/23/20	01/22/21	<ul style="list-style-type: none"> Required federally qualified health centers (FQHCs) in the 340B Drug Pricing Program to pass drug discounts received on insulin and EpiPens on to certain low-income patients as a condition of receiving federal grant funding 	<ul style="list-style-type: none"> Delayed implementation to March 22, 2021

CMMI Models Likely to be Reviewed in Response to Stakeholder Concerns

Model	Model Details	Implementation Date	Current Status	Biden Administration Actions
Medicare				
Geographic Direct Contracting (Geo)	<ul style="list-style-type: none"> Selected Geo Direct Contracting Entities (DCEs) take responsibility for the total cost of care for Medicare Fee-for-Service (FFS) beneficiaries in a specific region All Medicare FFS beneficiaries in a Geo Direct Contracting region will be attributed to a Geo DCE; attributed beneficiaries will have the option to switch DCEs or enroll in a Medicare Advantage plan but cannot remain in FFS Beneficiaries maintain freedom of provider choice but DCEs can provide incentives for beneficiaries to seek care from preferred providers 	1/1/22	Applications on hold	<ul style="list-style-type: none"> Changed status from accepting applications to “under review”
Most Favored Nation (MFN)	<ul style="list-style-type: none"> Mandatory model testing phase out of current provider reimbursement for Part B drugs (average sales price (ASP) +6% add on) to “target price” based on lowest price across 22 countries + flat fee add-on 	1/1/21	Delayed pending outcome of legal challenges	<ul style="list-style-type: none"> None to date
Radiation Oncology	<ul style="list-style-type: none"> Mandatory model testing prospective, site-neutral, modality agnostic, episode-based payments for radiotherapy services (RT) services for select types of cancer 	1/1/21	In 12/20, Congress passed legislation prohibiting start date until 1/1/22	<ul style="list-style-type: none"> None to date
Part D Senior Savings	<ul style="list-style-type: none"> Participating insurers offer Part D beneficiaries with supplemental insulin coverage Beneficiary copays capped at \$35 for a 30-day supply of insulin for the entire benefit year 	1/1/21	1,635 prescription drug plans in Year 1	<ul style="list-style-type: none"> 2022 Request for applications not yet made available Education for prospective 2022 participants delayed
Medicaid				
See “Medicare and Medicaid or Medicare-Medicaid Integration” Below				
Medicare and Medicaid or Medicare-Medicaid Integration				
Medicaid MCO-based Direct Contracting	<ul style="list-style-type: none"> Medicaid MCOs with parent organizations that have MMP or FIDE-SNP contracts with CMS (in any state) may apply to take responsibility for Medicare fee-for-service costs for their full-benefit dually eligible Medicaid MCO enrollees 	1/1/22	Announced	<ul style="list-style-type: none"> 2022 Request for applications not yet made available
Community Health Access and Rural Transformation	<ul style="list-style-type: none"> Rural hospital demonstration testing total cost of care payments to public health entities Requires participating hospital to partner with local entity to facilitate coordination of services 	1/1/22	Announced	<ul style="list-style-type: none"> None to date

Trump Administration Approved Waivers In Question

TN
Approved 1/8/21
(Now Pending)

- Aggregate cap on federal spending and permits state to share in any realized federal savings
- Closed Rx drug formulary enabling the state to cover the greater of either one drug per therapeutic class or the same number of drugs per class as a selected Essential Health Benefits benchmark plan in the Exchange, with an exceptions process for coverage of non-formulary drugs
- 10-year approval (through 12/31/30)

FL
Approved 1/15/21

- Extension of Medicaid managed care program
- Extension of \$1.5 billion annual uncompensated care pool
- 10-year approval (through 12/31/30)

TX
Approved 1/15/21

- Continues Medicaid managed care framework
- Creates Public Health Provider – Charity Care Program; \$500 million per year for first two years, then adjusted
- Extension of \$3 billion annual uncompensated care pool
- Proposes an additional \$3 billion in annual directed and supplemental payments on top of existing \$4 billion annually
- 10-year approval (through 12/31/30)

GA
Approved 10/15/20
(Now Pending)

- Limited expansion up to 100% FPL
- Traditional FMAP, not 90/10
- Community engagement requirements
- Premiums for Members over 50% FPL
- Member rewards accounts for payment of vision, dental, and over-the-counter drugs not otherwise covered
- Premiums accrue to rewards accounts
- Approved through 9/30/25

U.S. Supreme Court cases and Work Requirement provisions in 1115 waivers

- In December, the U.S. Supreme Court announced that it would hear appeals in cases from Arkansas and New Hampshire challenging the authority of the Secretary to approve waivers with work requirements.
- There are 19 states that have submitted 1115 waiver applications with work requirements.
- Of those, only two have been implemented and both of those have currently suspended them.

On February 12, 2021, CMS issued letters to at least nine states¹ noting the potential for partial withdrawal of section 1115 demonstration project waivers. CMS also issued letters to states rescinding “Letters of Agreement” signed during the Trump administration which required that the effective date of a waiver withdrawal be at least nine months after CMS transmits its withdrawal determination to the state

1. The nine states are: Arizona, Arkansas, Georgia, Indiana, Nebraska, Ohio, South Carolina, Utah, and Wisconsin

Communications to States

Communication	Summary	Implications
<p>HHS Letter to Governors</p> <p>January 22, 2021</p>	<ul style="list-style-type: none"> ▪ Indication that PHE is likely remain in place for the entirety of 2021 ▪ HHS will provide states with 60 days’ notice prior to termination of the PHE ▪ Reminder that enhanced FMAP expires at the end of the quarter in which the PHE ends 	<ul style="list-style-type: none"> ▪ Provides state Medicaid agencies and other stakeholders with greater certainty regarding 1) timeline for enhanced financing, and 2) permissibility of/reimbursement for various COVID-19 flexibilities

Policies to Watch Going Forward

HMA is carefully tracking campaign statements and announcements from the Administration in critical areas. We expect attention to critical issues and programs in the following areas over the coming months and as we move into 2022:

- **ACA reforms to improve access and reduce the cost-burden for individuals without access to employer coverage**
- **Prescription drug costs and rebate reforms are on the table for both Medicaid and Medicare**
- **Halting Trump-era Medicaid reforms like work requirements, but also seeking improvements to HCBS, extending coverage for pregnant women and incentivizing more states to expand adult coverage**
- **Medicare reform proposals are limited so far, but included 60-65 buy-in opportunities. In addition, the Medicare Trust Fund is again forecasted to be at a critical level soon, requiring action**
- **The Biden Administration would like to roll back many of the Trump-era changes to private insurance. They will chip away at things like high-deductible plans. And the passage of reforms to “surprise billing” last December need to be implemented**

QUESTIONS? CONTACT US



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