

## Federal Issues

### Legislative

#### **House, Senate Committees Hold Hearings on 2022 Health Budget**

Key committees in the House and Senate held hearings last week on President Biden's fiscal year (FY) 2022 budget request for the Department of Health and Human Services (HHS):

#### **House Ways and Means Committee:**

- The House Ways and Means Committee held a hearing on President Biden's 2022 proposed budget for HHS, which included testimony from HHS Secretary Xavier Becerra. In his opening remarks, Chairman Richard Neal (D-MA) lauded the Affordable Care Act for expanding access to health care, citing new data from HHS that estimates 31 million Americans were enrolled in marketplace or Medicaid expansion coverage in late 2020 and early 2021. Chairman Neal also expressed interest in working to expand Medicaid under the ACA in the twelve states that have not done so, and said Congress needs to make permanent recent enhancements to the Advanced Premium Tax Credit.

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- Importantly, Sec. Becerra requested Congress to provide him additional authority to limit short-term insurance plans, which are not defined in statute. Democratic members characterized the plans as dangerous and requested Becerra work to pull back on regulations finalized by the prior administration.
- Ranking Member Kevin Brady (R-TX) used his opening statement to criticize the Biden Administration's proposed budget, particularly in light of the nation's economic challenges, and Democratic proposals like "Medicare for all" and the [Elijah E. Cummings Lower Drug Costs Now Act](#), which empowers HHS to negotiate the prices of certain prescription drugs. During the hearing, Rep. Brady and other Republican lawmakers also questioned Secretary Becerra about the migrant crisis at the southern border and the outsized number of unaccompanied migrant children under the Department's care.

## Pennsylvania

### *Legislative*

- **House Committee Holds Informational Meeting on Claims Data Sharing for Groups 51-100**
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## Industry Trends

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- **Drug Price Increases That Exceed Inflation Are Costing Medicare Part D Billions**

## Senate Finance Committee:

- The Senate Finance Committee similarly held a hearing with HHS Secretary Becerra on the Department's proposed FY 2022 budget. Chairman Ron Wyden (D-OR) focused his opening remarks on the rising cost of prescription drugs, specifically referencing the Food and Drug Administration's recent accelerated approval of Biogen's Aduhelm, a treatment for Alzheimer's patients that is expected to cost \$56,000 a year. Chairman Wyden added that he was working on prescription drug pricing legislation and would like to see Medicare have the authority to negotiate drug costs.
  - In his opening statement, Ranking Member Mike Crapo (R-ID) recognized the success of the public-private partnerships that brought safe and effective COVID-19 vaccines to the public in record time, and commended HHS for its efforts to expand telehealth and provide other emergency flexibilities during the height of the pandemic. Sen. Crapo also said President Biden's budget request "highlights the importance of value-based care, which will prove indispensable as we work to lower health care costs while increasing care quality." Additionally, Sen. Crapo raised concerns with proposals to lower the Medicare eligibility age and give HHS the authority to negotiate drug costs, as well as any potential cuts to Medicare Advantage.
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## Federal Issues

Regulatory

### **Biden Administration Releases First Unified Agenda of Regulatory and Deregulatory**

#### **Actions**

On Friday, the White House Office of Management and Budget (OMB) posted the 2021 Spring regulatory [agenda](#). The Department of Health and Human Services (HHS) incorporated several Medicare Advantage proposed rules in the agenda, including:

- [Policy and technical changes](#) for Contract Year 2023
- The [codification](#) of MA and Part D [payment policies](#) outside the scope of the annual Advanced Notice/Rate Announcement
- A [final rule](#) on risk adjustment data validation provisions
- [Proposed rulemaking](#) on a mandatory Alternative Payment Model, which would be piloted through CMS's Innovation Center (CMMI) and intended to reduce Medicare expenditures.

**With regards to the Medicaid program, HHS propose several rules, including but not limited to:**

- A [rule](#) that would expand the prohibition on adding/modifying a risk mitigation arrangement to prospective Medicaid managed care contract rating periods
- A [rule](#) to streamline eligibility and enrollment processes
- The [establishment of mandatory requirements](#) for Medicaid and CHIP Core Set Reporting

Following a recent Executive Order, the Department of Homeland Security will publish an [advance notice of proposed rulemaking](#) and re-define the term "public charge."

**Impacting the commercial market related to the No Surprises Act (NSA), HHS intends to:**

- Issue an [interim final rule](#) to address Surprise Billing Protections
- Issue a second [interim final rule](#) to address the [Independent Dispute Resolution process](#)
- Propose an enforcement [rule](#) regarding [Air Ambulance Reporting Requirements](#) and [Agent and Broker compensation](#) information
- Propose a [rule](#) regarding [Provider Nondiscrimination Requirements](#)

Finally, HHS's Office of Civil Rights will propose changes the 2020 Final Rule implementing the ACA's Section 1557 [nondiscrimination](#) policies.

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### **CMS Increases Payments for At-Home COVID-19 Vaccinations for Medicare Beneficiaries**

The Centers for Medicare & Medicaid Services (CMS) [announced](#) an additional payment amount for administering in-home COVID-19 vaccinations to Medicare beneficiaries who have difficulty leaving their homes or are otherwise hard-to-reach.

Medicare is incentivizing providers and will pay an additional \$35 per dose for COVID-19 vaccine administration in a beneficiary's home, increasing the total payment amount for at-home vaccination from approximately \$40 to approximately \$75 per vaccine dose. For a two-dose vaccine, this results in a total payment of approximately \$150 for the administration of both doses, or approximately \$70 more than the current rate. The additional payment amount also accounts for the clinical time needed to monitor a beneficiary after the vaccine is administered, as well as the upfront costs associated with administering the vaccine safely and appropriately in a beneficiary's home. The payment rate for administering each dose of a COVID-19 vaccine, as well as the additional in-home payment amount, will be geographically adjusted based on where the service is furnished.

Medicare established the following coding [guidance](#) to reflect this announcement.

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### **Biden Administration Outlines Health Care, Pharmaceutical Supply Chain Vulnerabilities**

The Biden administration released a [report](#) detailing vulnerabilities within specific supply chains that were revealed from the COVID-19 pandemic, highlighting issues within the pharmaceutical sector in particular. The report identifies risks, addresses vulnerabilities, and “promotes resilience.”

The pandemic highlighted shortages of active pharmaceutical ingredients (API) and critical generic drugs (p.9). The review identified that 87 percent of API facilities are overseas. It also exposed multiple issues within the generic pharmaceutical market that provides access to affordable medication to 90 percent of Americans (p. 208).

Over time, this market has consolidated and outsourced its production to countries with lower manufacturing costs. These actions have resulted in a multinational supply chain with many complexities, reduced incentives, increased production risks from natural disasters, and limited just-in-time inventories (p. 208).

#### **The report details numerous recommendations to improve pharmaceutical supply chain complexities (p. 240). Two prioritized objectives are:**

- Improve supply chain transparency and incentivize resilience
- Increase the economic sustainability of U.S. and allied drug manufacturing and distribution

#### **Furthermore, to promote a more sustainable supply chain, three overarching principles should guide policy:**

- Rigorous assessment of benefits and costs
- Distribution of benefits and costs across affected stakeholder groups
- Support for market-based mechanisms that serve public health for drug production and distribution

#### **Lastly, the report addresses three sets of recommendations to promote domestic growth, equity, and resilience:**

- Boost local production and foster international cooperation

- Build emergency capacity
- Promote international cooperation and partner with allies

**Next steps:** The White House and the U.S. Department of Health and Human Services (HHS) will host a high-level summit bringing together experts from the emergency medicine and critical care fields, along with individuals from the public health, the non-profit, and private sectors. This consortium will review the U.S. Essential Medications list and identify 50-to-100 drugs that are “most critical to have available at all times for U.S. patients (p. 243).” HHS, along with pharmaceutical supply chain experts, will develop a resilience framework. HHS also will determine if there’s a need to increase production or stockpile of APIs for the Critical Drug List.

**Why this matters:** Departments and Agencies across the federal government have already begun to implement the reports’ recommendations. These include steps to strengthen U.S. manufacturing capacity for critical goods, to recruit and train workers to make critical products here at home, to invest in research and development that will reduce supply chain vulnerabilities, and to work with America’s allies and partners to strengthen collective supply chain resilience.

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## COVID-19 Updates

- Johnson & Johnson [announced](#) that the Food and Drug Administration has approved an extension of its COVID-19 vaccine shelf life by one-and-a-half months. The decision extends the vaccine's shelf life from three months to four-and-a-half months and comes at a time when hundreds of thousands of doses were set to expire at the end of June.
  - HHS Secretary Becerra [sent a letter](#) to issuers and providers reminding health care providers of their signed agreements to cover the administration of COVID-19 vaccines free-of-charge to patients, and group health plans and health insurers of their legal requirement to provide coverage of COVID-19 vaccinations and diagnostic testing without patients shouldering any cost.
  - On June 8, the U.S. Department of Health and Human Services (HHS) announced the launch of a first-of-its-kind national hotline to connect people with disabilities to information and services to improve access to COVID-19 vaccines. The Disability Information and Access Line (DIAL) is now available to help people with disabilities find vaccination locations in their communities, assist callers with making vaccination appointments, and connect callers to local services – such as accessible transportation – to overcome barriers to vaccination. DIAL was created through a [partnership](#) between the Administration for Community Living and the Centers for Disease Control and Prevention to help older adults and people with disabilities get COVID-19 vaccines.
    - Website: [acl.gov/dial](http://acl.gov/dial)
    - Phone: 888-677-1199 from 9:00 AM to 8:00 PM ET
    - Email: [DIAL@n4a.org](mailto:DIAL@n4a.org)
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## HHS Releases New Data on Health Coverage Trends Under the ACA

The Department of Health and Human Services (HHS) released a new [report](#) this weekend entitled “Health Coverage Under the Affordable Care Act: Enrollment Trends and State Estimates.”

The report shows 31 million Americans have health coverage through the ACA’s Health Insurance Marketplaces and Medicaid expansion. According to the data in the report, 11.3 million people enrolled in the ACA Marketplace plans as of February 2021 and 14.8 million newly-eligible people enrolled in Medicaid through the ACA’s expansion of eligibility to adults as of December 2020. In addition, 1 million individuals were enrolled in the ACA’s Basic Health Program option.

HHS simultaneously released a [report](#) with additional data on effectuated enrollments, premiums, advance payments of the premium tax credit (APTC) and cost-sharing reduction (CSR) data for the Marketplaces for February 2021 and the full 2020 plan year.

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### **FDA Alzheimer’s Drug Approval Leads to Mixed Reactions**

The Food and Drug Administration (FDA) approved Aduhelm to treat people with Alzheimer’s disease. This is the first approval of a drug to treat Alzheimer’s since 2003 and the first given to a drug intended to address the causes of Alzheimer’s rather than manage the symptoms.

While the approval was cheered by many Alzheimer’s advocates who have long been frustrated by a string of clinical failures in the space and few therapies, it has been sharply criticized by others who believe the data is questionable and that the decision amounts to approval of an expensive drug offering little to no benefit. The FDA approved the drug using the Accelerated Approval pathway which enables an approval based on a surrogate endpoint and will require the sponsor, Biogen, to conduct further confirmatory or phase 4 trials, the results of which could take up to nine years. If the confirmatory trials fail to demonstrate efficacy, FDA can revoke the approval, though the agency has been criticized for rarely doing so in other cases.

The agency’s approval was in conflict with a recommendation from an outside advisory committee that in November recommended non-approval. Following the decision, three members of that panel, the Peripheral and Central Nervous System Advisory Committee, have resigned in protest. Biogen has set a sticker price of Aduhelm of \$56,000 annually. The decision comes as the Accelerated Approval pathway is being scrutinized by other entities including the Institute for Clinical and Economic Review (ICER) and the Medicaid and CHIP Payment and Access Commission (MACPAC), which has been working on proposals to increase Medicaid rebates for drugs approved under the pathway until FDA grants a drug full approval.

Given the majority of patients who take the drug will be Medicare beneficiaries, eyes now turn to CMS to determine the coverage parameters for the Part B therapy, which could lead to a National Coverage Determination or deference to local decisions made by regional Medicare contractors.

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### **OSHA Issues COVID-19 Emergency Temporary Standard for Health Care**

The Occupational Safety and Health Administration (OSHA) issued an [emergency temporary standard](#) (ETS) for occupational exposure to COVID-19 that requires certain health care employers to help protect their workers in settings where suspected or confirmed COVID-19 patients are treated.



The ETS requires covered health care employers to conduct an assessment to identify COVID-19 hazards and implement a COVID-19 plan to mitigate virus spread in the workplace, if they have not done so already. Covered employers also must implement other requirements to reduce transmission of COVID-19 in their workplaces including providing certain employees with N95 respirators or other personal protective equipment, ensuring six feet of distance between workers and in situations where distancing is not possible, erecting barriers between employees where feasible.

The ETS exempts fully vaccinated workers from masking, distancing and barrier requirements when in well-defined areas where there is no reasonable expectation that any person will be present with suspected or confirmed coronavirus.

Among other provisions, the standard also requires employers to provide reasonable time and paid leave for employee vaccinations and any side effects. Provision of the ETS require that employees who have COVID-19 or who may be contagious work remotely or otherwise be separated from other workers if possible, or be given paid time off up to \$1,400 per week.

OSHA also [posted](#) related summaries, fact sheets, and compliance assistance materials and tools.

The ETS, which was released as an interim final rule, is effective immediately upon publication in the *Federal Register*. Employers must comply with most provisions within 14 days of publication, and with the remaining provisions within 30 days. Comments on the ETS are due by 30 days after it is published in the *Federal Register*.

**Why this matters:** Through its enforcement efforts to date, OSHA has encountered significant obstacles, revealing that existing standards, regulations, and the OSH Act's General Duty Clause are inadequate to address the COVID-19 hazard for employees covered by this ETS. The agency has determined that a COVID-19 ETS is necessary to address these inadequacies.

Additionally, as states and localities have taken increasingly more divergent approaches to COVID-19 workplace regulation—ranging from states with their own COVID-19 ETSS to states with no workplace protections at all—it has become clear that a Federal standard is needed to ensure sufficient protection for healthcare employees in all states.

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## State Issues

### New York

#### Legislative

### Legislative Update

The Legislature concluded its 2021 Legislative Session late last week. Legislative leaders did leave the door open to returning for a special session later this summer, however, the major legislative priorities that remain unresolved do not include health care issues.

**The following is a summary of the bills that passed both houses that impact health insurers:**

- **Mid-year formulary change prohibition** – Prohibits health insurance plans from making mid-year pharmacy formulary changes.
  - **Pharmacy mail order** – Limits pharmacy mail order options for health insurance purchasers.
  - **Medicaid Reimbursement to Retail Pharmacies** – Requires Medicaid reimbursement to retail pharmacies at the fee-for-service dispensing fee rate and establishes an “any willing provider” provision to allow all pharmacies to receive Medicaid reimbursement whether contracted with a health plan or not.
  - **Covered Lives Assessment** – Mandates commercial insurance coverage of early intervention services through a covered lives assessment rather than as a claims-based reimbursement, which would increase the assessment by \$40 million, or 4 percent. The money is to be distributed to New York City and 57 other county governments, nominally to finance their expenses for providing “early intervention” services for developmentally disabled preschool children.
  - **Pharmacy Benefit Managers** – Requires registration and licensing of pharmacy benefit managers.
  - **Rx Explanation of Benefits** – Requires insurers to provide an explanation of benefits on prescriptions including the cost of the medication.
  - **Prior Authorization for SUD Treatment** – Prohibits prior authorization for medication assisted treatment for substance use disorder treatment for Medicaid recipients.
  - **Newborn Screenings** – Requires newborn screening for adrenoleukodystrophy and glucose-6-phosphate dehydrogenase deficiency.
  - **Medical Claims** – Requires specification between partial approval of medical claims and full denial of medical claims on written notices.
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## State Issues

### Pennsylvania

Legislative

#### **House Committee Holds Informational Meeting on Claims Data Sharing for Groups 51-100**

On Wednesday, June 9, the House Insurance Committee held an informational meeting to discuss [House Bill 947](#) (Zimmerman, R-Lancaster). House Bill 947 would require insurance companies to provide businesses, that have between 51 to 100 employees, an aggregate on claims data for the past two years within 30 days of being requested.

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#### **House Advances Insurance Coverage for Long-Term Antibiotic Treatment for Lyme Disease**

On Monday, June 7, the House advanced [House Bill 1033](#), (Rapp, R-Warren). House Bill 1033 would require health insurers to cover treatment plans for Lyme disease or related tick-borne illnesses as prescribed by a patient’s health care practitioner, regardless of if the treatment plan includes short-term or long-term antibiotic treatment.

The legislation will now be considered in the Senate and has been referred to the Senate Banking and Insurance committee.

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## House of Representatives and Senate Swear in New Members

As a result of the special elections that occurred on May 18, four new legislators officially joined the Pennsylvania General Assembly last week.

- On Monday, June 7, the House of Representatives swore in Leslie Rossi (R-Westmoreland) and Abby Major (R-Armstrong). Representative Rossi fills the seat of the late Representative Mike Reese and Representative Major fills the seat vacated by Representative Jeff Pyle.
- On Wednesday, June 9, the Senate swore in Marty Flynn (D-Lackawanna) and Chris Gebhard (R-Lebanon). Senator Flynn fills the seat vacated by Senator John Blake and Senator Gebhard fills the seat of the late Senator Dave Arnold.

This brings the make-up of the state Senate to 28 Republicans, 21 Democrats and 1 Independent (Senator John Yudichak, I – Luzerne).

Currently in the House, the Republicans still lead the Democrats by a count of 113 to 89, with one vacancy in the 113th House District, Senator Flynn's former seat. Speaker of the House Bryan Cutler (R – Lancaster) announced that the special election for the 113th House District is scheduled for the same date as the General Election on Tuesday, November 2, 2021.

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## Industry Trends

Policy / Market Trends

### Drug Price Increases That Exceed Inflation Are Costing Medicare Part D Billions

AARP released a [new report](#) detailing how drug price increases that exceed the rate of inflation are costing the Medicare Part D program billions of dollars in additional spending.

According to the report, the Part D program spent approximately \$77 billion on the top-50 most sold brand name drugs in 2019. The costs for the same drugs, had they been capped to grow at the rate of inflation, would have been \$60.5 billion, a more than \$16 billion difference.

And between 2015 and 2019 the Part D program spent \$289.1 billion on these top-50 drugs — compared to a \$250.8 billion price tag had there been an inflation cap. The difference: An extra \$38.3 billion in spending for taxpayers.

The report also found brand name drug companies hiked prices at rates exceeding inflation on nearly 90 percent of the same top-50 drugs — underscoring the urgency for policymakers in Washington to act on drug pricing legislation and anti-competitive practices.

In another [report](#) released by the AARP, the findings showed insurance-negotiated prices of 260 brand-name prescription drugs have increased, on average, faster than general inflation every year since 2006.

**Why this matters:** As prescription drug prices grow, consumers can expect increasing out-of-pocket costs, including higher deductibles, premiums and cost sharing.

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The Pennsylvania General Assembly is in session June 14-16.

The Delaware Legislature is in session June 15-17.

The New York Legislature concluded session on June 10.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House is in session June 14-17. The U.S. Senate is in session June 14-18.

**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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