



## Federal Issues

### Legislative

#### House Passes Infrastructure Bill, Laying Groundwork for Reconciliation Vote

On Friday, the U.S. House passed a \$1.2 trillion bipartisan [infrastructure package](#) that had been languishing since the Senate passed the deal in August. House Progressives had held up passage of the deal, insisting for months that it be voted on in concert with a larger budget reconciliation package still under development.

House Speaker Nancy Pelosi (D-CA) negotiated a deal Friday that allowed a vote on the infrastructure bill, followed by a vote on the rule for the “Build Back Better” budget reconciliation bill, which will be taken up once the Congressional Budget Office (CBO) finishes its analysis of the package. Several high-profile progressives still voted against the infrastructure bill, but it drew the support of 13 Republicans, which paved the way for passage by a vote of 228-205.

**Next steps:** The House reconciliation vote could come as early as next week, although some are speculating it will take the CBO multiple weeks to finish its work. However, negotiations on the package continue behind the scenes and the Senate is sure to make changes to the House package, which will

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necessitate another House vote. With Thanksgiving and a looming December 3 deadline by which time Congress must address government funding and the debt ceiling, the endgame on reconciliation won't likely come before mid-to-late December.



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## **Congressional Democrats Announce Prescription Drug Pricing Deal**

Congressional Democrats [announced](#) an agreement to include several provisions to lower prescription drugs prices in their budget reconciliation bill, known as the Build Back Better Act. The package contains a wide range of health provisions, including enhanced Affordable Care Act (ACA) tax credits, Medicare hearing benefits, enhanced funding for Medicaid, public health infrastructure and programs to address maternal mortality. However, drug pricing had remained a major sticking point among Democrats.

**Why it matters:** Although substantially scaled back from earlier versions of drug pricing reform, if passed, the [package](#) would allow the federal government for the first time to directly negotiate the prices of some drugs with manufacturers, which has been a priority of Democrats for decades.

### **The Details:**

- Medicare will be able to negotiate prices for up to 10 high-price, single-source drugs in 2025, increasing to up to 20 drugs in 2028, with manufacturers subject to an excise tax if they refuse to negotiate.
- Mandatory manufacturer rebates to the federal government for drug prices that grow faster than inflation based on increases in drug prices across the market.
- A redesigning of the Medicare Part D benefit, including an annual out-of-pocket patient spending cap of \$2,000, \$35 per month cap on copays for insulin, and a rebalancing of the costs borne by plans, manufacturers, and the federal government.
- Requiring PBMs to provide reports on manufacturer rebates and other information to employers and plan sponsors.

Despite the drug pricing agreement, much work still needs to be done on the reconciliation package, particularly in the Senate, with a final vote not expected before late this year.

**The Campaign for Sustainable Rx Pricing (CSRxP)**, a coalition promoting bipartisan, market-based solutions to lower drug prices in America, [released a statement](#) reacting to the drug pricing compromise package to be included in the Build Back Better Act.

“CSRxP looks forward to reviewing the final details of the compromise package but applauds the inclusion of solutions to lower prescription drug prices for the American people,” said CSRxP executive director Lauren Aronson.

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## Federal Issues

Regulatory

### **OSHA and CMS Issue Workforce Vaccination Mandate Rules**

The Occupational Safety and Health Administration (OSHA) has released its [Emergency Temporary Standard](#) (ETS) governing the requirement for employers with at least 100 employees to adopt vaccination or testing policies for their employees. The ETS stipulates these employers must ensure each of their workers are fully vaccinated or tested for COVID-19 on at least a weekly basis. The enforcement of the testing requirement for unvaccinated employees begins on January 5, 2022. Employers are not required to pay for or provide testing to employees who decline to be vaccinated.

The ETS exempts those workers who work from home, work where no other people are present, or work exclusively outside. In addition, the rule does not require immunization for those who object on religious grounds, except where necessary for the protection of the health or safety of others. The rule also requires unvaccinated workers to wear face coverings and covered employers to provide paid leave for employees to get vaccinated beginning on December 5, 2021.

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Additionally, CMS released an [interim final rule](#) requiring health care workers at facilities participating in Medicare and Medicaid be fully vaccinated. Employees covered by ETS, CMS, or federal contractor rules will need to have their final vaccination dose by January 4, 2022 unless otherwise exempted.

Comments are due on December 6 to OSHA and January 4 to CMS.

**Legal challenge:** However, on Saturday, the U.S. Court of Appeals for the Fifth Circuit ruled to temporarily stop the vaccine mandate for employers with 100 or more employees citing “grave statutory and constitutional issues.” The suit was brought by state attorneys general, led by Texas Attorney General Ken Paxton, from Louisiana, Mississippi, Utah, and South Carolina. At least 26 states are opposing the vaccine mandate and several coalitions of states have also filed challenges.

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## **CMS Finalizes the Outpatient Prospective Payment System (OPPS) Rule**

The Centers for Medicare & Medicaid Services (CMS) issued a [final rule](#) with comment that revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2022.

**Why this matters:** CMS is retreating from policies established by the last Administration that were intended to shift services from inpatient hospitals to outpatient departments and ASCs. Specifically, the agency is halting the elimination of the inpatient only (IPO) list, a list of services Medicare will only pay for when performed in the inpatient setting, and adding back most of the procedures removed in CY 2021. The agency is also reinstating the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020 and adopting a process for stakeholders to nominate procedures they believe can safely be performed at ASCs.

CMS finalized modifications to the hospital price transparency regulation that are designed to increase hospital compliance by setting a minimum Civil Monetary Penalty (CMP) of \$300/day for hospitals with a bed count of 30 or fewer, and a penalty of \$10/bed/day for hospitals with a bed count greater than 30 up to a maximum daily dollar amount of \$5,500. The minimum total penalty amount would be \$109,500 per hospital/year, and the maximum total penalty amount would be \$2,007,500 per hospital/year. CMS also specifically required the machine-readable files be accessible to automated searches and direct downloads.

The final rule includes a 30-day comment period from the date the rule is published in the *Federal Register* on classifications assigned to interim ambulatory payment categories.

For more information on the OPPS rule, please see CMS' [fact sheet](#).

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## **CMS Finalizes the Physician Fee Schedule (PFS) Rule**

CMS issued a [final rule](#) that revises the Medicare Physician Fee Schedule (PFS) for calendar year 2022.

**Why this matters:** CMS will retain certain services temporarily added to the Medicare telehealth services list during the COVID-19 public health emergency (PHE) through December 31, 2023 to allow additional time to evaluate whether the services should be permanently added to the Medicare telehealth services list. CMS finalized changes to expand access to mental health services furnished via telehealth, even after the PHE ends, including removing geographic and originating site restrictions and permitting audio-only communications, subject to certain restrictions such as use of an audio-only modifier.

In addition, CMS will maintain the current payment rate of \$40 per dose for administration of COVID-19 vaccines, as well as the \$35 add-on fee for home administration of COVID-19 vaccines, through the end of the CY in which the PHE ends. Effective January 1 of the year following, the payment rate for COVID-19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines (95% of Average Wholesale Price for physician offices and reasonable costs for outpatient departments).

CMS finalized the creation of seven MIPS Value Pathways (MVPs) starting 2023, which are groups of cost and quality measures as well as performance improvement activities associated with specific specialties,

medical conditions, or episodes of care. Previously, physicians were able to choose which measures to report precluding easy cross comparisons of physicians by consumers due to differing measures.

For more information on the rule, please see this CMS [fact sheet](#).

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## COVID-19 Updates

- The U.S. Food and Drug Administration (FDA) [announced](#) they have authorized the emergency use of the Pfizer-BioNTech COVID-19 vaccine to include children ages 5 through 11. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) met on Tuesday, November 2, and [voted](#) unanimously (14-0) to recommend the Pfizer-BioNTech COVID-19 vaccine for children 5-11 years of age under the Food and Drug Administration (FDA)'s Emergency Use Authorization (EUA).
  - Pfizer [announced](#) its experimental antiviral pill reduces hospitalization and death from the coronavirus as much as 89%. Pfizer's new data on the drug, Paxlovid, came from an interim analysis of its Phase II/III trial among more than 770 high-risk adults with COVID-19 who were treated within three days of the onset of symptoms. Pfizer is halting trials after this interim analysis and filing with the Food and Drug Administration (FDA) shortly.
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## State Issues

### New York

#### Regulatory

#### Department of Financial Services Reviews No Surprises Act Implementation in New York

The Department of Financial Services last week hosted a call to discuss the various issues and challenges of implementing the federal No Surprises Act, given New York has had its own, similar state law since 2015. In addition to asking for details on time frames for implementation of provisions in the NSA, noting that plans need adequate time to operationalize changes, the New York Health Plan Association (HPA) had provided DFS with an overview of the areas where plans are seeking guidance on the Department's interpretation of the intersection of the state and federal rules.

Key areas reviewed included provider directory requirements, continuity of care, ID cards and independent dispute resolution provisions. DFS staff said it has been working on updating regulations for IDR, ID cards and provider directory misinformation. A pre-proposed draft regulation on this was recently shared with plans for comment and the ID card and IDR drafts are expected to be issued in the coming weeks. The Department is also preparing Circular Letters on these issues to provide guidance on implementation of the updates and changes to state law necessary to comply with the federal rules.

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#### Department of Financial Services Allows Credit Card Surcharges for Insurance Premium Payments

DFS recently has formally changed its opinion on credit card service fees, reversing a 2006 rule that prohibited insurers from placing a surcharge on premium payments made using a credit card.

Communication from DFS's office of general counsel states, "an entity that provides a service to insurers that permits policyholders to pay their insurance premiums by credit card may charge those policyholders an additional fee to cover credit card and other service expenses if the entity posts the total dollars-and-cents price charged." The policy change is based on a 2018 New York Court of Appeals decision (*Expressions Hair Design v. Schneiderman*, 32 N.Y.3d 382).

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### **Hospital Staffing Executive Order Extended**

On October 27, Governor Hochul issued [Executive Order 4.1](#), continuing the declaration of a statewide disaster emergency due to health care staffing shortages until November 26, which continues the requirement that plans suspend certain utilization review requirements and appeal time frames for institutions that submit a certification.

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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/>

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