

## Federal Issues

### Legislative

#### **Suits Challenging Medicare Price Negotiations Pile Up with New Multi-Stakeholder Led Suit**

On Wednesday, a multi-stakeholder group of plaintiffs consisting of the National Infusion Center Association, Global Colon Cancer Association, a patient advocacy non-profit organization, and PhRMA, the leading pharmaceutical trade association, [filed suit](#) challenging the constitutionality of the Medicare drug pricing negotiation provisions enacted as part of the Inflation Reduction Act (IRA).

The suit was filed in federal district court for the Western District of Texas and is the fourth major lawsuit in recent months seeking to block the implementation of the Medicare drug price negotiations. The process is expected to begin in September with the first list of Part D drugs for which CMS will seek negotiations with manufacturers.

Similar lawsuits have been filed by employer groups (led by the U.S. Chamber and its local affiliates), as well as two manufacturers, Bristol Meyers Squibb and Merck, each of which their own suits.

**Why this matters:** The PhRMA lawsuit however brings two additional types of parties, providers and

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patients, which have joined the suit to argue the law jeopardizes a provider's ability to prescribe treatments that are in the patient's best interest as well as impairing the U.S. market's leadership in delivering to the world new therapies that, according to the lawsuit, are at risk.

Specifically, the lawsuit argues the IRA imposes a tax that is disproportionate to the purported offense thus making it an excessive fine prohibited by the Eighth Amendment, violates the Fifth Amendment's due process clause in depriving drugmakers of their investment-backed patent rights and common-law right to sell their products at market prices, and violates the Constitution's separation of powers clause in giving CMS virtually unfettered discretion to set drug prices.

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### **Congressional Request for Information (RFI) on 340B Drug Discount Program**

On June 16, Sens. John Thune (R-S.D.), Debbie Stabenow (D-Mich.), Shelley Moore Capito (R W.Va.), Tammy Baldwin (D-Wis.), Jerry Moran (R-Kan.), and Ben Cardin (D-Md.), all members of the Senate 340B bipartisan working group, [issued](#) an [RFI](#) to stakeholders seeking feedback on ways to improve the 340B program. Specifically, the senators are seeking input on bipartisan policy solutions that would provide stability and appropriate transparency to ensure the 340B program can continue to achieve its original intent of supporting entities serving eligible patients. Comments are due **by the deadline, July 28, 2023**.

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## **Federal Issues**

### Regulatory

#### **President Biden Signs Executive Order to Expand Contraception Access**

President Biden signed an [Executive Order](#) (EO) on "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services." The White House also issued a corresponding [fact sheet](#) outlining the details in the EO.

**Why this matters:** The EO includes several provisions important to health insurers, including:

- **New Federal Guidance to Improve Contraception Access for Women with Health Coverage:** Directing the Departments of the Treasury, Labor, and Health and Human Services (HHS) to consider issuing new guidance to ensure health insurance providers cover all contraceptives approved by the Food and Drug Administration (FDA) without cost-sharing, under the Affordable Care Act (ACA) and to streamline the process for patients and health care providers to request coverage, without cost sharing, of medically-necessary contraception. [Sec. 2]
- **Expanding Over-the-Counter (OTC) Contraception Access:** Directing the above Departments to consider new actions to “promote increased access to affordable OTC contraception, including emergency contraception.” They intend to collaborate with pharmacies, employers, and health insurance providers to support seamless coverage of OTC options, including considerations of best practices regarding coverage at no-cost to patients. [Sec. 2]
- **Support Family Planning through Medicaid:** Directing CMS to expand access to family planning services and supplies in Medicaid (including Medicaid managed care), such as identifying and sharing best practices. [Sec. 3]
- **Improve Contraction Coverage in MA & Part D** [Sec. 3]
- **Identifying Best Practices to Expand Contraception Access for Employer-Provided Coverage** [Sec. 4]
- **Supporting Research and Data Analysis on Contraception Access:** Directing HHS to take action to support research and data analysis that documents gaps and disparities in access to contraception, as well as the benefits of comprehensive coverage for contraception and family planning services through public and private health care programs. [Sec. 4]

The EO emphasizes efforts to expand availability and quality of family planning services, provide technical assistance and training to health care providers, support culturally and linguistically appropriate care, and provide guidance on contraception-related rules including confidentiality protections. These measures build upon guidance set forth in the ACA and two prior Executive Orders signed by the President on access to contraception.

**Also, HHS [announced](#) a new public-private partnership with Upstream**, a nonprofit organization that provides training and resources to health centers across the U.S. to improve contraceptive care. HHS and Upstream will collaborate to help health care providers receive free technical assistance, training, and education on contraceptive care in primary care settings to strengthen health systems and promote comprehensive patient-centered care for people of reproductive age.

Read the [full EO](#) and White House [fact sheet](#).

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**CMS Office of the Actuary Releases 2022-2031 National Health Expenditure Projections**

The Centers for Medicare & Medicaid Services' (CMS) Office of the Actuary [released projections of National Health Expenditures](#) (NHE) and health insurance enrollment for the years 2022-2031.

**Why this matters:** CMS projects that over 2022-2031, average annual growth in NHE (5.4%) will outpace average annual growth in gross domestic product (GDP) (4.6%), resulting in an increase in the health spending share of GDP from 18.3% in 2021 to 19.6% in 2031. The insured percentage of the population is projected to have reached a historic high of 92.3% in 2022 (due to high Medicaid enrollment and gains in Marketplace coverage). If current law provisions expanding premium tax credit subsidies for Exchange coverage are allowed to expire at the end of 2025, the insured share of the population is projected to be 91.2%. In 2031, the insured share of the population is projected to be 90.5%, similar to pre-pandemic levels.

The report contains expected impacts from the Inflation Reduction Act (IRA), including that people with Medicare prescription drug coverage (Part D) are projected to experience lower out-of-pocket spending on prescription drugs for 2024 and beyond as several provisions from the law begin to take effect. These provisions have notable effects on the growth rates for total out-of-pocket spending for prescription drugs, which are projected to decline by 5.9% in 2024, 4.2% in 2025, and 0.2% in 2026.

**Finally, the report contains estimates for NHE spending by major payer and sector:**

- On average, over 2022-2031, Medicaid expenditures are projected to grow by 5.0%.
  - Over 2022-2031, private health insurance spending growth is projected to average 5.4%.
  - Over 2022-2031, hospital spending growth is expected to average 5.8% annually.
  - Total expenditures for retail prescription drugs are projected to grow at an average annual rate of 4.6% over 2022-2031.
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## **HHS Issues Advisory on Impacts of Long COVID on Mental Health**

The U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), has issued an advisory: [Identification and Management of Mental Health Symptoms and Conditions Associated with Long COVID](#).

**Why this matters:** The advisory notes the critical role primary care providers have played in increasing our understanding of Long COVID and the importance of a greater familiarity with the associated mental health conditions and related symptoms. Mental health conditions associated with Long COVID include, but are not limited to, depression, anxiety, psychosis, obsessive compulsive disorder, and post-traumatic stress disorder. Other symptoms of Long COVID include cognitive impairment, sleep disturbances, and fatigue.

The advisory discusses the epidemiology of mental health symptoms and conditions of Long COVID and provides evidence-based resources for their assessment that can be used by primary care providers and others as best practices for the assessment and treatment of Long COVID continue to emerge. This effort is part of a whole-of-government response to the longer-term impacts of COVID-19. Related resources include SAMHSA's [Overview of the Impacts of Long COVID on Behavioral Health](#).

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## **CMS Issues Notice on Medicare Coverage Pathway for Breakthrough Medical Devices**

CMS issued a [notice with comment](#) and a [fact sheet](#) that proposes a new Medicare coverage pathway for breakthrough medical devices. The proposed Transitional Coverage for Emerging Technologies (TCET) pathway is voluntary for manufacturers and uses the current national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain breakthrough devices.

**Why this matters:** CMS proposes an evidence development framework that allows for evidence gaps to be addressed through “fit-for-purpose” studies, including those that make secondary use of real-world data, and where the study design, analysis plan, and study data are appropriate for the question the study aims to answer.

The notice will be published in the June 27 Federal Register and there will be a 60-day public comment period.

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## **CMS Announces New Details of Plan to Cover New Alzheimer’s Drugs**

The Centers for Medicare & Medicaid Services (CMS) released a [fact sheet](#) with additional details on how a registry will work to provide Medicare coverage for monoclonal antibody medications directed against amyloid for the treatment of Alzheimer’s Disease approved under the Food and Drug Administration’s (FDA’s) traditional pathway.

**Why this matters:** The fact sheet notes if the FDA grants traditional approval, Medicare will cover the drug in appropriate settings that support the collection of real-world information to study the usefulness of these drugs for Medicare beneficiaries. Specifically, Medicare will cover drugs with traditional FDA approval when a physician and clinical team participate in the collection of evidence about how these drugs work in the real world, also known as a registry. Clinicians will be able to submit this information through a nationwide, CMS-facilitated portal via an easy-to-use format that will adhere to robust privacy protections in accordance with applicable federal laws and regulations, including HIPAA.

CMS and researchers will have access to the information to conduct studies, furthering knowledge of how these drugs can potentially help people. The approach is consistent with CMS’ [National Coverage Determination](#) issued on April 7, 2022. **To get Medicare coverage people will need to:**

- Be enrolled in Medicare;
- Be diagnosed with mild cognitive impairment or mild Alzheimer’s disease dementia; and,
- Have a physician participating in a registry with an appropriate clinical team and follow-up care.

CMS stated the Agency is working with multiple organizations preparing to open their own registries. When available, registries will be listed at <https://www.cms.gov/medicare/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad>.

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### **CMS Releases *No Surprises Act* Resources**

The Centers for Medicare & Medicaid Services (CMS) released a new set of [web pages](#) aimed at providing easy-to-read information on the consumer protections made available in the *No Surprises Act*.

**Why this matters:** The *No Surprises Act* continues to work for patients and has protected [millions of Americans](#) from surprise medical bills. The Coalition Against Surprise Medical Billing (CASMB) continues to urge the Biden Administration to stand firm to protect patients and the cost-saving measures of the *No Surprises Act*, especially as private equity-driven lawsuits seek to alter the qualifying payment amount and raise health care costs for patients in the process.

### **Guidance featured on the new CMS web pages include:**

- Helping individuals understand their rights under the NSA, including out-of-network billing protections and good faith estimates for future care.
- Identifying actions people can take to exercise their rights and find a resolution if they receive an unexpected medical bill, using a Q&A tool that asks about a person's situation.
- How to submit a complaint if a person believes their provider, facility, or insurance company didn't follow the rules of the NSA through an optimized process and redesigned form.
- How to dispute a bill if a person is uninsured or didn't use insurance and were charged more than their good faith estimate.
- How to find guides that will help a person navigate medical billing questions, as well as learning how to connect with the No Surprises Help Desk.

### **Additional resources posted to the site include:**

- *No Surprises Act* Consumer Webpage: <https://www.cms.gov/medical-bill-rights>; Español: <https://www.cms.gov/derechos-facturas-medicas>
- New Protections for Consumers: <https://www.cms.gov/medical-bill-rights/know-your-rights>

Find the full set of resources [here](#).

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## **State Issues**

## New York

### Regulatory

#### **DFS to Examine Mental Health, SUD Appointment Wait Times**

Through the Health Plan Association, the Department of Financial Services (DFS) has reached out to plans to gather information about health plans' appointment wait time requirements for outpatient mental health and substance use disorder services. DFS staff said the information will assist the Department in implementing the behavioral health provisions of the 2023-24 State Budget (Part II), which require DFS and DOH to issue regulations addressing network adequacy standards for those services. The request has been forwarded to HMK subject matter experts.

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#### **Out of Pocket Max Lowered for Essential Plan 1**

The NY State of Health last week notified plans about an update to the maximum out of pocket dollar amount for enrollees in the Essential Plan 1, which takes effect January 1, 2024. The new maximum out of pocket for EP1 will be \$360 per year, down from the current \$2,000. NYSOH described the update as "a positive step toward removing cost barriers for the EP1 enrollees may face."

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## State Issues

### Pennsylvania

#### Legislative

#### **Two Gov. Shapiro Cabinet Picks Confirmed by Senate**

The Senate on Wednesday unanimously confirmed Dr. Latika Davis-Jones as Secretary of the Department of Drug and Alcohol Programs and voted 49-1 to confirm Nancy Walker as Secretary of Labor and Industry. Davis-Jones had previously been senior director of Behavioral Health at Highmark Wholecare and SCA Administrator for the Allegheny County Department of Human Services. Walker previously served as the first Chief Deputy Attorney General of the Pennsylvania Office of Attorney General's Fair Labor Section and worked as a private-practice attorney focused on labor and employment law.

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#### Regulatory

#### **PID Announces Reinsurance Program to Continue & Program Parameters for 2024**

In April, the Pennsylvania Insurance Department (PID) published Notice 2023-05 at 53 Pa.B. 2273, proposing to submit a request to suspend the Section 1332 Innovation Waiver (2020 Waiver). The 2020 Waiver authorized the Department to create and implement a reinsurance program. Notice 2023-05 sought public comment on the proposed plan of suspension.

In Notice 2023-07, published at 53 Pa.B. 3387 (June 24, 2023), the Department expressed gratitude for the comments received and announced that it will not be pursuing its proposal and that the reinsurance program will remain in place for Plan Year 2024.

**Why this matters:** The reinsurance program is a very important part of the state-based insurance exchange (Pennie) program which allows insurers like Highmark to keep products affordable and accessible to more Pennsylvanians.

- The reinsurance program is a claims-based, attachment point reinsurance program that will reimburse health insurers for claims costs of qualifying Affordable Care Act-compliant individual enrollees, where a percentage of the claims costs exceeding a specified threshold (attachment point) and up to a specified ceiling (reinsurance cap) will be reimbursed.

The PID also released a notice (2023-08) regarding the 2024 program parameters for the state's reinsurance program.

Beginning January 1, 2024, the program [adopted parameters](#) will provide an attachment point of \$60,000, a cap of \$100,000 and a coinsurance rate of 50%.

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## Industry Trends

Policy / Market Trends

### Implications of Braidwood Management Inc. v. Becerra

A [recent analysis](#) by the Employee Benefit Research Institute assessed the impact of imposing cost sharing on the services and prescription drug classes **receiving an “A” or “B” recommendation from the USPSTF** if the Braidwood Management Inc. v. Becerra court case is upheld.

**Why this matters:** Their analysis found that if the Braidwood decision were to be upheld and employers reimposed cost sharing on preventive services that are currently free to enrollees, individuals using those services could face a significant increase in out-of-pocket spending. Although this potentially onerous financial burden could deter care on the individual beneficiary level and likely worsen health inequities, employers would see little impact on their overall spending.

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### CMS Health Equity Conference Takeaways

The Centers for Medicare & Medicaid Services Office of Minority Health (CMS OMH) hosted the inaugural [CMS Health Equity Conference](#) on June 7–8, 2023. The conference was an opportunity for CMS leadership to share foundational information about current initiatives and plans for the future. McDermott+ consulting shared [key takeaways](#) from the conference, including plenary and breakout sessions, poster presentations and specific initiatives, as CMS renews its commitment to achieve health equity.

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**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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