



Health Policy Briefing

November 16, 2020

Biden Announces Chief of Staff, COVID Advisory Council, HHS Transition Team

President-elect Joe Biden has selected his long-time aide Ron Klain to be his chief of staff. Klain is the nation's former Ebola czar who led the nation's response to the West Africa Ebola outbreak in 2014 and 2015. Klain previously served as chief of staff to Biden at the beginning of his vice presidency and also worked as chief of staff to Vice President Al Gore toward the end of President Bill Clinton's administration.

Biden and Vice President-elect Kamala Harris met for the first time last week with their advisory council that will support them and their transition team in its response to the coronavirus pandemic. The virus panel will be co-chaired by former commissioner of Food and Drugs David Kessler, former Surgeon General Vivek Murthy and Marcella Nunez-Smith, Yale University professor of public health. Other members include Atul Gawande, Brigham and Women's Hospital surgeon; Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota; Celine Gounder, professor of Medicine and Infectious Diseases at New York University; Ezekiel Emanuel, a former Obama administration health adviser; Luciana Borio, vice president at In-Q-Tel, Rick Bright, the former director of the Biomedical Advanced Research and Development Authority (BARDA); Julie Morita, the executive vice president of the Robert Wood Johnson Foundation; Loyce Pace, president of Global Health Council; Robert Rodriguez, a professor of emergency medicine at the UCSF School of Medicine; and Eric Goosby, professor of medicine at the UCSF School of Medicine. The group will be charged with mapping out the public health and economic approach necessary to respond to the pandemic. Ron Klain also stated last week that the President-elect plans to appoint a White House coronavirus response coordinator to provide daily briefings. Biden also announced the members of his Health and Human Services transition team. The agency review team will be led by

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Chiquita Brooks-LaSure, who worked as Democratic staff for the House Ways and Means Committee during the passage and implementation of the Affordable Care Act (ACA). She later served as deputy director for policy at the Center for Consumer Information and Insurance Oversight (CCIIO) within the Centers for Medicare and Medicaid Services (CMS). Robert Gordon will serve as co-leader of the team. He is the director of the Michigan Department of Health and Human Services who was acting deputy director for the Office of Management and Budget (OMB) under President Barack Obama.

Biden Awaits Official Ascertainment for Transition

President Donald Trump continues to dispute the results of the presidential election as President-elect Joe Biden presses the administration to release the funding and access provided to allow the presidential transition team to contact federal agencies, access nonpublic information, and set up government offices. The General Services Administration (GSA) has yet to sign the necessary paperwork to initiate a formal government transition as President Trump moves forward with legal challenges to overturn Joe Biden's win with unsubstantiated claims of voter fraud. The President has received some support from Republicans in Congress for his efforts to challenge the election results. Senate Majority Leader Mitch McConnell (R-Ky.) has declined to recognize Biden's victory and stated in a floor speech last week that President Trump is "100 percent within his rights" to do so. Only four Republican senators have publicly acknowledged Biden's victory: Susan Collins (Maine), Mitt Romney (Utah), Lisa Murkowski (Alaska), and Ben Sasse (Nebraska). According to the Associated Press (AP), Biden has currently secured 290 Electoral College votes while President Trump has 232. Biden's chief of staff Ron Klain is specifically pushing for the incoming administration to be able to take part in the planning process for the distribution of an eventual coronavirus vaccine and to enable Biden's plans for a rapid scale-up of the federal COVID response come January. President Trump has until December 8 to complete any legal challenges to the election. December 8 marks the "safe harbor" date for which a state's electors are accepted by Congress. The Electoral College will meet on December 14 to cast their votes for Biden, and Congress is scheduled to accept the results on January 6.

Senate Appropriators Release FY21 Spending Bills

Senate appropriators released a \$1.4 trillion package of all 12 fiscal year (FY) 2021 appropriations bills last week to jumpstart bicameral negotiations on the passage of an omnibus spending measure during the lame-duck session of Congress. The Labor-Health and Human Services-Education bill includes \$195.1 billion in discretionary funding. Lawmakers propose \$43.6 billion for the National Institutes of Health (NIH), a \$2 billion increase. More than \$4 billion is appropriated for pandemic preparedness programs, an increase of \$161 million, including an increase of \$30 million for the Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness cooperative, and an increase of \$50 million for the Biomedical Advanced Research and Development Authority (BARDA). The bill also includes \$518 million for the White House initiative to end the spread of HIV/AIDS (an increase of more than \$200 million), \$3.9 billion to combat the opioid epidemic (an increase of \$88 million), with new approval for funds to be used to curb methamphetamine and other stimulus misuse, and \$4 billion for mental health programs (an increase of \$194 million). The \$153 billion Agriculture bill includes \$23.3 billion in discretionary funding. The Food and Drug Administration (FDA) would receive \$3.2 billion. Additionally, the State and Foreign Operations committee report calls for \$118 million for the World Health Organization (WHO), despite President Trump's push to withdraw from the international body. While Health and Human Services Subcommittee Chair Roy Blunt (R-Mo.) stressed the bipartisan nature of the appropriations measures, Appropriations Committee Ranking Member Patrick Leahy (D-Vt.) criticized the absence of emergency funding to respond to COVID-19. The Senate package would not exempt any coronavirus-related funding from statutory spending caps, while the previously passed House bill included more than \$230 billion in cap-exempt emergency spending. House Democrats have so far largely refrained from commenting on the substance of the Senate bills. The current stopgap spending measure is set to expire on December 11.

Likelihood of Lame Duck COVID Stimulus Remains Low

Senate Majority Leader Mitch McConnell (R-Ky.) has renewed his calls for Congress to pass a targeted coronavirus stimulus package before the end of the year in light of the positive results from Pfizer Inc.'s COVID vaccine trial. Democrats, however, continue to push for a larger relief bill. While Senate Republicans support a \$500 billion package, without another round of individual stimulus checks or aid to state and local governments, Democrats continue to push for a \$2.4 trillion measure. The House returns to session this week, though there are no talks scheduled to renew negotiations on new coronavirus stimulus legislation.

McConnell, Schumer Reelected as Senate Leaders

Majority Leader Mitch McConnell (R-Ky.) was reelected to lead Senate Republicans during the 117th session of Congress, while Chuck Schumer (D-N.Y.) will remain as the top Democrat in the chamber. Republican Whip John Thune (R-S.D.) and Republican Conference Chair John Barrasso (R-Wyo.) will return to their leadership positions, with the addition of Rick Scott (R-Fla.) who will serve as chair of the National Republican Senatorial Committee. Democratic Senate leadership will also remain the same, with party Whip Dick Durbin (D-Ill.) and Assistant Democratic Leader Patty Murray (D-Wash.), alongside Cory Booker (D-N.J.) who will serve as Vice Chair of the Democratic Policy and Communications Committee and Catherine Cortez Masto (D-Nev.) who will serve as Vice Chair of Outreach. Please see [HERE](#) for Hart Health Strategies Inc. updated 2020 Political/Elections Overview document.

Alaska Incumbent Wins Reelection

Senate Republican incumbent Dan Sullivan has won his race for reelection in Alaska, bringing the GOP to 50 votes in the upper chamber. Given the results of Sullivan's race, control of the Senate will now depend on the winners of two runoffs in Georgia. If Republicans win either one, they will retain control of the Senate during the 117th Congress.

Lawmakers Question Medicaid, Exchange Changes in GA

Democratic leaders of the congressional health committees have [written](#) to top administration officials criticizing the White House's decision to approve Georgia's planned overhaul of its Medicaid program and health care exchange. The waiver would permit the state to impose a Medicaid work requirement and privatize its Affordable Care Act (ACA) market. Sens. Ron Wyden (D-Ore.) and Patty Murray (D-Wash.), and Reps. Richard Neal (D-Mass.), Frank Pallone (D-N.J.), and Bobby Scott (D-Va.) characterize the proposals as "blatant violations of federal law." Their [letter](#) to the U.S. Department of Health and Human Services (HHS), the Treasury Department, the Centers for Medicare and Medicaid Services (CMS), and the Internal Revenue Service (IRS) outlines how these waivers would be harmful to Georgia residents, violate federal law, and increase challenges related to the COVID-19 pandemic.

Key Justices Appear to Support Severability of Individual Mandate

Oral arguments began last Tuesday before the Supreme Court in *California v. Texas*, the case in which the high court will rule on the constitutionality of the Affordable Care Act (ACA). The case was brought by a group of Republican-led states and is supported by the current administration. They argue that the individual mandate, which was originally tied to a tax penalty for noncompliance, was central to a 2012 Supreme Court ruling upholding the law, and that since Congress eliminated the individual tax mandate in 2017 the entire law must now be invalidated. Members of the court, including Chief Justice John Roberts and Justice Brett Kavanaugh, signaled last week that they would support allowing the individual mandate to be severed from the remainder of the 2010 health care law, meaning that the rest of the ACA could stand even if the court decides to invalidate the individual mandate provision.

Promising New Data on COVID Vaccine Development

Pfizer and BioNTech published positive results for their COVID-19 vaccine candidate in a press release last week. Their data from a trial of more than 40,000 volunteers suggests that the vaccine is more than 90 percent effective in preventing symptomatic infections. Their results are based on an interim analysis completed after 90 participants, split between those who received the placebo and those who received the vaccine, contracted COVID-19. The trial will continue until 164 infections have occurred. The U.S. and Europe are first in line to receive doses of the vaccine, with regulators working to quickly review the safety and efficacy data.

In related news, Novavax has been granted a fast track designation by the Food and Drug Administration (FDA) for its COVID-19 vaccine candidate. The company plans to begin its phase three clinical trial in the U.S. and Mexico by the end of this month. The FDA also granted Eli Lilly's antibody therapy an emergency use authorization (EUA) for the treatment of COVID-19. Early evidence indicates that the treatment is effective in preventing hospitalization in people infected with the coronavirus.

Hart Health Strategies COVID-19 Resources

Hart Health Strategies Inc. continues to update the following resources related to the coronavirus pandemic. Please remember to clear your cache to ensure you download the most recent documents.

- [COVID-19 Testing](#)
- [Disaster Primer](#)
- [Federal Relief Overview](#)
- [Health Care Workers on the Front Lines](#)
- [Hospice and Palliative Care](#)
- [Nursing Resources](#)
- [Personal Protective Equipment](#)
- [Physician Provisions](#)
- [Re-Opening America](#)
- [Small Business Resources](#)
- [Small Business - Paycheck Protection Program](#)
- [Small Business – PPP FAQ](#)
- [State Resources](#)
- [Tax Provisions](#)
- [Telehealth Overview](#)

Upcoming Congressional Hearings and Markups

Senate Commerce, Science, & Transportation Subcommittee on Manufacturing, Trade, and Consumer Protection hearing “Examining the American Manufacturing Industry’s Response to the COVID-19 Pandemic;” 2:30 p.m., 253 Russell Bldg.; November 17

Senate Homeland Security and Governmental Affairs hearing “Early At Home Treatment: An Essential Part of a COVID-19 Solution;” 10:00 a.m., WEBEX; November 19

Recently Introduced Health Legislation

H.R.8732 — To modify reporting requirements under the Controlled Substances Act; Sponsor: Rep. Castor, Kathy [D-FL-14]; Committees: House - Energy and Commerce; Judiciary

H.R.8736 — To amend the Federal Food, Drug, and Cosmetic Act to allow the sponsor of a drug to use a non-animal test as an alternative to an animal test for purposes of demonstrating the safety and effectiveness of a drug if such approach satisfies the requirements of the applicable statutes and regulations; Sponsor: Rep. Boyle, Brendan F. [D-PA-2]; Committees: House - Energy and Commerce

S.4894 — A bill to amend title XXVII of the Public Health Service Act to improve health care coverage under vision and dental plans, and for other purposes; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions