

Federal Issues

Legislative

Senate Democrats Prepare Slimmed Down Reconciliation Bill

After talks broke down on a reconciliation package involving health care, climate and taxes late last week, Senate Majority Leader Chuck Schumer (D-NY) announced his intention to bring to the Senate floor a "health care only" package that combines a two-year extension of the enhanced Affordable Care Act (ACA) tax credits enacted under the American Rescue Plan (ARPA) and [drug pricing reform](#) -- including Medicare negotiations and Part D restructuring. Adding to the momentum, Sen. Joe Manchin (D-WV), who has been the swing vote in the Senate, has confirmed that he would support the narrow health care only package and President Biden also [indicated support](#).

Why This Matters: Once a foregone conclusion, the legislation formerly known as Build Back Better has been stalled since last fall. With the enhanced ARPA subsidies expiring at the end of the year, those enrolled in the individual market could see premiums rise by 53%, on average, next year. More than 14 million people will face a staggering \$12 billion cost increase and estimates suggest 3.1 million would become uninsured next year if the subsidies aren't extended, according to a [Families USA report](#).

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Next steps: The legislation will undergo review by the Senate parliamentarian later this week to determine if all the provisions comply with the rules of budget reconciliation. The intent is to vote on the legislation the first week in August. With the House leaving for recess at the end of July, timing of a vote in that chamber is unclear.

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House GOP Task Force Releases Health Care Affordability Proposals

The U.S. House Republican [Healthy Future Task Force](#) Subcommittee on Affordability released a [set of proposals](#) aimed at lowering health care costs. The reform ideas focus on health care for employees and small businesses, price transparency, and competition.

Why This Matters: The document provides a window into the type of legislation that may be advanced by a GOP majority in a future Congress.

Notable recommendations include:

- Making Health Savings Accounts (HSAs) accessible to more people;
- Allowing small business owners to join together through Association Health Plans;
- Removing barriers for employers to participate in advanced payment initiatives such as direct contracting, high performance networks, and centers for excellence for purchasing health care;
- Codifying Trump Administration rules that require hospitals, insurers, and middlemen to disclose cost information;
- Implementing the Advance Explanation of Benefits (AEOB);

- Empowering states to lift burdensome regulations that require “cookie-cutter coverage;”
 - Building upon the Trump administration’s site-neutrality rules 1) ensure CMS pays the same Medicare rates for drugs and clinic visits at physician offices and hospitals, 2) reform the inpatient-only list, and 3) end inappropriate billing practices
 - Repealing the moratorium on physician-owned hospitals; and
 - Conducting Congressional oversight of the Federal Trade Commission to ensure it is correctly utilizing its statutory authority to investigate harmful consolidation and promote competition.
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Federal Issues

Regulatory

HHS Renews COVID-19 Public Health Emergency Declaration Through October

The Department of Health and Human Services (HHS) Secretary Xavier Becerra [renewed](#) the COVID-19 public health emergency (PHE) declaration for an additional 90 days. The PHE is now set to expire on October 13, 2022, unless the HHS Secretary renews the emergency.

HHS will provide state officials and health care stakeholders at least 60-days notice before ending the PHE. The 60-day deadline notice date is now August 13, 2022.

HHS Issues Guidance Clarifying Existing Requirements for Emergency Abortion Services

The Department of Health and Human Services (HHS) issued new [guidance](#) and [provider communications](#) to clarify existing requirements for emergency abortion services under the Emergency Medical Treatment and Active Labor Act (EMTALA).

The guidance reaffirms the existing law in the following areas:

- **Federal preemption:** The guidance states that state law is preempted when it prohibits abortion without exception for life of the pregnant person or draws exceptions more narrowly than EMTALA, and that providers are protected when offering legally-mandated, life- or health-saving abortion services in emergency situations.
- **Examples covered under EMTALA:** An emergency medical condition under EMTALA is determined by the examining physician or qualified medical personnel and may include a condition that is likely or certain to become emergent without stabilizing treatment. The guidance lists examples of emergency medical conditions involving pregnant patients which may include, but are not limited to, ectopic pregnancy, complications of pregnancy loss, or emergent hypertensive disorders, such as preeclampsia with severe features.
- **Stabilization requirements:** EMTALA requires that hospitals provide an appropriate medical screening examination to determine whether an emergency medical condition exists, or whether the person is in labor. If so, the hospital must provide available stabilizing treatment or an appropriate

transfer to a hospital with such capabilities. The guidance asserts that if a physician believes that a pregnant patient is experiencing an emergency medical condition as defined by EMTALA and that abortion is the stabilizing treatment necessary to resolve that condition, the physician must provide that treatment.

The full HHS press release can be read [here](#).

OCR Issues Guidance to Retail Pharmacies on Access to Reproductive Health Care Services

The Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) issued [guidance](#) on Wednesday to retail pharmacies regarding their obligations under existing federal civil rights laws to ensure access to reproductive health care services. A press release is available [here](#).

The guidance details that under current law, including Section 1557 of the *Affordable Care Act* and Section 504 of the *Rehabilitation Act*, recipients of federal financial assistance, such as pharmacies, are prohibited from excluding, denying benefits, or discriminating against individuals on the basis of sex and/or disability, including basis of pregnancy or related conditions, in their programs or activities. Pregnancy discrimination includes discrimination based on current pregnancy, past pregnancy, potential or intended pregnancy, and medical conditions related to pregnancy or childbirth. The guidance specifically mentions activities such as supplying medications, making determinations regarding suitability of prescribed medication, or advising patients about medications and how to take them.

The guidance also details several examples of potential scenarios where pharmacies may be considered to discriminating on the basis of sex or disability, such as refusing to fill prescriptions needed to manage miscarriage or complications from pregnancy loss because these medications can also be used to terminate a pregnancy or otherwise providing contraceptives but refuse to fill a certain type of contraceptive because it may prevent a pregnancy.

The guidance does not address application of the Church Amendments, which protect health care personnel from discrimination related to their employment because they perform or assist in abortion or sterilization or refuse to perform or assist in abortion or sterilization because of their religious beliefs or moral convictions. OCR will evaluate and apply them on a case-by-case basis.

OCR encourages individuals who believe their or another person's civil rights, conscience rights, or health information privacy rights have been violated to file a complaint through the [OCR portal](#).

White House Outlines Strategy to Manage the BA.5 Subvariant

The White House announced its new [strategy](#) to manage BA.5, the subvariant of the Omicron COVID-19 variant. At a briefing, Centers for Disease Control and Prevention (CDC) Director Dr. Rochelle Walensky [stated](#) that BA.5 accounts for about 65% of U.S. COVID-19 cases, while the closely-related BA.4 subvariant makes up about 16% of infections.

The White House strategy includes:

- **Making COVID-19 testing widely available**, including at-home tests. The Administration highlighted in their strategy how health insurance providers are covering the cost of at-home tests.
- **Ensuring access to treatment** by working with government officials, local leaders, and health care stakeholders to boost awareness of lifesaving treatments, particularly in areas where BA.5 is spreading.
- **Making it easy to get vaccines and boosters** for those who need it.
- **Making free high-quality masks widely available** and communicate clear recommendations about when people should consider masking.
- **Prioritizing protections for immunocompromised individuals**, including initiating a communications campaign to ensure immunocompromised people are up to date on vaccines.

The Administration also highlighted the [COVID.gov](https://www.covid.gov) website to help Americans find where to access lifesaving tools like vaccines, tests, treatments, and masks.

FDA Authorizes EUA of Novavax COVID-19 Vaccine

On Wednesday, the U.S. Food and Drug Administration [issued an emergency use authorization](#) (EUA) for the Novavax COVID-19 Vaccine, Adjuvanted for individuals 18 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response. The vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. Overall, the vaccine was 90.4% effective in preventing mild, moderate or severe COVID-19 and for the subset of participants 65 years of age and older, the vaccine was 78.6% effective. The clinical trial was conducted prior to the emergence of delta and omicron variants.

Proposed Rule: 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1770)

On July 7, CMS [released](#) the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Proposed Rule and fact sheet. CMS also shared fact sheets on the [CY 2023 Quality Payment Program](#) proposed changes and [Medicare Shared Savings Program proposals](#). Lastly, CMS also published a [blog post](#) on the proposed behavioral health changes. Below are our key takeaways:

- **There are no MA specific provisions in this Proposed Rule.** However, CMS did note they are considering policy and program levers can advance health information exchange under the Trusted Exchange Framework and Common Agreement (TEFCA). Specifically, they are interested in opportunities to encourage exchange under TEFCA through CMS regulations for payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. We expect this to be first addressed by CMS in the “Interoperability and Prior Authorization (CMS-0057)” proposed rule targeted for release in September.

- **CY 2023 PFS Rate Setting and Conversion Factor.** The proposed CY 2023 conversion factor is \$33.08, a decrease of \$1.53 from the CY 2022 PFS conversion factor of \$34.61. This includes the required budget neutrality adjustments and the required statutory update to the conversion factor for CY 2023 of 0%. The conversion factor is lower due to the expiration of the one-year 3% increase in CY 2022 mandated by the Protecting Medicare and American Farmers from Sequester Cuts Act.
- **Medicare Shared Savings Program** – CMS makes several technical proposals [summarized here](#). Of interest to MA plans is the commentary on HCC risk model coding intensity. CMS is proposing a positive 3 percent cap (after accounting for changes in demographic risk scores) similar to the risk score cap for the ACO Reach Program. CMS believes that *“ACOs would be much less likely to have prospective HCC risk ratios for ESRD, disabled, and aged/dual eligible Medicare enrollment types capped under this proposed policy which would improve the incentives for treating these medically complex, high-cost populations. At the same time, we [CMS] believe that this proposed policy would continue to be protective of the Trust Funds by continuing to limit incentives for coding intensity.”*

Provisions important to hospitals:

- CMS recently released proposals related to conditions of participation for its new provider type, Rural Emergency Hospitals (REH). In this proposed rule, payment policies and provider enrollment procedures have been put forth. Covered outpatient department services provided by REHs will receive an additional 5 percent payment for each service. REHs also will receive a monthly facility payment. After the initial payment is established in CY 2023, the payment amount will increase in subsequent years by the hospital market basket percentage increase.
- The rule also proposes to restore the Medicare outpatient payment to average sales price plus 6 percent for CY 2023 following the unanimous ruling in the American Hospital Association’s 340B Supreme Court case. CMS is seeking comment on potential remedies for prior year cuts.
- Additionally, the rule includes proposals related to:
 - Inpatient only list
 - Behavioral health services
 - Rural Sole Community Hospital exemptions
 - Organ procurement and research
 - Hospital Outpatient Quality Reporting, Ambulatory Surgical Center Quality Reporting, and Rural Emergency Hospital Quality Reporting Programs

Comments are due September 5, 2022.

State Issues

Pennsylvania

Legislative

Governor Signs CHIP Choice Legislation

On Monday, July 11, the Governor signed [Senate Bill 1235](#) (DiSanto, R-Dauphin). Senate Bill 1235 would prohibit the Pennsylvania Department of Human Services from developing or utilizing bidding or service zones that limit a health service corporation or hospital plan corporation contractor from submitting a bid for CHIP. Senate Bill 1235 is Act 94 of 2022.

Regulatory

Governor Wolf Issues Reproductive Health Care Order

Governor Wolf last week signed an executive order focused on protections for reproductive health care providers and out-of-state residents seeking care in Pennsylvania.

The executive order follows the U.S. Supreme Court's recent opinion overturning Roe v. Wade and addresses the following issues:

- **Out-of-state investigations:** Governor Wolf and state agencies will decline requests from other states to issue warrants for the arrest of a person related to the provision, receipt of, or assistance with reproductive health care services unless the criminal charges also are a criminal offense under Pennsylvania law
- **Health care licensing:** State agencies are directed to work with professional licensing boards to consider the need for policies to protect reproductive health care providers from discipline related to out-of-state health care laws—as long as the services provided are lawful and consistent with standards for good professional practice in Pennsylvania
- **Communication:** The order directs state agencies to provide the public with information related to reproductive health, access to care, and education about patient information stored or accessed on personal devices

The executive order is available to review [online](#).

Why This Matters: Pennsylvania has joined New York, New Jersey, and Connecticut in offering protections for out-of-state women seeking reproductive health services, including abortion. While abortion remains legal in these states, reproductive health-care providers expect an influx of out-of-state patients from places where abortion is banned. Experts say these protections help reassure providers and patients from states that might try to intervene with their residents' attempts to travel elsewhere for treatment.

The executive order and its protections are set to take immediate effect. But unlike some states that have passed so-called safe-haven laws through their legislatures, Pennsylvania only has an executive order.

Industry Trends

Policy / Market Trends

CBO Scores Medicare Rx Proposal

The Congressional Budget Office (CBO) [released](#) an estimate on the budgetary effects of reconciliation [recommendations](#) for prescription drug legislation. The estimate projects allowing Medicare to negotiate directly with drug companies for lower prices would generate billions in savings and new revenue over ten years of implementation.

Key Stats: The CBO “estimates that enacting this legislation would result in a net decrease in the unified deficit totaling \$287.6 billion over the 2022-2031 period, including \$100 billion in savings from granting the HHS Secretary the ability to negotiate drug prices under Medicare, \$100 billion in savings for creating inflation rebates for drugs under Medicare Part B and Part D, and \$25 billion in costs to redesigning the Part D benefit. That decrease in the deficit would result from a decrease in direct spending of \$249.2 billion and an increase in revenues of \$38.4 billion.”

New Cost Estimate: CBO Releases Score for Insulin Cap Legislation

The Congressional Budget Office (CBO) released a [report](#) detailing the estimated budgetary effects of the Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act.

- **Why This Matters:** The [INSULIN Act](#), led by Sens. Jeanne Shaheen (D-NH) and Susan Collins (R-ME), would place a monthly cap on selected insulin products of the lesser of \$35 or 25% of the negotiated price for patients with private insurance as well as those enrolled in Medicare Part D.
 - **Key Takeaways:** CBO estimates the bill, as written, **would increase federal spending by \$23.3 billion from 2022-2032**. AHIP has expressed concerns with the current text of the legislation, including operational concerns, an unfeasible effective date, and uncertainties in the legislative language.
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Registration for the 2022 CMS National Training Program (NTP) Virtual Workshops Is Open

Session dates relevant to MA and Part D are listed below.

- **Aug. 2: [Social Security](#).** This workshop will explain retirement, disability, supplemental security income, and survivors benefits and how they can affect Medicare.
- **Aug. 4: [Medicare Supplement Insurance \(Medigap\)](#).** This workshop will discuss how Medicare Supplement Insurance policies (also known as Medigap) work with Medicare, what Medigap policies cover, how they're structured, and when to buy a Medigap policy.
- **Aug. 9: [Medicare Drug Coverage](#).** This workshop will explain drug coverage under the different parts of Medicare and describe how Medicare drug coverage (Part D) works, coverage rules, eligibility, enrollment, and Extra Help.
- **Aug. 10: [Medicare Advantage](#).** This workshop will explain Medicare health plan options other than Original Medicare with a primary focus on Medicare Advantage (sometimes called Medicare Part C).

- **Aug. 11: [Preventing Medicare & Medicaid Fraud, Waste, & Abuse](#).** This workshop will define health care fraud, waste, and abuse, identify causes of improper payments, and discuss the processes and organizations in place to prevent and detect Medicare and Medicaid fraud.
 - **Aug. 16. [Coordination of Benefits](#).** This workshop will explain different payers' responsibilities when people have both Medicare and certain other types of health and/or prescription drug coverage.
 - **Aug. 17. [Where Do I Find? \(Online Resources\)](#).** This workshop will identify key websites, like Medicare.gov, associated resources, and tools to help partners, stakeholders, not-for-profit professionals, and volunteers (who work with consumers and their families) help others make informed health care coverage decisions.
 - **Aug. 23: [Medicare Scenarios \(Casework Session\)](#).** This workshop will walk through examples of Medicare coverage scenarios in a casework format to evaluate the case, review possible resources and options, and discuss appropriate solutions.
 - **Aug. 24: [CMS and SAMHSA: Federal Partners addressing Behavioral Health](#).** This workshop will outline CMS' Behavioral Health Strategy which covers multiple elements including access to prevention and treatment services for substance use disorders, mental health services, crisis intervention, and pain care. The Workshop will also include program updates from the Substance Abuse and Mental Health Services Administration (SAMHSA).
 - **Aug. 30: [Medicare Current Topics](#).** This workshop will explain some of CMS' current priorities, initiatives, and recent programmatic updates.
 - **Aug. 31: [The Public Health Emergency \(PHE\) and CMS Programs \(this topic is subject to change\)](#).** This workshop will explain temporary flexibilities to CMS Programs in response to the Public Health Emergency (PHE) declaration for COVID-19, coverage for COVID-19-related treatments, vaccination efforts, and transition activities to prepare for the end of the PHE.
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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.

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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