



Health Policy Briefing

January 11, 2021

Biden Certified As President Amidst Violent Clash at Capitol

Joe Biden was formally recognized as the next U.S. president by Congress last week. Supporters of President Trump marched on the Capitol as lawmakers were formally counting the Electoral College votes, breaking through security barriers and forcing themselves into the building. The clash with police resulted in at least five deaths, including a Capitol Police officer, and dozens of injuries. The President eventually released a video condemning the attack on the Capitol, but only after appearing to condone the violence and praising his supporters. The events resulted in the President being permanently banned from Twitter “due to the risk of further incitement of violence.” Two cabinet members – Education Secretary Betsy DeVos and Transportation Secretary Elaine Chao – and several other senior White House officials, including head of the Substance Abuse and Mental Health Services Administration (SAMHSA) Elinor McCance-Katz and coronavirus task force member Matthew Pottinger, have resigned in response to the riot on Capitol Hill. The chief of the Capitol Police has also resigned and the House and Senate Sergeant-at-Arms have been removed from their posts.

Democratic lawmakers, joined by a number of Republicans, are demanding that the President resign or be removed from office for the role he played in encouraging the mob that stormed the Capitol. Democratic leadership attempted to pressure Vice President Mike Pence and the President’s cabinet to invoke the 25th amendment and remove Trump from office, although Pence has reportedly dismissed the idea as not feasible. The President has given no indication that he will resign.

On Sunday, House Speaker Nancy Pelosi (D-Calif.) announced that the House will bring a vote this week on impeachment in the absence of Vice President Pence invoking the 25th Amendment as well as a separate resolution urging action under the 25th

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amendment. The articles of impeachment currently has more than 200 co-sponsors, and the measure will be introduced in the House of Representatives today. Even if the vote on impeachment occurs this week, top Democrats want to avoid hamstringing the first days of Joe Biden's presidency with a Senate trial, so the House would likely delay sending the article to the Senate, which would postpone the trial. On Friday, Senate Majority Leader Mitch McConnell (R-Ky.) sent a memo to senators outlining the procedure for holding a trial in the Senate. President-elect Biden has avoided weighing in on the matter, saying that it should be the judgement of the Congress.

Democrats Win Control of Senate for First Time in Six Years

Last Tuesday's runoff election in Georgia resulted in Democratic victories for both Raphael Warnock and Jon Ossoff leading to a 50-50 seat split in the Senate. Warnock and Ossoff beat incumbent Republican opponents Kelly Loeffler and David Perdue. Each Georgia county must now certify their elections by January 15. The state faces a January 22 deadline for certification. Once the certification process is complete, Warnock and Ossoff can be sworn in to the Senate. The Georgia election results mean that incoming majority leader Chuck Schumer (D-N.Y.) will preside over the narrowest possible majority in the U.S. Senate under which Vice President Kamala Harris will provide the tie-breaking vote. The chamber has only seen an even divide three times before in history: 1881, 1953, and 2001. The Democratic Senate majority will ease the path to confirmation for members of Biden's cabinet – only 51 votes are required to confirm political appointees. Senate rules will still require most legislation to have a super-majority support of 60 senators to receive a vote on the floor; Democratic centrists including Joe Manchin (D-W.V.) have already come out in opposition to abolishing the filibuster. Democrats, however, have indicated that they plan to use the fast-track budget reconciliation process for certain revenue-related bills which would allow them to pass legislation with a simple majority. The chamber is expected to negotiate a power-sharing plan for the 117th Congress. Committee chairmanship would reside with the party of the Vice President. Sen. Patty Murray (D-Wash.) is in line to lead the Senate Health, Education, Labor, and Pensions (HELP) Committee, while Sen. Ron Wyden (D-Ore.) would take the gavel at the Senate Finance Committee.

More Lawmakers Test Positive for COVID-19

House Appropriations Committee Ranking Member Kay Granger (R-Texas) and House Ways and Means Committee Ranking Member Kevin Brady (R-Texas) have tested positive for COVID-19 after returning to Washington for the start of the 117th Congress. The positive tests follows their receipt of the first dose of the Pfizer-BioNTech vaccine last month. Rep. Jake LaTurner (R-Kansas) also announced that he had tested positive for the virus. At least 53 members of Congress or lawmakers-elect have tested positive for COVID-19 since March, and dozens more have been exposed to the virus or found to have antibodies. According to other lawmakers present, about half of the 400 lawmakers and staff who were moved from the House chamber to a different secure location during the certification of the presidential election results refused to wear masks. The Capitol's attending physician confirmed over the weekend that lawmakers may have been exposed to COVID-19 while in protective isolation. The Food and Drug Administration (FDA) also warned last week that the tests being used to screen members of Congress and their staff for COVID-19 poses a risk of false results, particularly false negative results.

Wenstrup, Harris to Lead Doc Caucus

Reps. Brad Wenstrup (R-Ohio) and Andy Harris (R-Md.) have been selected to lead the House GOP Doctors Caucus during the 117th Congress. The two lawmakers will succeed Rep. Phil Roe (R-Tenn.), who retired from Congress this year. Dr. Wenstrup is a Doctor of Podiatric Medicine, and Dr. Harris is an anesthesiologist.

Biden to Release All Available Vaccine Doses

President-elect Joe Biden announced plans to release nearly all available vaccine doses upon his inauguration. Because both COVID-19 vaccines that have received an emergency use authorization (EUA) require two doses, the current administration has been holding approximately half of its supply in reserve to ensure that those who have received their first dose are able to complete the two-shot sequence. But vaccine distribution and administration has faced missteps nationwide with vaccination rates varying widely across states. Only 5.9 million people have received their first dose so far, out of the 21.4 million doses that have been shipped out by the federal government. The Biden administration will retain Moncef Slaoui, chief scientific adviser to Operation Warp Speed (OWS), as a temporary consultant for a period of four to six weeks to ensure continuity of work on vaccine rollout. OWS's chief operating officer Gen. Gustavo Perna will also continue in his role controlling the logistics of vaccine distribution.

Woodcock to Serve as Advisor to FDA Commissioner

Former Director of the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) Janet Woodcock, M.D. is now the principal medical advisor to FDA Commissioner Stephen Hahn. Woodcock had stepped aside from her role at CDER earlier this year to join Operation Warp Speed (OWS). She will retain her role at OWS and recuse herself from decision-making on COVID-19 therapeutics. Patrizia Cavazzoni, M.D. will continue as Acting Director of CDER.

PHE Declaration Extended

As a result of the continued COVID-19 pandemic, U.S. Department of Health and Human Services (HHS) Secretary Alex Azar renewed the public health emergency (PHE) declaration effective January 21, 2021. The renewal lasts for the duration of the emergency or 90 days, and may be extended again by the Secretary. The nationwide PHE was first declared on January 27, 2020.

SBA/IRS Release Regulations and Guidance Related to the PPP

The *Economic Aid Act* enacted at the end of 2020 as part of the *Consolidated Appropriations Act, 2021* established "Second Draw" Paycheck Protection Program (PPP) loans for certain eligible borrowers and made other changes to the underlying program. On Wednesday January 6, 2021, the Small Business Administration (SBA) and the Department of Treasury issued final rules and guidance implementing the new law (links below). Per a recent [announcement](#), these loans will be made available starting this week.

Despite controversy over this issue last year, the new law and subsequent implementing documents establish that deductions are allowed for otherwise deductible expenses paid with the proceeds of a PPP loan that is forgiven, and that the tax basis and other attributes of the borrower's assets will not be reduced as a result of the loan forgiveness. That particular provision is effective retroactively, as of the date of enactment of the *CARES Act*. The provision provides similar treatment for Second Draw PPP loans, effective for tax years ending after the date of enactment of the provision.

The PPP program is extended through March 31, 2021, after which time loans will be unavailable. As with the first round, the loans will be made on a first come, first serve basis. Note that the PPP is also open again to first-time eligible borrowers (including newly eligible borrowers) in addition to second draw applicants. The new law allows for certain 501(c)(6) organizations to receive PPP loans. Specifically, 501(c)(6) entities are eligible, provided that not more than 15% of receipts come from lobbying activities; lobbying activities are not more than 15% of total activities; the cost of lobbying did not exceed \$1 million during most recent tax year ending before February 15, 2020; and the entity had less than 300 employees. With some exceptions as outlined herein, the mechanics of first and second loans are identical.

To be eligible for a PPP second draw loan, an employer must have used, or will use, the full amount of the initial PPP loan, have no more than 300 employees (500 if more than one location), and demonstrate at least a 25% reduction in gross

receipts as compared to the same quarter in 2019 (with caveats for new businesses). Any forgiveness amount of a First Draw PPP Loan that a borrower received in calendar year 2020 is excluded from a borrower's gross receipts. A borrower can provide annual tax return forms to substantiate its revenue reduction. The maximum loan amount (except for certain entities in the hospitality industry) is the lesser of: \$2 million or 2.5 times the average monthly payroll during 2019 or during one-year period before the loan date, whichever the borrower chooses.

For Second Draw PPP Loans, the number of employees per physical location is limited to 300 rather than 500 for most borrowers. With some exceptions, the same affiliation rules apply. Businesses that are part of a single corporate group shall in no event receive more than \$4 million of Second Draw PPP Loans in the aggregate.

If your First Draw PPP loan is under review by SBA or information in SBA's possession indicates that the borrower may have been ineligible for the First Draw PPP Loan, the lender will receive notification from SBA when the lender submits an application for a guaranty of a Second Draw PPP Loan and will not receive an SBA loan number until the issue related to your First Draw PPP Loan is resolved.

The applicant must submit to the lender SBA Form 2483-SD (Paycheck Protection Program Second Draw Borrower Application Form, which is forthcoming) or the lender's equivalent form including the required certifications. Documentation requirements are described in the Interim Final Rules (IFRs).

Wednesday's IFRs and guidance documents can be accessed via the following links:

- Interim Final Rule: [Paycheck Protection Program \(PPP\) as Amended by the Economic Aid Act](#) (01/06/2021)
- Interim Final Rule: [Paycheck Protection Program \(PPP\) Second Draw Loans](#) (01/06/2021)
- IRS guidance on [deductibility](#) (01/06/2021)

HHS Finalizes Regulatory Review Rule

The U.S. Department of Health and Human Services (HHS) has finalized its Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule which requires an assessment of HHS regulations every 10 years to determine whether they are subject to review under the Regulatory Flexibility Act (RFA), which requires regular review of significant regulations. If a given regulation is subject to the RFA, the Department must review the regulation every ten years to determine whether the regulation is still needed and whether it is having the appropriate impacts. Regulations will expire if the Department does not assess and, if required, review them in a timely manner.

TN Medicaid Block Grant Waiver Approved

The Trump administration has approved Tennessee's request for a Medicaid block grant, the nation's first such overhaul of the safety-net health program. Medicaid has historically been supported by open-ended financing through which states receive a set percentage of federal funding for beneficiaries' care. Under the block grant model, Tennessee will instead receive fixed payments that increase with program enrollment and inflation. Supporters of the change assert that block grants will help control program spending and give states more flexibility to improve Medicaid. The plan, which was approved by the Centers for Medicare and Medicaid Services (CMS) under Medicaid waiver authority, is expected to face legal challenges from stakeholders who argue that the change would result in cuts to health care coverage for the state's most vulnerable populations. The incoming Biden administration could also choose to roll back the change. CMS, however, is moving to make it more difficult for the next administration to overturn Medicaid waivers, asking states to sign on to an agreement that would provide for a nine-month process if the agency would decide to terminate, amend, or withdraw a Medicaid waiver in the future. While CMS is currently allowed to end experiments that do not meet the goals of the Medicaid program, waivers already typically include language allowing states to request a hearing to challenge CMS's decision to change or withdraw a waiver.

Hart Health Strategies COVID-19 Resources

Hart Health Strategies Inc. prepared a new COVID-19 resource document on the topic of [Vaccines](#) and continues to update the following resources related to the coronavirus pandemic. Please remember to clear your cache to ensure you download the most recent version of the 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](#)
- [Vaccines](#)

Upcoming Congressional Committee Activity

Senate Armed Services Committee hearing to examine the expected nomination of Lloyd J. Austin III, to be Secretary of Defense; 3:00 p.m., G50 Dirksen Bldg.; January 19

Senate Veterans' Affairs Committee hearing to examine the expected nomination of Denis R. McDonough, to be Secretary of Veterans Affairs; 3:00 p.m., 106 Dirksen Bldg.; January 27

Recently Introduced Health Legislation

H.R.31 — To amend title XXVII of the Public Health Service Act to provide for a definition of short-term limited duration insurance, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.32 — To amend the Public Health Service Act to provide for cooperative governing of individual health insurance coverage; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.33 — To abolish the Agency for Toxic Substances and Disease Registry, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.53 — To amend the Internal Revenue Code of 1986 to allow for tax-advantaged distributions from health savings accounts during family or medical leave, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Ways and Means

H.R.56 — To amend the Orphan Drug Act with respect to the definition of medical food, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Armed Services; Energy and Commerce; Ways and Means

H.R.64 — To amend the Internal Revenue Code of 1986 to provide an exemption to the individual mandate to maintain health coverage for individuals residing in counties with fewer than 2 health insurance issuers offering plans on an Exchange; to require Members of Congress and congressional staff to abide by the Patient Protection and Affordable Care Act with respect to health insurance coverage; and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Oversight and Reform; House Administration; Energy and Commerce; Ways and Means

H.R.66 — To amend title XXI of the Social Security Act to permanently extend the Children's Health Insurance Program, and for other purposes; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Energy and Commerce

H.R.67 — To direct the Secretary of Veterans Affairs to conduct an independent review of the deaths of certain veterans by suicide, and for other purposes; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Veterans' Affairs

H.R.70 — To support the advanced manufacturing technologies program of the Food and Drug Administration, to establish National Centers of Excellence in Advanced Pharmaceutical Manufacturing, and for other purposes; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Energy and Commerce

H.R.79 — To authorize funding for the creation and implementation of infant mortality pilot programs in standard metropolitan statistical areas with high rates of infant mortality, and for other purposes; Sponsor: Rep. Cohen, Steve [D-TN-9]; Committees: House - Energy and Commerce

H.R.107 — To provide funds to the Centers for Medicare & Medicaid Services to provide grants to entities to establish lung cancer screening registries approved by the Centers for Medicare & Medicaid Services for submission of certain data required for reimbursement under the Medicare program for certain screening services, and for other purposes; Sponsor: Rep. Higgins, Brian [D-NY-26]; Committees: House - Energy and Commerce; Ways and Means

H.R.109 — To amend title 38, United States Code, to establish an advisory committee on the implementation by the Department of Veterans Affairs of an electronic health record; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Veterans' Affairs

H.R.112 — To make certain improvements in the provision of medical care by the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Veterans' Affairs

H.R.113 — To provide for research and education with respect to triple-negative breast cancer, and for other purposes; Sponsor: Rep. Jackson Lee, Sheila [D-TX-18]; Committees: House - Energy and Commerce

H.R.120 — To enhance public health and safety by improving the effectiveness and efficiency of the Federal prison system for incarcerated pregnant women and mothers by establishing a pilot program of critical-stage, developmental nurseries in Federal prisons for children born to inmates, with risk and needs assessments, and risk and recidivism reduction; Sponsor: Rep. Jackson Lee, Sheila [D-TX-18]; Committees: House - Judiciary

H.R.124 — To amend title XIX of the Social Security Act to provide incentives for education on the risk of renal medullary carcinoma in individuals who are receiving medical assistance under such title and who have Sickle Cell Disease; Sponsor: Rep. Green, Al [D-TX-9]; Committees: House - Energy and Commerce

H.R.137 — To authorize funding to increase access to mental health care treatment to reduce gun violence; Sponsor: Rep. Jackson Lee, Sheila [D-TX-18]; Committees: House - Energy and Commerce; Judiciary

H.R.142 — To amend title XVIII of the Social Security Act to require hospitals reimbursed under the Medicare system to establish and implement security procedures to reduce the likelihood of infant patient abduction and baby switching, including procedures for identifying all infant patients in the hospital in a manner that ensures that it will be evident if infants are missing from the hospital; Sponsor: Rep. Jackson Lee, Sheila [D-TX-18]; Committees: House - Ways and Means; Judiciary; Energy and Commerce

H.R.145 — To amend the Patient Protection and Affordable Care Act to ensure that preexisting condition exclusions with respect to enrollment in health insurance coverage and group health plans continue to be prohibited; Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House - Energy and Commerce

H.R.151 — To address the public health risks posed by wildlife markets, and for other purposes; Sponsor: Rep. Quigley, Mike [D-IL-5]; Committees: House - Foreign Affairs; Energy and Commerce; Judiciary; Ways and Means; Financial Services; Natural Resources

H.R.153 — To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes; Sponsor: Rep. Rush, Bobby L. [D-IL-1]; Committees: House - Energy and Commerce; Judiciary

H.R.171 — To require the Secretary of Commerce to establish a task force to identify vulnerabilities in supply chains for United States entities, and for other purposes; Sponsor: Rep. Stevens, Haley M. [D-MI-11]; Committees: House - Energy and Commerce

H.R.173 — To amend the Public Health Service Act to authorize the Secretary to make grants and enter into cooperative agreements with entities to expand and support activities with respect to the prevention and treatment of a covered condition, and for other purposes; Sponsor: Rep. Velazquez, Nydia M. [D-NY-7]; Committees: House - Energy and Commerce

H.R.182 — To improve the provision of health care by the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Wittman, Robert J. [R-VA-1]; Committees: House - Veterans' Affairs

H.R.189 — To amend the Public Health Service Act to provide that the authority of the Director of the National Institute on Minority Health and Health Disparities to make certain research endowments applies with respect to both current and former centers of excellence, and for other purposes; Sponsor: Rep. Barragan, Nanette Diaz [D-CA-44]; Committees: House - Energy and Commerce

H.Res.20 — Expressing support for the goals and ideals of “National Hydrocephalus Awareness Month”; Sponsor: Rep. Doggett, Lloyd [D-TX-35]; Committees: House - Energy and Commerce

H.R.217 — To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to enforce the licensure requirement for medical providers of the Department of Veterans Affairs; Sponsor: Rep. Cloud, Michael [R-TX-27]; Committees: House - Veterans' Affairs

H.R.223 — To direct the Secretary of Health and Human Services to reimburse qualified health care providers for the costs of purchasing, leasing, installing, and operating qualified equipment for cold storage of COVID-19 vaccines; Sponsor: Rep. Espaillat, Adriano [D-NY-13]; Committees: House - Energy and Commerce