



## Federal Issues

### Legislative

#### House Committees Advance Budget Reconciliation Proposals

Last week, several House committees advanced their policy proposals for the upcoming budget reconciliation package aimed at providing additional COVID-19 relief. Key elements of the packages are largely consistent with many priorities suggested by America's Health Insurance Plans, the American Hospital Association, and the Blue Cross Blue Shield Association. Health related highlights in the bills include:

- **COVID Testing/Vaccines:** The [House Energy and Commerce Committee](#) proposal includes additional funding for COVID-19 testing, treatment and vaccine distribution, monitoring, and awareness.
- **COBRA Assistance:** Both the [Education and Labor](#) and [Ways and Means](#) Committees passed legislation to provide an 85% COBRA premium reduction available through September 30, 2021, provides for an extended election period, and provides a payroll tax credit to allow employers and plans to be reimbursed for the full amount of COBRA premiums not paid by workers, among other provisions.

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- **ACA Enhancement:** The bill advanced by the Ways and Means Committee includes temporary premium tax credit modifications for those getting coverage through the Exchanges:
  - For 2021 and 2022 - expands eligibility for premium tax credit by removal of the existing 400% FPL subsidy cliff and capping required contribution at 8.5% of income
  - For 2021, calculates advanced premium tax credits (APTC) as if the taxpayer's income was no higher than 133% of the federal poverty line (FPL) for individuals receiving unemployment compensation for one week during 2021
  - APTC paid in excess for tax year 2020 is not required to be repaid when reconciling tax credits during tax filing
- **Medicaid/CHIP Changes:** The Energy and Commerce package also makes several changes to the Medicaid and CHIP programs:
  - Requires Medicaid and CHIP coverage of COVID-19 vaccines and treatment at no cost with vaccines matched at 100% FMAP through one year after the end of the Public Health Emergency
  - Incentivizes states that haven't expanded Medicaid to do so by enhancing their FMAP by five percentage points for two years
  - Allows states to expand Medicaid and CHIP eligibility to women for up to 12 months postpartum for five years
  - Expands Medicaid eligibility to inmates 30 days before they are released from prison for five years
  - Eliminates the cap on Medicaid drug rebates, starting in calendar year 2023
  - Provides a temporary FMAP increase of 7.35 percentage points for states to make improvements to Medicaid home- and community-based services (HCBS) for one year

**What comes next:** The House Budget Committee will package the Committees' responses together and vote to report the collective bill to the House floor.

**Hospital advocacy:** The American Hospital Association (AHA) currently is spearheading hospital advocacy in pursuit of:

- Significant funding for COVID-19 vaccination outreach, planning, administration, and distribution efforts;
- More funding for the Provider Relief Fund;
- Forgiveness for Medicare accelerated payments for hospitals;

- An extension of the moratorium on the Medicare sequester cuts; and
- More federal support for frontline health care workers.

Hospital advocates also are reinforcing the need for Congressional action to provide more support for state health programs, including FMAP, and increased coverage options for those who are uninsured, and emphasize that Congress should not include any provisions that would require new, unrealistic, and burdensome Occupational Safety and Health Administration standards.

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### **Health Care Stakeholders and Employers Call for Universal Coverage**

The Affordable Coverage Coalition, which includes groups representing the nation's doctors, hospitals, employers, and health insurance providers have issued a [call](#) to achieve universal health coverage by expanding financial assistance to consumers, bolstering enrollment and outreach efforts, and taking additional steps to protect those who have lost or are at risk of losing employer-based coverage because of the economic downturn caused by the COVID-19 pandemic.

Outlined in the [Principles for Extending Coverage and Protecting Patients](#), the organizations support the following steps to make health coverage more accessible and affordable:

- Protect Americans who have lost or are at risk of losing employer-provided health coverage from becoming uninsured;
  - Make Affordable Care Act (ACA) premium tax credits and cost-sharing reductions more generous and expand eligibility for them;
  - Establish an insurance affordability fund to support any unexpected high costs for caring for those with serious health conditions or to otherwise lower premiums or cost-sharing for ACA marketplace enrollees;
  - Restore federal funding for outreach and enrollment programs;
  - Automatically enroll and renew individuals eligible for Medicaid and premium-free ACA marketplace plans; and
  - Provide incentives for additional states to expand Medicaid, in order to close the low-income coverage gap.
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### **Congressional Effort Underway to Protect 340B Drug Pricing Program**

A bipartisan coalition of U.S. House members is circulating a [“Dear Colleague” letter](#) to U.S. Department of Health and Human Services (HHS) Secretary nominee Xavier Becerra urging him to take immediate action to restore many covered entities' access to lawful drug discounts under the 340B Drug Pricing Program.

To date, five members of the Pennsylvania delegation have signed on: Brian Fitzpatrick (R, PA-01), Dwight Evans (D, PA-03), Mary Gay Scanlon (D, PA-05), Fred Keller (R, PA-12), and Conor Lamb (D, PA-17).

#### **The Congressional “Dear Colleague” letter urges Becerra to:**

- Take action against manufacturers that are not in compliance with their obligations under the statute
- Require manufacturers to refund covered entities for unlawful overcharges
- Halt manufacturers' attempts to unilaterally overhaul the structure of the 340B program
- Seat the Administrative Dispute Resolution panel to adjudicate disputes within the program

The letter is consistent with two previous bipartisan letters sent last Congress:

- A [September 2020 letter](#) urging HHS to take action and protect covered entities' access to discounts on drugs shipped to contract pharmacies
- A [November 2020 letter](#) urging HHS to halt the imposition of extralegal requirements on covered entities that would undermine their ability to participate in the 340B program

The letter has earned the endorsement of the following organizations: 340B Health, Ryan White Clinics for 340B Access, the National Association of Community Health Centers, American Hospital Association, America's Essential Hospitals, Children's Hospital Association, National Rural Health Association, California Primary Care Association, Association of American Medical Colleges, National Hemophilia Foundation, Hemophilia Federation of America, AIDS United, San Francisco AIDS Foundation, Vivent Health, and APLA Health.

**Why this matters:** The letter is in response to actions by several large drug manufacturers, starting last summer, to withhold discounts to covered entities that utilize contract pharmacies to deliver 340B drugs to their patients. The HHS Office of the General Counsel issued a [December 30 advisory opinion](#) finding the actions unlawful.

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## Federal Issues

Regulatory

### Hospitals Ask the U.S. Supreme Court to Hear Cases about 340B Cuts and Hospital Outpatient Cuts

On February 10, 2021, the American Hospital Association (AHA) and others petitioned the U.S. Supreme Court to reverse lower court decisions in two important cases for patients and providers, arguing that both decisions conflict with Congress' clear intent and defer to the government's inaccurate interpretation of the law.

#### The two cases being appealed to the U.S. Supreme Court are:

- A lawsuit challenging the U.S. Department of Health and Human Services' (HHS) nearly 30% cut to 2018 and 2019 Medicare outpatient prospective payment system (OPPS) drug payments for certain hospitals participating in the 340B Drug Pricing Program. A district court sided with the AHA and found that the payment reductions were unlawful. Last July, two members of the three-judge panel of the U.S. Court of Appeals agreed to overturn that ruling, despite a spirited dissent questioning the majority's deference to the government's position.
- A lawsuit challenging HHS' payment reductions in the 2019 outpatient payment rule for certain hospital outpatient off-campus provider-based departments. A lower court found twice that HHS exceeded its statutory authority when it reduced these payments. Last July, a three-judge appeals panel reversed this decision.

These petitions ask the court to review these cases on the basis of the excessive deference the appeals court gave to the government's inappropriate interpretation of the respective governing statutes. It is known as "Chevron" deference, in reference to the line of cases on which it is based. Such deference appears misplaced in these cases, particularly considering the solid opinions in favor of the hospital field in the district courts which first heard the cases. The two petitions are complementary and persuasive.

**Hospital industry position:** “In an era of skyrocketing drug prices, the 340B program has been critical in helping hospitals expand access to comprehensive health services to vulnerable communities, including lifesaving prescription drugs. Many of the important programs and services that the 340B program allows eligible hospitals to provide would otherwise be unavailable. These cuts have resulted in the continued loss of resources during this pandemic, which comes at the worst possible time for patients and communities,” said AHA President and CEO Rick Pollack.

Joining the AHA in the 340B litigation are the Association of American Medical Colleges (AAMC), America’s Essential Hospitals, and hospital plaintiffs: Northern Light Health in Brewer, Maine; Henry Ford Health System in Detroit, Michigan; and AdventHealth Hendersonville in Hendersonville, North Carolina.

Joining the AHA in the outpatient cuts litigation are the AAMC and hospital plaintiffs: Olympic Medical Center in Port Angeles, Washington; Mercy Health in Muskegon, Michigan; and York Hospital in York, Maine.

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### **U.S. Government Now Defends Affordable Care Act in *CA v. TX***

As expected, the U.S. Department of Justice formally changed its position in the ACA constitutionality case, *California v. Texas*. The DOJ [filed](#) a letter indicating that following the change of Administration the Department has reconsidered its position and determined that:

- The individual mandate provision of the ACA remains constitutional despite Congress reducing the amount of the shared responsibility payment to zero; and
- Should the Supreme Court find the individual mandate provision to be unconstitutional, the provision is severable from the rest of the ACA and therefore no other portion of the law should be struck down.

**Why this matters:** This reverses the Government’s prior position in the case, and now aligns with the positions taken by the California-led group of states and U.S. House of Representatives, both of which had intervened in the case to defend the ACA. The Government has asked that its letter be circulated to each of the Justices for their consideration as they weigh a decision.

**What’s next:** No supplemental briefing was requested, and the change is unlikely to determine the outcome of the case after oral arguments were held in November 2020. Republican-led state attorneys general continue to challenge the ACA’s constitutionality. A decision is expected by July 2021.

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### **CMS Launches Outreach for February 15 ACA Special Enrollment Period**

The Centers for Medicare & Medicaid Services (CMS) [launched](#) outreach efforts through stakeholders and partners to prepare for and build awareness of the special enrollment period (SEP), which begins Monday, February 15 . CMS will begin consumer-facing outreach and education when the SEP opens. In the 36 states using [healthcare.gov](#), the SEP will run from February 15 through May 15 and is open to anyone eligible for Marketplace coverage to newly enroll or switch plans. At least 13 other states and the District of Columbia are offering similar enrollment opportunities.

CMS has committed to a \$50 million budget for its SEP-related communications campaign. Consumer outreach will focus on building awareness of the enrollment opportunity, emphasizing dates, increasing awareness of affordable options for the uninsured, and encouraging people who begin an application to complete enrollment. Target audiences will include the uninsured, people with incomes less than 400% of the federal poverty line (FPL), and demographic groups with traditionally lower access to care. An overview of

CMS' communications plan is posted on a new [website](#), which will be updated with additional materials like resources for education through social media.

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## Coronavirus Updates

- President Biden [announced](#) the launch of the Federally Qualified Health Center program that will provide more vaccines for Community Health Centers beginning next week in an effort to reach some of the nation's most vulnerable populations. The initial phase will include at least one Community Health Center in each state, expanding to 250 centers in the coming weeks. Additionally, the administration will increase the weekly vaccine supply to states, Tribes, and territories to 11 million doses beginning this week.
- Wearing a cloth mask over a medical procedure mask significantly helps reduce exposure to COVID-19, according to [a new CDC study](#). Researchers determined double-masking or wearing tightly fitted medical masks can reduce exposure to infectious aerosols by 95%.
- The Centers for Disease Control and Prevention (CDC) [announced](#) that people who are fully vaccinated no longer need to quarantine after exposure to someone infected with the coronavirus.
- The Food and Drug Administration (FDA) [issued](#) an emergency use authorization for the use of Eli Lilly's two monoclonal antibodies, bamlanivimab and etesevimab, administered together to treat mild to moderate COVID-19. The treatments administered together led to a decreased risk of developing resistant viruses during treatment than with bamlanivimab administered alone. In clinical trials, the two treatments reduced COVID-19-related hospitalization and death for patients with high risk of disease progression.
- President Biden announced that the Department of Health and Human Services (HHS) and Department of Defense (DoD) finalized the [purchase](#) of an additional 100 million doses of COVID-19 vaccines from both Pfizer Inc. and Moderna Inc. These orders placed bring the total vaccine purchased by the U.S. government from these two companies to a total of 600 million doses. President Biden indicated the additional doses will be available in May, which would put the country on track to vaccinate more than 300 million people by the end of July. AHIP and its member plans are committed to supporting the equitable, effective, and efficient distribution and administration of the COVID-19 vaccines.
- At a White House press briefing, Chief Medical Advisor Dr. Anthony Fauci reiterated that the U.K. COVID-19 variant, B.1.1.7, is projected to likely become the dominant coronavirus strain in the U.S. by the end of March.
- South Africa suspended plans to roll out the AstraZeneca and Oxford University COVID-19 vaccine after a small trial suggested it isn't effective in preventing mild to moderate illness caused by the more novel dominant strain in the country.
- CDC will [host](#) a virtual forum February 22-24 to bolster public confidence in a coronavirus vaccine and promote equitable distribution of the shots.

- House Energy and Commerce Oversight and Investigations Subcommittee has invited officials from AstraZeneca, Johnson & Johnson, Moderna, Novavax, and Pfizer to testify on producing and developing COVID-19 vaccines at a fully remote hearing on Tuesday, February 23.
  - CDC [released](#) new [guidance](#) to help public schools reopen for in-person learning. The guidance contains five key mitigation strategies, including the universal and correct wearing of masks, physical distance, washing hands, cleaning facilities and improving ventilation, doing contact tracing, and isolation and quarantining. The Education Department also released what it described as the [first volume of a handbook](#) meant to guide educators on masking and physical distancing, which officials said was intended to supplement the CDC operational strategy.
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## State Issues

### Pennsylvania

Legislative

#### **Gov. Tom Wolf, Lawmakers Form Joint COVID-19 Vaccine Task Force**

Governor Tom Wolf's administration is teaming up with several state lawmakers on a new task force to help foster communication, ideas, and collaboration regarding the state's COVID-19 response. The task force will include key members of the Wolf administration and Democratic and Republican lawmakers in the House and Senate: Acting Secretary of Health Alison Beam; Randy Padfield, director of the Pennsylvania Emergency Management Agency; Democratic Sen. Art Haywood; Democratic Rep. Bridget Kosierowski; Republican Sen. Ryan Aument; and Republican Rep. Tim O'Neal.

Meanwhile, the state Health Department launched a new online tool to help Pennsylvanians keep track of when it's their turn to schedule an appointment to get the COVID-19 vaccine. The "Your Turn" tool on the agency's website is available to Pennsylvanians aged 65 and younger who are eligible for the vaccine. People without internet access can call the Health Department at 877-PA-HEALTH to obtain the same information.

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#### **State Budget Hearings Get Underway**

Along with all of the adjustments made due to the COVID-19 pandemic, the state Senate and House of Representatives Appropriations Committee budget hearings will be slightly different this year as well. Both committees will hold their virtual hearings on the floor of their respective chambers.

The House will hold hearings beginning this week. Anticipating the potential for additional federal funds during the next month, the Senate will begin hearings during March.

Key hearings to watch include:

#### **House Appropriations:**

- February 17, 1 p.m.—Department of State
- February 22, 1 p.m.—Department of Drug and Alcohol Programs
- February 25, 10 a.m.—Department of Health
- March 3, 10 a.m.—Department of Human Services

- March 10 a.m.—Budget and Governor’s Office

[Live feeds](#) of the hearings, as well as a full [schedule](#), can be found at the House Majority Appropriations Committee website.

**Senate Appropriations:**

- March 10, 10 a.m.—Department of Human Services
- March 11, 1:30 p.m.—Department of State
- April 22, 10 a.m.—Department of Health
- April 22, 2 p.m.—Budget and Governor’s Office

[Live feeds](#) of the hearings, as well as a full [schedule](#), can be found at the Senate Majority Appropriations Committee website.

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## State Issues

### Pennsylvania

#### Regulatory

#### **New Department of Health COVID-19 Vaccination Policy Order**

On February 12, Gov. Wolf and the Acting Secretary of Health issued an [order](#) outlining new expectations for Pennsylvania vaccine providers who have a valid COVID-19 Provider Agreement. The order sets forth new requirements for the timely administration of vaccines and the establishment of website and phone-based scheduling capabilities. Additionally, the order reiterates expectations for compliance with existing requirements for reporting COVID-19 vaccination administration data and adherence to the Department of Health’s (DOH) Phase 1A prioritization.

The order sets forth the requirements, including the following, for enrolled vaccine providers **outside of Philadelphia**:

**Accountability for quickly using vaccine:** Enrolled providers must use, at a minimum, 80% of first doses within seven days of receipt. Second doses are to be used as clinically prescribed. DOH will offer dispensation for inclement weather or infrastructure failures outside of a vaccine provider’s control.

**Adherence to Phase 1A:** Enrolled providers must provide vaccines within the current phase of Pennsylvania’s rollout—presently Phase 1A. DOH is not looking to enforce against circumstances where providers are in isolated circumstances vaccinating non-1A-eligible individuals in order to use up leftover doses and prevent waste. The intent is to ensure providers are not designing and implementing vaccine administration strategies that expand outside of the 1A-eligible populations. DOH has been clear in recognizing that individuals within a particular occupation—such as teachers, firefighters, and public transit workers—may qualify under 1A based on age or comorbidities. A clinic targeting 1A-eligible individuals within a certain occupation would be permissible.

**Website and phone-based scheduling:** By Friday, February 19, enrolled vaccine providers must put forward a public-facing website for scheduling vaccine appointments and establish an answered phone line for eligible



persons who need assistance scheduling or who are unable to schedule via the internet. DOH does not plan to monitor or enforce against the performance of the phone number, but warned against using the phone service to direct callers back to the website for scheduling.

**Reporting vaccine administration data, including race and ethnicity data, in the Pennsylvania Statewide Immunization Information System (PA-SIIS) within 24 hours:** By Monday, February 15, enrolled providers must be in full compliance with existing requirements—[Order Requiring Reporting of Data Related to Each Administration of an Immunization for COVID-19](#)—that vaccines administered need to be reported within 24 hours. This order rescinds and replaces the *Order of the Secretary of the Pennsylvania Department of Health Requiring Health Systems, Hospitals, Federally Qualified Health Centers and Pharmacies to Vaccinate Certain Health Care Personnel*, dated December 30, 2020.

**Enforcement:** To promote compliance of these orders, starting the week of February 22, DOH will reduce or suspend a non-compliant provider's first dose vaccine allocation for one week or until the provider comes into compliance with the order.

**Why this matters:** Hospitals and health systems are the largest vaccine providers in the commonwealth. Hospitals need to closely evaluate the changes in this revised order which will have a significant impact on vaccination operations.

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## State Issues

### West Virginia Legislative

#### West Virginia Begins Legislative Session Focused on Tax Reform and Health Care

The 2021 Regular Session of the West Virginia Legislature convened for its 60-day term on Wednesday, February 11 and Governor Jim Justice announced during the "State of the State" address his proposal for repealing the state's personal income tax.

The governor's vision is that a repeal of the tax will be transformative for the state's economic future and attractiveness as a location for new workers and businesses in order to reverse the state's ongoing and dramatic declines in population over the past two decades and more.

#### The Governor's Tax Reform Plan

- For this year, Governor Justice is proposing approximately a 50% overall reduction in the personal income tax at a revenue cost of approximately \$1 billion.
- To account for these forgone revenues in the first year, the governor is proposing that all of the state's running cash surplus of approximately \$400 million be used to replace the PIT revenues and that an unspecified amount of federal CARES Act funds that he has been holding in reserve be diverted into the general budget to account for another portion of the revenue loss.
- Additionally, the governor proposes to:
  - Increase the state's general consumer sales tax by 1.5%;
  - Tier the state's severance taxes on coal, oil, and natural gas to capture more revenues;
  - Increase the state taxes on soda and cigarettes;

- Expand a range of “professional services” to be subject to sales tax (legal, accounting, engineering, advertising, medical, etc.); and
- Enact a new “wealth tax” that would apply to luxury purchases.

## Health Care

The House Health Committee has already taken action on a number of major bills of interest. On Thursday, the House panel endorsed **HB 2004**, **HB 2005** and **HB 2264**.

- **HB 2004** essentially proposes to codify the emergency orders that were issued by Governor Justice early in the COVID-19 crisis, loosening the restrictions on the use of telehealth services and allowing for out-of-state licensed professionals to serve West Virginians.
- **HB 2005** proposes a wide ranging scope of requirements pertaining to hospitals and health plans regarding price transparency for healthcare services, timely and updated disclosure of provider participation in health plan networks and for the management of surprise billing disputes.
- **HB 2264** proposes a significant modification to the state’s Certificate of Need laws pertaining to hospitals. However, the language of the bill is written in a manner that seems to open wide the prospect that a variety of services could become exempt from CON as long as they are to be delivered from the main campus of the hospital in question.

## PBM Legislation

The House Health Committee also considered **HB 2263**, which revises current law pertaining to pharmaceutical benefit managers (PBMs) by requiring:

- Any health plan with an ownership interest in a PBM to disclose that relationship;
- Disclosure of information concerning the prices of drugs, the amounts of rebates received from PBMs and how those rebates will be transmitted to the benefit of plan members at the point of sale of a prescription or through the premium calculations on a forward reaching basis; and
- PBMs to reimburse pharmacists in a manner designed to prevent pharmacies from being forced to accept reimbursements at a level less than the cost of a pharmaceutical product.

This bill is similar to a bill that passed the House in 2020 but was not considered in the Senate. However, this year’s legislation is also modified to reflect a recent US Supreme Court decision (*Rutledge v. Pharmaceutical Care Management Association*) allowing for Employee Retirement Security Act (ERISA) plans’ pharmacy benefits to be subject to state regulation.

## Telehealth Payment Parity

**SB 1** proposes to require health plans to reimburse providers on a parity basis for telehealth visits in comparison with reimbursements already made for in-person services. The Senate Health Committee is likely to consider SB1 this week.

## Insulin Copay Caps

There have been multiple bills introduced in the first days of the session seeking to expand the scope of last session’s insulin cost limitation bill to lower the monthly customer obligation limit to \$25 for insulin and for all other diabetic medications, monitors, equipment, and supplies. These bills have received two committee references in both chambers and will be reviewed by the Insurance Committees this year.

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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 and the U.S. Senate return to session the week of February 22.

**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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