

## Federal Issues

### Legislative

#### Senate Democrats Announce Budget Resolution Deal

Senate Majority Leader Chuck Schumer (D-NY) [announced](#) last week that Senate Democrats had reached a preliminary agreement on a \$3.5 trillion budget resolution to advance President Biden's social welfare and families aid agenda.

**Why it matters:** a joint House-Senate budget resolution is necessary to advance key components of President Biden's [American Jobs Plan](#) and [American Families Plan](#) proposals, which served as the blueprints for the deal.

Key health care components of the deal include:

- Add a new Dental, Vision, and Hearing benefit to Medicare
- Home and Community-Based Services expansion
- Extend the Affordable Care Act Expansion from the ARP
- Close the Medicaid "Coverage Gap" in the States that refused to expand

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**Next steps:** Schumer has said that he hopes to adopt the budget resolution on the Senate floor in the next few weeks. If also passed by the House, this would allow Congressional committees to move forward on development of the final reconciliation bill. It is unlikely any Republicans will support the resolution, meaning there will have to be unanimity among Senate Democrats for it to pass.



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### House Subcommittee Marks Up SDOH, Maternal Health Legislation

On Thursday, the House Energy and Commerce Subcommittee on Health held a [markup](#) to advance 19 health care bills, including legislation on maternal health and social determinants of health (SDOH).

The subcommittee advanced the following proposals by voice vote:

- [H.R. 2503](#), the Social Determinants Accelerator Act of 2021 – this bill would provide \$25 million in planning grants and technical assistance to state, local and Tribal governments to help them devise innovative, evidence-based approaches to coordinate services and improve outcomes and cost-effectiveness.
- [H.R. 951](#), the Maternal Vaccination Act – this bill establishes a national campaign to raise awareness and increase rates of maternal vaccinations.
- [H.R. 925](#), the Data to Save Moms Act – this bill expands data collection and research on maternal morbidity and mortality among minority populations.

The subcommittee passed several other bills during the markup, full list available [here](#).

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### Senate Panel Holds Hearing on Anticompetitive Conduct in Prescription Drug Markets

On Tuesday, the Senate Judiciary Subcommittee on Competition Policy, Antitrust and Consumer Rights held a [hearing](#) with medical and industry experts, as well as patient advocates, on anticompetitive practices in the prescription drug market.

The Details:

- During the hearing, lawmakers asked about practices that impact the cost of prescription drugs, as well as direct-to-consumer advertising, pharmacy benefit managers (PBMs), biosimilars and

generics, and “pay-for-delay” arrangements. The witnesses also testified in support of greater transparency for PBMs in terms of pricing, including their ability to provide rebates and discounts to consumers.

- Subcommittee Chair Amy Klobuchar (D-MN) called for Congress to pass legislation to address pay-for-delay, product hopping, and access to generic drugs. Senators and witnesses also discussed other policy issues, such as allowing Medicare to negotiate drug prices and allowing for the reimportation of drugs.
- Full Committee Chair Dick Durbin (D-IL) referenced a meeting he had with a health insurance provider, noting that they told him the high cost of prescription drugs was “the number one reason” premiums are going up.

The Campaign for Sustainable Rx Pricing published a [blog post](#) ahead of the hearing, emphasizing the growing bipartisan momentum in D.C. to take action to lower prescription drug prices. The post also underscores the industry’s anti-competitive tactics and rhetoric around innovation.

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## Federal Issues

### Regulatory

#### **CMS Proposes Changes to Physician Payment and Telehealth in Proposed Rule**

On July 13, CMS [proposed](#) its annual Medicare Physician Fee Schedule rule for 2022. The agency proposes a lower conversion factor for Medicare physician payment in 2022 (\$33.58). CMS notes that this reduction is primarily caused by a statutory update of 0 percent plus required adjustments based on changes in relative value units (RVUs). CMS also proposes a number of telehealth-friendly policies in the draft rule. This includes codifying the appropriateness of telehealth for the diagnosis, evaluation, and treatment of mental health disorders. CMS also proposes to codify that Medicare beneficiaries can access telehealth in their homes. The proposed rule would permit Medicare to pay eligible providers for audio-only telehealth services for certain mental and behavioral health services.

Beyond physician payment and telehealth, CMS proposes policy tweaks to the Medicare Diabetes Prevention, evaluation and management (E/M) billing requirements, ACO quality and risk methodologies, and, for the first time, authorizing direct payments to Physician Assistants. As part of the Biden administration’s focus on health equity, CMS requests feedback on the collection of health equity data based on race and ethnicity, dual-eligibility, disability, LBGTQ status, and rural location.

Public comments will be accepted through September 13. For more information on the rule, please see this [fact sheet](#).

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#### **CMS Begins National Coverage Determination Process for Aduhelm**

The Centers for Medicare & Medicaid Services (CMS) [announced](#) it was opening a National Coverage Determination (NCD) analysis for “monoclonal antibodies targeting amyloid for the treatment of Alzheimer’s disease.” The announcement notes the NCD process was initiated by CMS via an internally-generated request. Earlier this month, AHIP sent a letter formally [requesting](#) the agency develop a national coverage

policy for Aduhelm (aducanumab) with evidence development applicable to the Medicare population, including Medicare Advantage organizations, and specify if, and under what conditions, Medicare will cover aducanumab.

**Why this matters:** The NCD analysis will determine whether Medicare will establish a national Medicare coverage policy for aducanumab, as well as other future monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease.

CMS is opening a 30-day comment period on the initiation of the NCD process, seeking input on information the agency should consider while conducting its analysis. Following the analysis, CMS will post a *proposed* national coverage determination, which will be open to a second 30-day public comment period. Following the second public comment period, CMS will announce a final decision. A proposed decision is expected to be posted within 6 months and a final within 9 months. However, it should be noted these timelines are not fixed and may take longer.

**More details:** A number of health insurers and health systems announced that they will not administer the drug, at least for the time being. It was reported that at least six Blue Cross Blue Shield companies have declined to cover Aduhelm because it is "investigational" and its "clinical benefit has not been established." Also, one of the nation's largest health insurers reportedly announced it will not adopt a coverage policy until after Medicare's National Coverage Decision is made by CMS, a process that commonly takes about six months. Meanwhile, at least two prominent health systems have also reportedly decided not to administer the drug.

All of this occurs as the FDA conducts an independent review of Aduhelm's approval and some Medicare coverage policy experts encourage CMS to allow Medicare to begin temporary coverage of Aduhelm under Medicare's Coverage with Evidence Development authority.

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## **HHS Announces Over 2 Million New Plan Selections during 2021 SEP**

The U.S. Department of Health and Human Services (HHS) [announced](#) over 2 million Americans have newly signed up for coverage nationwide from the beginning of the 2021 Marketplace Special Enrollment Period (SEP) through June 30.

The updated Centers for Medicare and Medicaid Services (CMS) 2021 Marketplace SEP [report](#) shows 1.5 million Americans made a plan selection in the 36 states that use healthcare.gov during this period, 373,000 of which occurred during June. An additional 600,000 Americans used the SEP to sign up for coverage in the 15 states that run their own exchanges.

Since April 1, 2.5 million consumers have returned to healthcare.gov to access increased advance payments of premium tax credit (APTC), which were included in the American Rescue Plan Act (ARPA). Returning consumers saw their monthly premiums decrease by 40 percent, from \$104 to \$62, after APTCs were applied. Related, 30 percent of returning consumers newly selected plans for \$10 or less per month after APTCs. The average monthly premium for consumers selecting new plans during the SEP, the average monthly premiums decreased by 25 percent. Additionally, out-of-pocket costs have decreased – the median deductible for new SEP enrollees fell by 90 percent, from \$450 before April 1 to \$50 following April 1.

Consumers in healthcare.gov states have until August 15 to enroll in coverage or update their application to access enhanced subsidies.

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### **HHS Updates Interoperability Standards to Support SDOH**

The HHS Office of the National Coordinator for Health Information Technology [released](#) the United States Core Data for Interoperability version 2 (USCDI v2), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Importantly, the updated version includes three new data classes: sexual orientation, gender identity, and social determinants of health (SDOH). The update will encourage healthcare professionals to record the new data elements and promote interoperability of these data to help healthcare professionals meet the needs of marginalized communities. USCDI v2 does not require health professionals to record the data or individuals to share the data, although it is encouraged. While SDOH have been around for a while, the COVID-19 pandemic exposed many challenges in the nation's healthcare system that SDOH addresses. Insight into SDOH factors is sparse among healthcare facilities which can impact a healthcare professional's ability to manage their patients' health.

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## Industry Trends

Policy / Market Trends

### **White Paper Offers Health Care Coverage Options for Congressional Consideration**

A diverse group of 18 health care stakeholders, including AHIP, Families USA, and BCBSA, released a [white paper](#) on policies that would help Americans gain and keep equitable access to affordable, high-quality, high-value health care. The white paper highlighted a number of policies Congress could consider, including:

- Strengthening funding, care continuity, and eligibility for Medicaid and the Children's Health Insurance Program;
  - Improving the affordability of coverage people buy for themselves on the individual market, including health insurance exchanges; and
  - Increasing access to telehealth services.
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The Pennsylvania General Assembly returns to session in September.

The Delaware Legislature concluded session on June 30.

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 July 19-22. The U.S. Senate is in session July 19-23.

**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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