

## Federal Issues

### Legislative

#### **Biden Addresses Congress, Announces New Spending Proposal**

President Biden delivered his first [joint address](#) to Congress on Wednesday. The address came on the heels of release of the details of the [American Families Plan](#), a new \$1.8 trillion spending proposal designed to spur economic recovery from the COVID-19 pandemic. The American Families Plan is primarily focused on enhancing the social safety net including poverty, childcare, education, and paid family leave program enhancements.

**Health care priorities:** In his speech, Biden highlighted how “outrageously expensive drugs are in America.” He suggested price negotiation as means to lower drug prices, which is a key element of House Democrat’s [drug pricing bill](#). President Biden also called on Congress to make permanent the enhanced Affordable Care Act premium tax credits, which were temporarily expanded in the American Rescue Plan.

**Not in the plan:** Several major policies that were known to be under discussion were omitted from the American Families Plan. These include proposals to lower the Medicare eligibility age, expand Medicare benefits, reform Part D, and – despite being called out

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in his speech - permit Medicare to negotiate drug prices. Despite the omission, President Biden has supported all these policies, and they could resurface in a future White House proposal.



**What's next:** Congress will begin putting the president's proposals into legislative form as well as addressing other priorities. Most of the proposals will likely be wrapped into a larger package that will be voted on at the end of the year.

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### President Biden Signs Prescription Drug Reform Bills

President Biden has signed two prescription drug reform bills into law — the Ensuring Innovation Act and the Advancing Education on Biosimilars Act, bipartisan measures aimed at increasing generic and biosimilar competition. On April 14, the House passed both proposals which had previously passed in the Senate by unanimous consent.

- The [Ensuring Innovation Act](#), narrows the definition of the types of new drugs that can receive five years of exclusivity. The bill ensures that the new chemical entity eligibility does not extend to drugs with components previously approved, limiting exclusivity to original, innovative medications and allowing generic market entry.
- The [Advancing Education on Biosimilars Act](#) of 2021, aims to increase competition and lower drug prices by increasing patient and provider education on biologics and biosimilars. The legislation requires the Food and Drug Administration (FDA) to establish a public website with educational materials on biosimilars and biologics, including information on interchangeability, and the process for reporting adverse events.

### Elsewhere on the Hill

- The Senate Health, Education, Labor and Pensions (HELP) Committee on Wednesday held a [hearing](#) titled “*Examining Our COVID-19 Response: Using Lessons Learned to Address Mental Health and Substance Use Disorders*”. The hearing focused on the unique mental health challenges many Americans have faced during the COVID-19 pandemic and ways for policymakers to meet Americans’ mental health care needs moving forward. Notably, witnesses also testified before the panel about the benefits of telehealth in providing equitable mental health care and steps Congress should take to support substance use disorder prevention and treatment efforts, among other topics.
- The Ways and Means Health Subcommittee held a [hearing](#) titled “*Charting the Path Forward for Telehealth*”. During the hearing, lawmakers from both parties expressed their support for making permanent telehealth flexibilities established during the COVID-19 pandemic and agreed that broadband internet access is one of the most significant barriers to using telehealth services. Democrats on the Subcommittee also raised concerns about equitable access to telehealth, including concerns that language barriers and audio-only services could harm communities of color and low-income, rural communities.

- The House Energy and Commerce Health Subcommittee held a [hearing](#) Tuesday on several drug pricing bills, including the newly re-introduced [H.R. 3](#), which passed the House in the last Congress.
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## Federal Issues

### Regulatory

#### **CMS Releases Medicare Inpatient Payment Proposed Rule**

The Centers for Medicare & Medicaid Services (CMS) [issued](#) the proposed rule for fiscal year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH).

**Why this matters:** The rule is a mix of provisions to implement new statutory requirements, roll back Trump-era policies, and advance policies that have been presaged by executive orders and other White House goals, such as taking an all-of-government approach to combating the COVID-19 pandemic.

- First, as part of the Consolidated Appropriations Act, the rule would gradually phase in 1,000 new Medicare-funded medical residency positions to train physicians to eligible hospitals starting in 2023, including those located in rural areas and those serving areas with a shortage of health care professionals.
- Second, in a policy reversal, hospitals would no longer be required to report median payer-specific negotiated charges that the hospital has negotiated with all its Medicare Advantage organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021. The Trump administration was interested in using this cost report data to potentially adjust Medicare fee-for-service payments to levels more like Medicare Advantage.
- Third, CMS proposes several COVID-19 relief measures, including suppressing readmission measures and continuing add-on payments for certain COVID-19-related treatments.
- Finally, CMS is seeking to advance the Biden administration's health equity efforts by enhancing hospital-specific reports that stratify measure results by Medicare/Medicaid dual eligibility and other social risk factors, ways to improve demographic data collection by requiring hospitals to collect at the time of admission, and the potential creation of a hospital equity score to synthesize results across multiple measures and social risk factors modeled off the Health Equity Summary Score used for Medicare Advantage plans.

Comments are due to CMS by June 28, 2021.

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#### **CMS Publishes the Notice of Benefit and Payment Parameters**

The Centers for Medicare and Medicaid (CMS) [released](#) part two of the final [Notice of Benefit and Payment Parameters](#) (NBPP) for 2022 impacting health plans in the commercial health insurance market. Friday's final rule addresses provisions in the 2022 proposed Payment Notice that were not finalized in [part one](#) of

the final rule, published January 19 under the Trump Administration. An overview of key provisions and updates in this final rule is below:

- **Premium Adjustment Percentage Index (PAPI).** The 2022 premium adjustment percentage is finalized as 1.3760126457, an increase of about 1.6% over the 2021 premium adjustment percentage.
- **Maximum Annual Limitation on Cost-Sharing.** The final 2022 maximum annual limitation is \$8,700 for self-only coverage and \$17,400 for other than self-only coverage.
- **User Fees.** CMS will propose in future rulemaking new user fee rates for the 2022 plan year of 2.75% of premiums for issuers in the Federally-facilitated Exchange (FFE) and 2.25% in the State-based Exchanges on the Federal Platform (SBE-FP).
- **ACA Risk Adjustment.** CMS finalized the proposal to include use of the same three years of EDGE data for model recalibration for the 2022 benefit year as was defined for the 2021 benefit year and pricing adjustment for hepatitis C drugs that has been in place since the 2020 benefit year.
- **Special Enrollment Period (SEP).** Clarifies individuals enrolled in COBRA continuation coverage are eligible for an SEP upon cessation of employer contributions or cessation of government subsidies (as under ARPA).
- **MLR.** The rule finalized the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes, including a definition of “bona fide services,” with additional technical clarifications.

CMS will issue new rulemaking this spring to address the Exchange Direct Enrollment option for states and changes incorporate the [2018 State Relief and Empowerment Guidance](#) in regulation to ensure any proposed changes align with President Biden’s Executive Order (EO) 14009 to strengthen Medicaid and the Affordable Care Act.

CMS also released a [fact sheet](#) for the final rule.

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## **HHS Releases New Buprenorphine Practice Guidelines**

As of Wednesday, all eligible providers as listed in statute (physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives) are exempt, under certain conditions, from the certification requirements associated with obtaining an X waiver, also known as a DATA waiver, to be able to administer buprenorphine to treat opioid use disorder.

Current law mandates that outside of a SAMHSA-certified opioid treatment program (OTP), qualified practitioners must obtain the DATA waiver, a statutory certification requirement that mandates providers go through additional training before prescribing medication assisted treatment. As a result of this burdensome process, only a fraction of eligible providers has obtained this waiver.

**Why this matters:** [The new practice guidance released by HHS last week](#) now removes this waiver as a requirement for providers to treat OUD with buprenorphine.

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## Coronavirus Updates

- The Centers for Disease Control and Prevention (CDC) updated [guidelines](#) for people who are fully vaccinated. The guidelines now clarify that fully vaccinated individuals can gather or conduct activities outdoors without wearing a mask, except in certain crowded settings. The guidelines also note that outdoor visits and activities are safer than indoor activities, and fully vaccinated people can participate in some indoor events safely.
- White House Press Secretary Jen Psaki announced that the government will restrict travel from India starting at midnight on Tuesday, May 4 at the advice of the CDC. The Biden Administration cited a steep rise in coronavirus cases in the country and the possible emergence of multiple variants. This announcement comes as India is currently facing the worst COVID-19 outbreak in the world.
- The CDC recommended pregnant people take the coronavirus vaccine. Preliminary CDC data published last week showed no obvious safety risks among over 35,000 pregnant people who received mRNA vaccines.
- White House Press Secretary Jen Psaki announced that the United States will share up to 60 million doses of the AstraZeneca coronavirus vaccine with other countries. The AstraZeneca vaccine has not yet received authorization in the United States. Before any doses are shipped, Psaki said that “the FDA will confirm any such doses meet its expectations for product quality.”
- Sanofi announced that they had entered into an agreement with Moderna to manufacture the Moderna COVID-19 vaccine. Sanofi said that it will fill up to 200 million doses of the COVID-19 vaccine starting in September 2021.

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## State Issues

### Pennsylvania

Legislative

#### **Hospitals Support Efforts to Retain Telehealth and Other Regulatory Flexibilities, Pass Informed Consent Legislation**

Hospitals urged state lawmakers to retain the COVID-19 flexibilities that have improved access to telehealth during the pandemic and to pass legislation related to informed consent.

The Hospital & Healthsystem Association of Pennsylvania (HAP) and WellSpan Health testified before state lawmakers Tuesday about continuing the regulatory flexibilities that have improved access to telehealth during the pandemic.

During a hearing before the House Republican Policy Committee, David Vega, MD, MBA, senior vice president, and chief medical officer at WellSpan Health, outlined how hospitals have transformed to meet the needs of patients during the pandemic, particularly when it comes to telehealth.

**Among the key takeaways from the hearing:**

- Expanded use of telehealth has offered significant benefits in behavioral health and to address staffing challenges in rural areas;
- Sustainable reimbursement models are needed to build upon the progress in telehealth;
- Staffing and licensure flexibilities have protected the health care workforce and allowed health care facilities to respond quickly to public health emergencies; and
- Streamlined data reporting to state and federal agencies can relieve the administrative burden and ensure consistent reporting.

**Why this matters:** Pennsylvania needs a coordinated transition to address the state's COVID-19 waivers and flexibilities after the pandemic ends. These enhanced flexibilities have played an important role to ensure safe care during the pandemic and will continue to benefit patients and providers after the pandemic ends. Hospitals support legislative initiatives, such as [House Bill 1011](#), that would retain these waivers and flexibilities after the pandemic.

In addition, on Wednesday, the Pennsylvania Senate approved legislation outlining when physicians can employ the assistance of other practitioners to obtain a patient's informed consent prior to surgery, radiation, chemotherapy, or other specified procedures. The proposal, which was approved 47-0, moves to the House for consideration.

**Sponsored by Senator John Gordner (R-Columbia), [Senate Bill 425](#) would:**

- Allow physicians to receive information from another qualified practitioner on the care team to obtain a patient's informed consent;
- Define the caregivers who qualify as a qualified practitioner;
- Identify informed consent requirements in human research conducted pursuant to approval by an institutional review board or similar entity; and
- Outline when a physician or qualified staff person is required to obtain a separate or new informed consent from a patient when informed consent already was obtained.

**Why this matters:** The legislation provides a critical legislative update to address a 2017 Pennsylvania Supreme Court decision that limited a physician's ability to delegate the duty to obtain informed consent prior to specified procedures.

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The Pennsylvania House of Representatives is in session May 3 - 5. The Pennsylvania Senate will return to session May 10.

The Delaware Legislature returns to session May 11.

The New York Legislature is in session May 3 - 5.

The West Virginia Legislature concluded session on April 10.

**Congress**

The U.S. House has committee work May 3 - 7.

**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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