



### Federal Issues

#### Legislative

#### House Passes \$1.9 Trillion COVID-19 Relief Package

The U.S. House [passed](#) a sweeping \$1.9 trillion coronavirus aid package by a 219-212 vote early Saturday morning. The vote cut largely along party lines with all Republicans and two Democrats opposed.

**Why this matters:** The move advances President Biden's top legislative priority, which, among other things, will provide billions in funding for COVID-19 testing and vaccines, support for state and local governments, and assistance for individuals and businesses to maintain health coverage.

**Next steps:** The Senate will take up the measure with the goal of getting the package to the president's desk before current unemployment benefits expire in mid-March. Because of limitations in Senate rules related to the budget reconciliation process, some pieces of the House-passed measure will have to be stripped. This includes an increase in the minimum wage to \$15/hour, which the Senate parliamentarian ruled last week could not be included.

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## House Panel Holds Hearing with COVID-19 Vaccine Manufacturers

On February 22, the House Energy and Commerce Subcommittee on Oversight and Investigations held a [hearing](#) titled “Pathway to Protection: Expanding Availability of COVID-19 Vaccines.” The hearing examined drug manufacturers’ ongoing efforts to develop and expand production of COVID-19 vaccines in the United States.

Subcommittee Chair Diana DeGette (D-CO) described the development of multiple safe and effective COVID-19 vaccines as “nothing short of a scientific marvel,” but stated that her primary concern now is the lack of supply of vaccine doses, pointing out that some manufacturers have not met dosage quantities they promised last year. Ranking Member of the Subcommittee Morgan Griffith (R-VA) similarly recognized the importance of a robust vaccine supply but noted that increasing vaccine manufacturing capacity is a complex process that takes time.

**Testimony highlights:** Executives from Pfizer and Moderna, the two companies with approved vaccines, provided updates on the status of vaccine shipments.

- Pfizer group president John Young anticipates that all 300 million contracted doses will be made available for shipment to the points of use by the end of July. He also said Pfizer believes the vaccine should provide protection against the new U.K. and South African variants, citing laboratory data and “real-world evidence” from the U.K. and Israel.
- Moderna president Stephen Hoge, M.D. said the company is on track to deliver the first 100 million doses of the vaccine by the end of March. Moderna has moved up its timeline for delivery of the second and third sets of 100 million doses to the end of May and July, respectively.

Lawmakers also heard from executives at Johnson & Johnson, AstraZeneca and Novavax, Inc., companies with COVID-19 vaccines in development.

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## Biden Health Nominees Testify Before Senate Panels

On February 22, the Senate Health, Education, Labor and Pensions (HELP) Committee [considered](#) the nomination of HHS Secretary-designate Xavier Becerra, followed by a Senate Finance Committee confirmation [hearing](#) on Wednesday.

During the hearings, Becerra touted his experience as Attorney General of California, including his defense of the ACA before the U.S. Supreme Court, and as a 12-term Member of Congress. While he faced some more challenging questions, the two sessions were generally collegial and offer insights into President Joe Biden's health policies priorities some of which are highlighted below.

- **COVID-19:** Most of the questions were focused on specific proposals within the COVID-19 relief package currently moving through the reconciliation process. Policies including expanding Medicaid coverage to postpartum mothers received support from the nominee along with other issues like expanded COBRA subsidies.
- **Prescription Drugs:** Becerra indicated the administration will potentially modify a November 2020 final rule that would transform the Medicare Part D drug rebate system.
- **Telehealth:** Becerra indicated that he would continue to advocate and support policies that expand telehealth services. He acknowledged that COVID-19 has dramatically changed how people receive care and prefer to receive care and it is important to talk with the communities who have benefitted from telehealth.
- **Health Coverage & Medicare:** Expanding health coverage was a major component of President Biden's campaign run and will become a cornerstone of his health care agenda moving forward, including Medicaid expansion incentives and increased affordability for ACA plans. Becerra did state support for a public option. Most specifically, he stated the Biden administration would expect to use general government resources to pay for any efforts to expand access to coverage by letting some people "buy into Medicare." Becerra committed to Medicare Advantage, the private Medicare option, stating, "We see that Medicare Advantage gives us an easier chance to create what are called wraparound programs, to reach out to more people with more services." He did opine, however, that the program was too generous and there should be better parity between Original Medicare and Medicare Advantage.
- **Mental Health:** It is evident that HHS and Congress will prioritize and work diligently to expand coverage of mental health services after the effect of COVID-19. This includes policies that build on SAMHSA guidelines as well as policies in the reconciliation package to encourage state Medicaid programs to provide community-based mobile crisis interventions rather than responding with police force. Becerra also emphasized enforcement of federal mental health parity standards for health insurance and employer-sponsored coverage in particular.

Additionally, the HELP Committee on Thursday [considered](#) nominations for Dr. Vivek Murthy and Dr. Rachel Levine for the positions of Surgeon General and Assistant Secretary for Health at HHS, respectively. Both nominees spoke at length about their prior experience as health care providers, including their work to address opioid misuse and other substance use disorders, and committed to doing their part to end the COVID-19 pandemic.

**Next steps:** Expect committee votes soon, followed by confirmation by the full Senate. Based on the hearings, it does not appear any of the nominees' confirmations, which require the votes of a simple majority of senators, are in jeopardy.

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## Federal Issues

### Regulatory

#### **New Guidance Clarifies COVID-19 Health Coverage and Testing Requirements for Commercial Plans**

The Department of Labor (DOL), Health and Human Services (HHS), and the Treasury (the Tri-Agencies) [released](#) several [frequently asked questions \(FAQs\)](#) regarding implementation of the Families First Coronavirus Response Act, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) and other COVID-19 related issues. The FAQs address a number of topics including: COVID-19 testing services that must be covered, rapid coverage of COVID-19 preventive services (vaccines), notice requirements regarding changes to benefits, excepted benefits, and the provider relief fund.

**Why this matters:** The FAQs reiterate that health plans:

- Must provide coverage of COVID-19 diagnostic testing of asymptomatic individuals when the purpose of the testing is for individualized diagnosis or treatment of COVID-19, including both point of care testing and testing provided at state or locally administered locations;
- Are not required to cover testing such as for public health surveillance or employment purposes; and
- Are prohibited from using medical screening criteria to deny (or impose cost sharing on) a claim for COVID-19 diagnostic testing for an asymptomatic person who has no known or suspected exposure to COVID-19.

The guidance also instructs providers on how to get reimbursed for diagnostic testing or administering COVID-19 vaccines to people without health coverage.

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#### **DOL Clarifies Expiration of COBRA, ERISA Relief**

The Department of Labor's Employee Benefits Security Administration (EBSA) [issued Disaster Relief Notice 2021-01](#) to clarify outstanding questions regarding a [prior notice](#) providing relief for certain actions required to be taken under ERISA. This included an extension for former employees to elect COBRA coverage past the typical 60-day election period, COBRA premium payments, notification of disability, benefit claims filing, internal appeals, and external review. The relief became effective March 1, 2020, but the prior notice was less than clear regarding the expiration of such election period.

**Why this matters:** The notice clarifies individuals can elect COBRA coverage the earlier of:

- One year from the date they were first eligible for relief, or
- 60 days after the announced end of the COVID-19 National Emergency.

This means the COBRA election period for workers who were eligible for relief on March 1, 2020, expired on February 28. As noted, Congress is considering passing COBRA subsidies so former employees can afford often-expensive COBRA coverage. Such subsidies presumably will not be available to a worker who did not elect COBRA coverage during their election period.

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## Justice Department Asks Supreme Court to Vacate Medicaid Work Requirements Case

The Justice Department took action this week, following up on CMS's actions to rescind Trump-era policy guidance and to notify states that it will review (and likely revoke) federal approval of Section 1115 waivers permitting states to tie Medicaid eligibility with completion of work or community engagement activity reporting.

Specifically, the Justice Department filed a motion asking the U.S. Supreme Court to remove cases involving the Arkansas and New Hampshire waiver approvals from its docket and send them back to the agency. The move is designed to avoid a decision on the merits in the cases this term, though the cases may end up at the Court if the states appeal any revocations. Oral arguments in the cases are scheduled for the end of March.

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## Coronavirus Updates

- President Biden signed an [Executive Order](#) to help create more resilient and secure supply chains for critical and essential goods. First, the order directs an immediate 100-day review across federal agencies to address vulnerabilities in the supply chains of pharmaceuticals and active pharmaceutical ingredients (APIs), critical minerals, semiconductors, and large capacity batteries. Second, the order calls for a more in-depth one-year review of a broader set of U.S. supply chains, including the public health and biological industrial bases.
- During a weekly call with Governors, the Administration announced [the fifth consecutive week of supply increases](#) with states now receiving 14.5 million doses this week, up from 8.6 million doses per week when the President took office.
- Pfizer and BioNTech [announced](#) the start of a study examining whether a third dose of their COVID-19 vaccine provides additional protection against the virus and its variants.
- The White House extended the [National Emergency for COVID-19](#), originally declared on March 13, 2020.
- Moderna [announced](#) it finalized a modified vaccine that targets a COVID-19 variant first found in South Africa for human clinical trials. The company is also researching if a third dose of its authorized COVID-19 vaccine provides additional protection to individuals who already are vaccinated.
- The Food and Drug Administration's (FDA) on Saturday issued an emergency use authorization for Johnson & Johnson's one-shot coronavirus vaccine.
- FDA [announced](#) that Pfizer's COVID-19 vaccine can be transported and stored at temperatures commonly found in standard freezers, rather than the ultracold temperatures originally required.
- FDA released new [guidance](#) on emergency use authorizations for COVID-19 vaccines, specifically targeted to review and approval of modifications to COVID-19 vaccines to address variant strains of the virus.

- FDA [released guidance](#) outlining how emerging variants will impact the agency's reviews of COVID-19 tests.

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## State Issues

### Pennsylvania

#### Legislative

#### **State Legislative Hearings Feature COVID-19 Response, “Right-to-refuse” Legislation**

The Pennsylvania House of Representatives wrapped up its second week of budget hearings with an in-depth discussion with leaders on February 25 from the Department of Health (DOH), which was represented by Acting Secretary of the Department of Health, Alison Beam, Executive Deputy Secretary Keara Klinepeter, Budget Director Lori Stubbs, Acting Physician General Dr. Wendy Braund, and Director of Operational Excellence Brian Lentes.

The Governor’s proposed Fiscal Year 2021-2022 Budget seeks to spend \$37.83 billion in State funding, which is an increase of \$3.78 billion (11.1%) from the current 2020-2021 Budget. Within the Governor’s Budget, there is a General Fund allocation of \$928,298,000 to the Department of Health with a total appropriation, which includes all State and Federal transfers, of \$1,011,362,000.

During the marathon budget hearing, legislators used the time to re-examine the actions taken by the Wolf Administration during the COVID-19 pandemic, the actions taken for vaccine roll-out, along with the Department of Health’s COVID-19 guidance that led to patients being remitted to nursing homes when they tested positive.

Acting Secretary Beam provided insight about Governor Wolf’s 2021–2022 state budget proposal for the Department of Health; however, much of the hearing’s questioning focused on the commonwealth’s COVID-19 vaccine rollout and overall COVID-19 response. Among the key COVID-19 issues discussed:

- Ongoing DOH efforts to improve communications about vaccine allocations;
- COVID-19 vaccine distribution at long-term care facilities;
- Lack of transparency with how DOH makes allocation decisions to its vaccine provider network; and
- Lack of transparency in who DOH is consulting to make all COVID-related decisions.

Acting Secretary Beam was also asked to weigh in on proposals to create a statewide registry for vaccination appointments. She noted that the current logistics between the federal government, providers, and the Commonwealth do not allow for a centralized system, but that they are not closing the door on the idea.

Legislators also asked Acting Secretary Beam when Pennsylvania could expect to move to Phase 1B, citing the need to open schools and demands by unions to vaccinate teachers. She noted that the DOH wants to ensure it has an adequate vaccine supply before moving to the next priority phases of the rollout.

Additionally, on Thursday, February 25, members of the hospital and business communities appeared before the state House Labor & Industry Committee for a hearing to discuss proposed “right-to-refuse” legislation. Under [House Bill 262](#), sponsored by Russ Diamond (R-Lebanon), employees—including those

who work in hospitals—could refuse vaccines and medical screenings. The measure also would create new pathways for litigation for employees who refuse those tests and screenings.

Neil Fishman, MD, Chief Medical Officer for the Hospital of the University of Pennsylvania, provided testimony on behalf of HAP and the hospital community. Dr. Fishman said that, especially during a pandemic, hospitals need the flexibility to put in place policies that help protect patients and the hospital workforce from the spread of infectious diseases.

The hospital industry opposes House Bill 262.

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## State Issues

### Pennsylvania

Regulatory

#### **Insurance Department Discontinues Renewal and Continuing Education Extensions For Brokers**

In [Notice 2021-02](#), published in the *PA Bulletin* on Saturday, the Insurance Department advised all licensees of the Insurance Department on the impending discontinuation of licensing renewal and continuing education extensions in this Commonwealth. This most recent notice serves as a modification to Notice 2020-06 issued last year.

**Background:** On March 16, 2020, in light of the spread of the novel coronavirus (COVID-19) in the Commonwealth, the Department issued notice 2020-06, which temporarily extended the licensing renewal and continuing education deadlines for licensees impacted by extenuating circumstances related to COVID-19.

Although telework continues to be strongly encouraged and licensees have adapted to remote operations, business interruptions, as a result of COVID-19 that made it difficult to complete requirements in a timely manner have been mitigated.

**Why this matters:** As a result, effective May 14, 2021, the Department will suspend the renewal and continuing education extensions and require all licensees who were granted, benefitted from, or affected by temporary continuation of license renewal deadlines, including continuing education requirements and licensing fees, to come into compliance.

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#### **DOH Announces Updated Quarantine Recommendations for Vaccinated Individuals**

Last week, the state Department of Health (DOH) [publicly announced](#) that it has amended its quarantine guidance for people who are fully vaccinated against COVID-19. The update—released through the Health Alert Network (HAN)—aligns with new [quarantine recommendations](#) from the Centers for Disease Control and Prevention (CDC).

Under the updated [HAN 551](#), vaccinated people do not have to quarantine if exposed to a suspected or confirmed case of COVID-19, provided they meet the following criteria:

- They are fully vaccinated with a two-dose regimen at least two weeks apart or two weeks after receipt of a single-dose vaccine;
- They are within three months after receiving the last dose of the vaccine; and
- They have no COVID-19 symptoms after exposure to a person who is suspected or confirmed to be positive for COVID-19.

These recommendations only can be used to alleviate staffing shortages when a health care facility is in a crisis mode and used for staff who have higher risk exposures. The changes cannot be used for patients or residents of a health care facility.

Persons who develop COVID-19 symptoms during this three-month period need to isolate and be tested for SARS-CoV-2. For additional information, please see [HAN 551](#) or [CDC](#) recommendations.

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## **DOH Issues Updated Guidance for Hospital COVID-19 Response, Acute Care at Home**

The Pennsylvania Department of Health (DOH) has issued updated [guidance](#) for the hospital community's response to COVID-19. This update is in response to the continuous questions and requests for additional guidance.

The update includes a new section—"Acute Care at Home"—which was created in response to inquiries DOH received about the Centers for Medicare & Medicaid Services (CMS) Acute Hospital Care at Home (AHCH) program. Hospitals that have been approved by CMS for the AHCH program may provide acute care inpatient services at the patient's residency per the requirements.

Prior to offering services, a hospital must notify DOH's Division of Acute and Ambulatory Care (DAAC) and DAAC Field Office Health Facility Quality Examiner of CMS' approval for the acute hospital care at home services via [email](#). Once the information is submitted to DOH, hospitals may start providing services. **Approval from DOH is not required to begin services.**

A patient's residency is considered an extension of the hospital, and inpatient care provided at the residency must be consistent with existing hospital policies and procedures for inpatient admission. Additionally, DOH recommends an infection prevention and control (IPC) consultation to educate the patient and household about implementing and maintaining IPC practices consistent with [PA-HAN-524](#).

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## **State Issues**

### **West Virginia**

Legislative

### **Health Care Continues to Dominate Legislative Session**

Issues involving health care and health insurance remain predominant in the work of both houses and their respective Health and Insurance committees.

### **Pharmacy Benefit Managers**

**HB 2263**, which proposes a number of very significant changes and mandates affecting the operation of pharmaceutical benefit managers and their interaction with health plans, has already cleared the House of Delegates and is pending before the Senate Health Committee. The legislation would require health plans to pass through the full value of pharmaceutical manufacturer rebates to members at the point of sale, pay a statutorily defined dispensing fee to pharmacies and hospital pharmacies and force any pharmacy to be included in a plan network, along with other provisions governing the practices of PBMs in their relationships with pharmacies.

### **Telehealth Payment Parity**

**SB 1**, which proposes a mandate for payment parity on health plans for certain types of telehealth encounters in comparison with in-person payments, was considered in the House Health Committee last week and the Senate's version of the bill was rejected in favor of Governor Justice's more narrow approach to dealing with telehealth issues by permitting out of state licensed providers to serve in-state. However, efforts to modify the form of SB 1 in the House relative to the mandated payment parity and other provisions will continue.

### **Prior Authorization**

The Senate Health Committee endorsed **SB 39**, changing prior authorization standards for conducting cancer staging testing. The three physicians on the Health Committee voiced their concerns over the operations of the prior authorization reforms that were previously enacted by the legislature in connection with cancer testing and the bill was endorsed on for consideration by the Senate Finance Committee, where it will be more deeply reviewed because of its fiscal impacts on PEIA and Medicaid.

### **Alternative Opioid Treatment**

The House Banking & Insurance Committee endorsed **HB 2634**, which proposes to expand the current coverage mandate for alternative opioid treatment to clarify that 20 treatments of multiple providers is required to be covered under state law. In the current form of the bill, private plans, PEIA and Medicaid would be mandated to cover 20 visits of physical or occupational therapy or chiropractic as an alternative to opioids being prescribed. Additionally, since HB 2634 would increase the costs of PEIA and Medicaid, it seems likely that the bill could also be referred to the Finance Committee for additional analysis.

### **Price Transparency**

**HB 2005**, which has already passed the House and is pending with the Senate Health Committee, proposes a variety of significant measures affecting hospitals and health plans, including price transparency, resolution of surprise billing disputes and health plan network transparency. It has not been scheduled for consideration in committee at this point.

### **Insulin Copay Cap**

**HB 2708** was introduced in the House of Delegates. This bill seeks to dramatically expand the 2020 mandated benefit regarding the controlled cost of insulin prescriptions at \$100 monthly to become in line with recent legislation enacted by Connecticut to limit the monthly costs of all forms of diabetic medication, treatment, equipment and supplies to \$25. This bill would affect private plans, PEIA and Medicaid at a substantial cost.

### **Tax Reform**

Governor Jim Justice intensified his efforts to build support for phasing out the state's personal income tax. Governor Justice held two virtual town hall meetings to take questions from the public on his general proposal, which includes new or increased taxes as a way to make up for the estimated \$1.1 billion in

revenue the governor would need to replace to accomplish his goal of achieving a 50% reduction in the tax beginning in 2022. The governor envisions a three year phase out of the tax, which would ultimately reduce revenues by more than \$2.1 billion, or 43% of the state's current general revenue collections.

**The broad outline of the governor's plan is as follows:**

- First, he is proposing an increase in the consumer sales tax from its current 6% level to as much as 7.9%, making the overall sales tax as much as 8.9% since most state municipalities have a local 1% sales tax as well.
- He is seeking what is rumored to be more than \$100 million from the coal, oil, and natural gas sectors by creating a new tiered severance tax.
- A proposed elimination of sales tax exemptions on a number of professional services (legal, accounting, engineering, etc.) and other areas of the economy where sales taxation has not been applied (advertising, telephony services).
- The governor also envisions an unspecified "luxury" sales tax on certain purchases over \$5,000, as well as major increases on taxes applied to cigarettes, tobacco products, vaping products, sugary soda drinks, beer, wine, and liquor.

The governor also shared that his plan would not include an extension of the sales tax to food products, medical or healthcare related services or major budget cuts targeting higher education or Medicaid. The governor also promised to create a mechanism in his plan to ease the burden of sales tax increases on low-income residents who would not derive much benefit from a reduction or elimination of the income tax.

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The Pennsylvania General Assembly returns to session March 15.

The Delaware Legislature returns to session March 9.

The West Virginia session runs from February 10 through April 10, 2021.

Congress

The U.S. House committee work only and the U.S. Senate is in session March 1-5.

**Interested in reviewing a copy of a bill(s)? Access the following web sites:**

Delaware State Legislation: <http://legis.delaware.gov/>.

Pennsylvania Legislation: [www.legis.state.pa.us](http://www.legis.state.pa.us).

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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