

Federal Issues

Legislative

House Passes Inflation Reduction Act

On Friday, the U.S. House of Representatives passed the [Inflation Reduction Act](#) by a vote of 220-207. The Senate passed the legislation earlier in the week and President Biden is expected to sign the bill into law.

The bill passed by the House does not make any substantial changes from the Senate-passed bill.

As previously reported, major health provisions in the bill include:

- Extending the Affordable Care Act tax credits expanded by the American Rescue Plan Act (ARPA) for 3 years, through 2025;
- Allowing Medicare to negotiate drug prices, with a focus on high-priced drugs in Part B and Part D;
- Additional 5-year extension of Rebate Rule moratorium through 2032;
- Capping insulin copays in Medicare at \$35 a month for plan years 2023-2025 and for 2026 and beyond, capping cost-sharing at the lesser

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of \$35 or 25% of the negotiated price (for 2023, HHS will provide a temporary, retrospective subsidy to plans);

- Capping annual maximum out-of-pocket costs for Part D beneficiaries at \$2,000;
- A redesign of the Part D benefit with initial coverage phase liabilities of 65% plan, 10% manufacturer, 25% beneficiary and catastrophic phase liabilities of 60% plan, 20% manufacturer, 20% government and 0% beneficiary.
- Free vaccines for all adults covered by Part D plans and Medicaid and CHIP enrollees;
- New safe harbor for high-deductible health plans that do not apply a deductible for insulin products.

The Congress is now in recess and is expected to return after Labor Day.

Federal Issues

Regulatory

FTC Initiates Rulemaking Process on Commercial Surveillance and Data Security

On Wednesday, the Federal Trade Commission (FTC) [issued](#) a sweeping advance notice of proposed rulemaking (ANPR) to “request public comment on the prevalence of commercial surveillance and data security practices that harm consumers.” Specifically, through a series of detailed questions, the FTC asks whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive.

Why this matters: A regulation, if finalized, could impact the health sector in significant ways by setting forth new standards for third parties who handle health data but are not regulated under HIPAA.

Comments to the ANPR are due 60 days after the notice is published in the Federal Register in the coming days. A public forum will be held on September 8, 2022.

CMS Released Updated Enrollment Manual

CMS published the 2022 FFE and FF-SHOP Enrollment Manual. Updates to this year's version, which largely reflect policy changes made in the 2023 Payment Notice, include:

- Information on the extension of the annual Open Enrollment Period (Section 2)
- A new section on Electronic Notice Requirements (Section 2.5)
- Additional information on changes to Special Enrollment Period (SEP) Verification, accelerated SEP effective dates, and the SEP for enrollees who are eligible for APTC and have household income that is at or below 150% of the Federal Poverty Level (FPL) (Section 6)
- Information on changes to guaranteed availability regulations in the 2023 Payment Notice (Section 7.3)
- Sample Plan Display Error notices added as appendices

Links:

- [2022 Enrollment Manual](#)
 - [Redlined 2022 Enrollment Manual](#)
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CDC Eases COVID-19 Guidelines for Testing and Isolation

The Centers for Disease Control and Prevention (CDC) updated COVID-19 [guidelines](#) related to [testing](#) and [isolation](#).

Why this matters: The agency no longer recommends individuals be screened or tested for COVID-19 infection in most settings. "When considering whether and where to implement screening testing of asymptomatic people with no known exposure, public health officials might consider prioritizing high-risk congregate settings, such as long-term care facilities, homeless shelters, and correctional facilities, and workplace settings that include congregate housing with limited access to medical care," the CDC wrote in a [report](#) explaining the changes.

The new guidance also relaxes isolation procedures for unvaccinated individuals. According to the CDC, unvaccinated people who have had close contact with someone infected with COVID-19 no longer have to isolate for 5 days if they have not shown symptoms or tested positive themselves.

HHS Awards \$60 Million for Rural Health Care Improvement & Nearly \$90 Million to Community Health Centers

On Monday, the U.S. Department of Health and Human Services (HHS) [announced](#) nearly \$60 million in awards for growing the health care workforce and increasing access to care in rural communities. \$46 million is allotted to support 31 awardees for health care job training, development, and placement within underserved rural communities. \$10 million will be distributed to 13 organizations to increase the number of physicians practicing in rural areas through medical residency programs. The remaining \$4 million is designated to support 18 awards in rural areas to improve health care quality and outcomes for rural

veterans. The specific programs receiving funding through the Health Resources and Services Administration (HRSA) are:

- The Rural Public Health Workforce Training Network Program is awarding nearly \$46 million to 31 community-based organizations to expand public health clinical and operational capacity through workforce development. Additionally, a technical assistance provider was awarded \$500,000 to strengthen the ability for these networks to develop formal training and certification programs.
- The Rural Residency Planning and Development Program is awarding \$9.7 million to 13 organizations to establish new rural residency programs in rural communities to train resident physicians in rural clinical settings.
- The Small Health Care Provider Quality Improvement Program is awarding \$2.9 million to 15 community-based organizations improve patient health outcomes and quality and delivery of care throughout rural counties.
- The Rural Veterans Health Access Program is awarding nearly \$1 million to 3 organizations to improve access to health care services for veterans living in rural areas. This program is a collaboration between FORHP and the Veterans Health Administration to strengthen partnerships between rural health providers and the VA system.

HHS also [announced](#) that close to \$90 million from the American Rescue Plan will be awarded to over 1400 community health centers. The awards, distributed through the Health Resources and Services Administration (HRSA), are to be used in the health centers to eliminate COVID-19 treatment inequities and outcomes within underserved communities. The funding also supports improving data quality; advancing COVID-19 response, mitigation, and recovery efforts; and helping prepare for future public health emergencies. Over 30 million Americans are treated a year by the 1400 community health centers that are receiving the funding.

Industry Trends

Policy / Market Trends

Court Dismisses Effort to Invalidate *No Surprises Act*

Judge Ann Donnelly of the U.S. District Court for the Eastern District of New York rejected an effort by a New York doctor's group to prevent enforcement of the *No Surprises Act*. That motion for a preliminary injunction was the first step in the plaintiff's broader effort to invalidate the law on various constitutional grounds. Relying on the same rationale it set forth in denying the plaintiff's request for an injunction, the court went on to then grant the government's request to dismiss the case.

Why this matters: While this particular lawsuit (*Haller v. HHS*) is just one of at least eight cases currently pending in federal courts throughout the country, **this decision represents a victory for ongoing efforts to protect patients from surprise bills while also lowering health care costs.**

The plaintiff argued the *No Surprises Act* violated their rights under the Seventh Amendment by denying them the ability to bring suit against patients to recover their billed out-of-network charges while also

violating their due process rights and amounting to an unconstitutional taking under the Fifth Amendment. The Court soundly rejected both the Seventh Amendment and takings claims, finding the new law does not violate any such constitutional rights. It dismissed both of those claims with prejudice. In addition, the court also found that because the plaintiff's alleged due process violations relied on provisions of the interim final rule (IFR) previously invalidated in a separate lawsuit filed in Texas federal court, those claims were not "ripe" for review. It went on to dismiss those due process claims without prejudice.

Next steps: Insurers are closely monitoring each of the cases challenging either the No Surprises Act itself or the IFRs implementing the same. We also continue to await issuance of a final rule, which is expected in the coming weeks.

The Coalition Against Surprise Medical Billing (CASMB) issued a [statement](#) on the *Haller* case. "The Coalition applauds the New York court for siding with patients and their families by dismissing one of the eight provider-backed lawsuits intended to chip away at these vital protections. It is critical the *No Surprises Act* law and rules remain in place to ensure no American has to face a surprise medical bill that could lead to financial ruin," the statement reads.

Ruling on *Pfizer v. HHS*

In the case of *Pfizer v. United States Department of Health and Human Services (HHS)*, the Court upheld HHS's longstanding interpretation that the federal Anti-Kickback Statute prohibits drug manufacturers from providing patients in federal programs financial incentives to purchase their products.

AHIP issued the following statement in response: "Drug manufacturers alone set and control the launch price and every price increase for the prescription drugs they sell. The Anti-Kickback Statute is an essential protection against the risk of fraud, waste, and abuse that otherwise allows drug manufacturers to subsidize patients' up-front costs to induce purchases of their products. By upholding these protections, the courts have taken an important step to protect Americans from what would otherwise be an unchecked multi-billion-dollar price tag that would make coverage and care less affordable for everyone."

AHIP filed an [amicus brief](#) in *Pfizer v HHS*.

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.

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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