

Federal Issues

Legislative

Congress Clears Budget Resolution, Paving the Way for Reconciliation

The U.S. House on August 24 narrowly adopted a Senate-passed [budget resolution](#), which officially allows the budget reconciliation process to begin. The reconciliation process will allow Democrats to develop and pass their \$3.5 trillion spending package in a way that circumvents the Senate filibuster.

- **Why it matters:** Assuming unanimity among Senate Democrats and near unanimity among Democrats in the House, the massive spending package can be passed without any GOP support. Democrats are eyeing several big ticket health care items for the package, including: a continuation of ACA subsidies; adding dental, vision, and hearing to Medicare; Part D restructuring; and drug pricing reform, among other proposals.

What's next: The budget resolution sets a deadline of Sept. 15 for House committees to write their portions of the reconciliation package. The House Budget Committee is then tentatively expected to compile the committees' text the week after, followed by potential

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floor consideration of the bill in the last week of September.

Although several factors could cause this timeline to change, the goal is to have the reconciliation package ready for floor action at the same time the House aims to consider the \$1 trillion bipartisan infrastructure package that passed in the Senate earlier this month. To secure the votes of several centrist Democrats for the budget resolution, House Speaker Nancy Pelosi (D-CA) included a non-binding rule that the House would consider the infrastructure bill by Sept. 27.

The Senate will likely take a little longer to work on the package, with action possible in October. It is likely the overall spending number will have to come down from the \$3.5 trillion authorized to secure the support of all 50 Senate Democrats. In addition to the reconciliation and infrastructure efforts, lawmakers are expected to work on several other bipartisan health care priorities this fall, including improving pandemic preparedness, and addressing mental and behavioral health care.



Federal Issues

Regulatory

COVID-19 Updates

- The Food and Drug Administration (FDA) granted “full” [approval](#) for the use of the Pfizer-BioNTech COVID-19 vaccine, now marketed as [Comirnaty](#), for the prevention of COVID-19 in individuals 16 years of age and older.
 - The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.
- The FDA is requiring Pfizer to conduct post-marketing studies to further assess the risks of myocarditis and pericarditis following vaccination.

- These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination.
 - In addition, although not required by the FDA, Pfizer has committed to additional post-marketing safety studies, including a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of the vaccine during pregnancy.
- Two new studies from the Centers for Disease Control and Prevention (CDC) show fully vaccinated Americans' immunity to COVID-19 is waning as the more-transmissible Delta variant continues to spread across the country.
 - [One study](#), which focused on frontline health care workers, found vaccine effectiveness declined by nearly 30% since the Delta variant became the dominant strain in the U.S.
 - [The second study](#) examined 43,000 Los Angeles residents and found 25% of new infections from May to July were in fully vaccinated individuals, while 71% occurred in unvaccinated people. The study also showed the hospitalization rate was significantly lower for fully vaccinated people than for unvaccinated people.
 - Both CDC studies show breakthrough infections in vaccinated people are still rare, but they also add to growing evidence protection from COVID-19 shots lessens over time.
- The Centers for Medicare & Medicaid Services (CMS) [announced](#) additional payments for health care providers administering vaccines to multiple Medicare beneficiaries in one home setting.
- CMS released [findings](#) from a preliminary analysis of the impact of COVID-19 on Medicare beneficiaries in nursing homes.
 - Nursing home residents account for only 2% of the Medicare population, yet they have been disproportionately impacted by COVID-19 when compared to community residents.
 - The study found Medicare beneficiaries who reside in nursing homes were at an increased risk of COVID-19 infection, hospitalization for COVID-19, and mortality following a COVID-19 hospitalization.
- Johnson & Johnson (J&J) [announced](#) data supporting the use of its COVID-19 vaccine as a booster shot for people previously vaccinated with their single-shot vaccine. New interim data from their studies found a booster shot resulted in antibody levels that were nine times higher than 28 days after the initial dose. J&J said it would submit its new data to the Food and Drug Administration (FDA) for review as the agency considers the potential need for wide availability of vaccine boosters.
- The Centers for Medicare & Medicaid Services (CMS) released [guidance](#) to states about additional American Rescue Plan Act of 2021 (ARP) funding to promote the importance of COVID-19 vaccination for eligible children and adults enrolled in Medicaid.
- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) held a [meeting](#) to review safety updates related to COVID-19 vaccines and evaluate the data regarding approval of the Pfizer/BioNTech mRNA COVID-19 vaccine, following full FDA approval earlier last week.
 - ACIP voted unanimously to recommend the Pfizer/BioNTech mRNA COVID-19 vaccine for all individuals over the age of 16.
 - The Committee also reviewed the currently available evidence for booster doses of COVID-19 vaccines and discussed a framework for booster shots that would be executed in a similar

manner as the initial vaccine roll out, which started with the populations most vulnerable to serious illness (e.g., nursing home residents, health care providers, people aged 65+, those with comorbidities). ACIP is prepared to review additional evidence on booster doses following authorization by the FDA.

- Throughout the meeting, the Committee emphasized that the top priority should be continued vaccination of unvaccinated individuals, with a focus on equity.

CDC Reports Insurance Gains in 2020

Despite being a year of instability, 2020 saw a gain of 1.6 million more insured Americans on net, according to the Centers for Disease Control and Prevention (CDC). Early analysis shows the gains were helped by government policies, with losses in employment-sponsored coverage counteracted by larger gains in Medicaid and to a lesser extent, enhanced subsidized plans offered through the Affordable Care Act health insurance exchanges.

A record-level 81 million people are enrolled in Medicaid, with enrollment projections for the Medicaid program expected to potentially peak by the end of the year at 85 million, far eclipsing any other single coverage program, including Medicare. The gains are driven by income reductions and the retention of Medicaid enrollees during the public health emergency period. Every state opted for additional federal matching funds made available through federal stimulus legislation in exchange for agreeing to not terminate coverage for any enrollee during the PHE period.

Still, the uninsurance rate remains in the double-digits, with about 14% of Americans between the ages of 18 and 64 were uninsured last year, compared to 14.7% in 2019. This percentage varies considerably by state, with some states in the single-digits while other states' rates exceed 20%.

ICER to Assess Treatments for COVID-19

The Institute for Clinical and Economic Review ([ICER](#)) announced it will assess the comparative clinical effectiveness and value of the following treatments for COVID-19:

- casirivimab/imdevimab (REGEN-COV, Regeneron)
- sotrovimab (GlaxoSmithKline and Vir Biotechnology)
- molnupiravir (Merck)
- PF-07321332/ritonavir (Pfizer)
- fluvoxamine (Investigator initiated)

The assessment will be publicly discussed during a meeting of the Midwest Comparative Effectiveness Public Advisory Council ([Midwest CEPAC](#)) in April 2022. ICER posted a [Draft Scoping Document](#) outlining how they plan to conduct this assessment. Following the Open Input period, they will update the document on September 24, 2021.

CMS and CDC Hold Vaccine Coverage and Reimbursement Town Hall

The Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), along with the Departments of Treasury and Labor held a Town Hall geared toward health insurance

providers on COVID-19 vaccination efforts and payment system updates in preparation for widespread administration of vaccine boosters.

The CDC reiterated its [earlier recommendation](#) that individuals who are moderately to severely immunocompromised should receive a third mRNA vaccine. As boosters are not yet authorized for the general public, the Food and Drug Administration (FDA) and the CDC's Advisory Committee on Immunization Practices (ACIP) are evaluating data around third doses for the general population. In addition, the CDC indicated it is reviewing efficacy and safety data about the prospect of mixing vaccines but needs additional evidence before issuing formal guidance.

Why this matters: Officials encouraged clinicians and health insurance providers to be prepared for rapid changes around COVID-19 booster doses so operational systems are ready in advance of expansions in authorization for boosters or approvals to inoculate children under 12. The CDC intends to issue prospective and preliminary guidance on potential future developments in vaccination authorizations.

State Issues

New York

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Governor Hochul names Obama Economic Advisor Adrienne Harris Superintendent of DFS

On August 31, Gov. Kathy Hochul named Adrienne Harris Superintendent of the Department of Financial Services.

Ms. Harris began her career as an Associate at Sullivan and Cromwell LLP in New York City representing a number of U.S. and non-U.S. based corporations in various forms of litigation and regulatory matters, before accepting a position at the United States Department of the Treasury under President Obama.

While at the Treasury Department, Ms. Harris served as a Senior Advisor to both Acting Deputy Secretary and Under Secretary for Domestic Finance, Mary Miller, and Deputy Secretary, Sarah Bloom Raskin. As Senior Advisor, Ms. Harris focused on a number of financial policy issue areas which were, and continue to be, critical to the advancement of the national economy. This work ranged from helping jumpstart national financial reform efforts to finding ways to advance fintech, identifying solutions to the student loan crisis, analyzing the nexus between foreign investment and national security, and working to promote financial intelligence and health in communities throughout the country.

Following her time at the Treasury Department, Ms. Harris then joined The White House, where she was appointed as Special Assistant to the President for Economic Policy, as part of the National Economic Council. In this role, Ms. Harris managed the financial services portfolio, which included developing and executing strategies for financial reform and the implementation of Dodd-Frank, while also continuing to advance fintech initiatives, consumer protections for the American public, cybersecurity and housing finance reform priorities.

Since leaving the White House in January 2017, Ms. Harris went on to serve as General Counsel and Chief Business Officer, and presently as Advisor at States Title, Inc. (now DOMA), which provides title insurance and settlement services in a number of states throughout the nation. Ms. Harris also currently serves as a Professor and Faculty Co-Director at the Gerald R. Ford School of Public Policy's Center on Finance, Law and Policy at the University of Michigan, as well as a Senior Advisor at the Brunswick Group in Washington D.C. where she advises multinational corporations on mergers and acquisitions, stakeholder communications and management, future-proofing and policy intelligence.

Industry Trends

Policy / Market Trends

Release of 2021 Medicare Trustees' Report

The Medicare Trustees released the [2021 Medicare Trustees Report](#), which details the finances of Medicare's two main trust funds, and provides helpful information on Medicare program enrollment and spending. Key highlights of the report include:

- Medicare covered 62.6 million people in 2020, about 40% of whom were enrolled in Medicare Advantage.
- Medicare expenditures totaled \$925.8B in 2020. Medicare payments to Medicare Advantage plans totaled \$322.2B.
- The Trustees project enrollment in Medicare Advantage will grow from 40.1% of the Medicare population in 2020 to 49.2% in 2030.
- The Hospital Insurance (Part A) Trust Fund is projected to become insolvent in 2026, the same year projected in last year's report.
- While the Supplementary Medical Insurance Trust Fund, which funds Parts B and D, will remain solvent indefinitely due to the way it is funded, the trustees once again issued a Medicare funding warning, which (i) requires the President to submit to Congress proposed legislation to respond to the warning within 15 days after the submission of the Fiscal Year 2023 Budget and (ii) requires Congress to consider the legislation on an expedited basis. This is the fourth consecutive year that the Medicare funding warning has been triggered.
- The report does not consider potential costs related to Aduhelm, noting "given the uncertainty associated with these impacts, the Trustees believe that it is not possible to adjust the estimates accurately before a coverage determination is made."

To read the full report, please [click here](#).

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.

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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