

## Federal Issues

### Legislative

#### House Committees Begin Budget Reconciliation Work

Last week, the House Ways and Means Committee (W&M) began [marking up](#) provisions of the Democrats \$3.5 trillion budget reconciliation bill, including legislation to add dental, vision, and hearing (DVH) benefits to original Medicare. The committee is expected to continue its work this week, focusing on revenue titles of the budget reconciliation bill. In addition, the House Energy and Commerce (E&C) and Education and Labor (E&L) Committees are expected to also hold markups this week for items of the package under their jurisdiction.

The Medicare [legislation](#) passed by W&M would add new DVH benefits to Medicare Part B, with vision coverage beginning in 2022, hearing in 2023, and dental in 2028. Importantly, the legislation would adjust Medicare Advantage benchmarks to account for these benefits.

In preparation for its markup this week, the E&C committee released several proposals it intends to include in the package:

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- Adding DVH benefits to original Medicare with the same phase-ins and MA benchmark adjustment as the W&M bill.
- Establishment of a mandatory rebate for drug manufacturers for certain Medicare Part B drugs with prices increasing faster than inflation.
- Establishment of a \$2,000 maximum out-of-pocket cap for Part D enrollees;
- Permanent repeal of the Part D rebate rule.
- A 7% FMAP increase for states that implement a home-and-community-based improvement program to strengthen and expand HCBS.
- Establishment of a federal Medicaid program for individuals who reside in states that have not expanded Medicaid. The proposal would expand the ACA's premium tax credits to those with incomes below 138 percent of the federal poverty level and provide enhanced cost-sharing assistance for 2022-2024. In 2025, a federal Medicaid program would be established in the remaining non-expansion states, with a maintenance of effort provision to encourage states to keep their Medicaid programs at their current levels.
- Establishment of a new \$10 billion per year federal health insurance affordability fund beginning for plan year 2023 to allow states to establish a reinsurance program or lower cost-sharing.
- Permanent extension of the Children's Health Insurance Program (CHIP).

**Next Steps:** The House is hoping to vote on the package later this month or in early October, with the Senate expected to take somewhat longer in developing their version. The timing of votes is uncertain, however, as Congress must also focus on funding the government when the new fiscal year begins October 1 and raising the debt limit.

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## Biden Administration Releases Plan to Lower Drug Prices

Health and Human Services (HHS) Secretary Xavier Becerra released a [comprehensive plan](#) to lower drug prices. The plan comes in response to President Joe Biden's [Executive Order on Promoting Competition in the American Economy](#) and **identifies three areas the Administration will focus on:**

1. Supporting affordable and equitable drug prices through drug price negotiation.
2. Improving and promoting competition by supporting market changes that strengthen supply chains, promote biosimilars and generics, and increase transparency.
3. Fostering scientific innovation and ensuring that market incentives promote discovery of valuable and accessible new treatments, not market gaming.

### HHS also released legislative policies to advance these principles, including:

- Drug price negotiation in Medicare Parts B and D, with those negotiated prices also available to commercial plans (including the Marketplace) and employers who want to participate.
- Medicare Part D reform, including a cap on catastrophic spending.
- Legislation to slow price increases over time on existing drugs.
- Legislation to speed the entry of biosimilar and generic drugs.
- Prohibition on “pay-for-delay” agreements and other anti-competitive practices by drug manufacturers.

The discussion on prescription drug price transparency does not mention the recently deferred prescription drug transparency requirements for commercial market plans and instead focuses on forthcoming requirements for submission of drug pricing information to HHS under Section 204 of the No Surprises Act.

To read the Administration's full plan, please [click here](#).

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## Federal Issues

### Regulatory

#### **Proposed Rule Released on Surprise Billing and Transparency Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement**

The Biden Administration [released a proposed rule](#) with new regulations that would implement sections of Consolidated Appropriations Act of 2021 (CAA), including titles on surprise billing and transparency. These proposed rules from the Departments of Health and Human Services, Labor, the Treasury, and the Office of Personnel Management would implement certain provisions of the *No Surprises Act* including air ambulance reporting, agent and broker compensation reporting for individual market and short-term limited duration insurance, provider enforcement, complaints and civil monetary penalties; and air ambulance complaints and civil monetary penalties. Comments are due in mid-October

*Note: This is not the second Interim Final Rule on requirements related to surprise billing, which is expected imminently.*

You can read more about the rule in the HHS [fact sheet](#) and [press release](#). Concurrently, HHS also released a new [report](#) on air ambulance surprise billing.

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## COVID-19 Updates

President Biden announced a new [six-pronged national strategy](#) to combat COVID-19, keep schools safe, and protect the economy. The six broad prongs of the strategy include vaccinating the unvaccinated, further protecting the vaccinated, keeping schools safely open, increasing testing and requiring masking, protecting our economic recovery, and improving care for those with COVID-19. Specifically, the strategy calls for:

- Department of Labor's Occupational Safety and Health Administration (OSHA) to develop an Emergency Temporary Standard (ETS) requiring all businesses over 100 people to have a vaccination requirement or weekly testing of their employees. Employers will also be required to provide paid time off for the time it takes to get vaccinated or recover from the vaccine;
  - The Department of Labor's Occupational Safety and Health Administration (OSHA) has indicated it will release the Emergency Temporary Standard (ETS) requiring all businesses over 100 people to have a vaccination requirement or weekly testing of their employees in the coming weeks. It will be effective upon release, but will undergo a public comment period. A separate [Executive Order](#) provides more details around the vaccination requirements for Federal Contractors.
- Centers for Medicare & Medicaid Services (CMS) to require workers who work in health-care facilities that receive Medicare and Medicaid reimbursement to be 100% vaccinated, with no testing alternative; and
- An Executive Order requiring all federal executive branch employees to be vaccinated, and a separate Order requiring all federal contractors and their workers to be vaccinated as well, among other actions.
- The President emphasized his national strategy and encouraged all physicians to reach out to their unvaccinated patients and encourage them to be vaccinated in the next 2 weeks. To learn more about the national strategy, please [click here](#).
- Separately, HHS has taken action to increase access to critical COVID-19 monoclonal antibody therapeutics. HHS has executed a ninth [amendment](#) to the Public Readiness and Emergency Preparedness (PREP) Act Declaration that expands the pool of professionals for the administration of COVID-19 monoclonal antibody therapeutics. The recent amendment includes coverage of licensed pharmacists, pharmacy technicians, and pharmacy interns when administering COVID-19 monoclonal antibody therapeutics orally, through intramuscular injection, or through subcutaneous injection.
- The U.S. Department of Health and Human Services (HHS) [announced](#) that it was making \$25.5 billion in new funding available for health care providers affected by the COVID-19 pandemic. The funding, made available through the Health Resources and Services Administration (HRSA), includes \$8.5 billion in American Rescue Plan (ARP) resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP), or Medicare patients, and an additional \$17 billion for Provider Relief Fund.
- The Centers for Disease Control and Prevention (CDC) released [findings](#) from a study that showed full vaccination reduced the risk of COVID-19 infection by five times, reduced risk of hospitalization

by over ten times, and reduced risk of death by over ten times, when compared to unvaccinated individuals.

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## State Issues

### New York

#### Regulatory

#### **Governor Announces COVID Vaccine Requirement for State Employees**

Governor Kathy Hochul last week announced that state employees must be vaccinated by October 12 or face weekly testing. Health care workers in hospitals and nursing homes must be vaccinated by September 27, with no option to test out, while health care workers at home care agencies, hospices and adult care facilities must be vaccinated by October 7, also with no test-out option. State University of New York and City University of New York on-campus students must be fully vaccinated by September 27, with no option for testing. Additionally, last week Governor Hochul announced the official designation of COVID-19 as an airborne infectious disease under the state's new HERO Act, triggering requirements for all employers to implement workplace safety plans.

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#### **Administrative Simplification Workgroup Finalizing Recommendations to Streamline Health Care Payment and Delivery System**

After almost ten months of meetings, the Administrative Simplification Workgroup is wrapping up work and near to finalizing its report and recommendations. Created in the 2020 Executive budget, the workgroup is required to submit a report with recommendations for ways to streamline processes to help improve the health care payment and delivery system for the benefit of consumers, providers and health plans. The group met last week to review the latest draft of the report. Aside from some small additional changes, the Department of Financial Services expects to finalize the report, which is due to the DFS Superintendent, DOH Commissioner and Legislative leaders by October 3, 2021. Once that happens, DFS will turn to the task of implementing the report's recommendations. Staff indicated most recommendations should be able to be executed through regulation and circular letter guidance, but did acknowledge some might require statutory authority.

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## State Issues

### Pennsylvania

#### Regulatory

#### **BPOA Offers Clarity on Temporary Licenses for Out-of-State Nurses**

The Bureau of Professional and Occupational Affairs (BPOA) has provided a clarification regarding the expiration of temporary licenses issued to out-of-state practitioners during the pandemic.

**BPOA confirmation:**

- Temporary permits are good for one year from the date of issue
- The expiration of the emergency declaration on September 30 does not supersede the expiration date of the temporary license

**This confirms means that a temporary license set to expire on June 30, 2022, will still be valid until that date.**

**Why this matters:** During March 2020, the state provided a waiver for certain out-of-state health care practitioners to receive temporary licenses to assist with the pandemic response. This waiver is set to expire on September 30, along with a host of other waivers provided from the state's emergency disaster declaration. Clarification that temporary licenses will be valid for one year from the date of issue is vital to hospitals as they continue to deploy strategies to fill staffing positions due to significant staffing challenges.

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

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

New York Legislation: <https://nyassembly.gov/leg/>

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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