

## Federal Issues

### Regulatory

#### Public Health Emergency Extended Until Mid-April

On Jan. 11, the Department of Health and Human Services (HHS) Secretary Xavier Becerra [extended](#) the COVID-19 Public Health Emergency (PHE) for an additional 90 days, until mid-April.

**Why this matters:** Many policies and flexibilities waiving or requiring certain actions in response to the pandemic's effect on health care delivery are contingent on the public health emergency, though congressional and administrative actions have made that universe of policies smaller with extending certain actions for a temporary period regardless of when the PHE ends. For example, Congress in the omnibus gave state Medicaid agencies flexibilities to begin disenrolling individuals who are no longer eligible on April 1, 2023, and several telehealth flexibilities under the Medicare program are in place by statute through 2024.

**Next steps:** The Biden administration has consistently promised stakeholders it will give notice at least 60 days in advance of the expiration date of the PHE. With a recent uptick in COVID cases and a new variant

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becoming dominant, it remains possible for the Administration to renew the PHE again.

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## **CMS Announces Key Dates for the First Year of the Inflation Reduction Act's Medicare Drug Price Negotiation Program**

CMS [announced](#) initial plans and related timeframes for implantation of the drug pricing negotiation provisions in the Inflation Reduction Act (IRA). A full timeline can be found [here](#). Key dates include:

- By September 1, 2023, CMS will publish the first 10 Medicare Part D drugs selected for the Medicare Drug Price Negotiation Program
- The negotiated maximum fair prices for these drugs will be announced by September 1, 2024, and prices will be in effect starting January 1, 2026
- In future years, CMS will select for negotiation 15 more Part D drugs for 2027, 15 more Part B or Part D drugs for 2028, and 20 more Part B or Part D drugs for each year after that, as outlined in the IRA

Interestingly, the calendar does not reflect an intent by CMS to conduct extensive rulemaking regarding this process, suggesting CMS will look to adhere closely to the directives given to it by Congress. This is consistent with remarks made by White House officials regarding this aspect of the IRA's implementation. However, CMS states it will "provide additional information in the future related to any program guidance or rulemaking for initial price applicability years 2027 and beyond."

In related news, on Jan. 13, CMS hosted their monthly Medicare Parts C & D User Group call, where they made the following clarifications:

- The list of drugs qualifying for Part B rebatable drugs can change every quarter
- For the insulin special enrollment period (SEP), customer service representatives for 1-800-Medicare can provide general Medicare information, help beneficiaries identify options in their

areas and understand the differences between plans, and assist with enrollment and disenrollment. Beneficiaries must call 1-800-Medicare to utilize the SEP and process enrollment. Plan sales agents can provide information on plan benefits and options, but members must call the Medicare line to complete the enrollment.

- CMS clarified that \$0 cost-sharing for vaccines under the IRA does not apply to pediatric vaccines. The IRA only applies to vaccines licensed as adult vaccines and administered to an adult.

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## **CMS Requests Feedback on ACA Essential Health Benefits Policies**

On Dec. 2, CMS [released a Request for Information](#) (RFI) to solicit public comment on a variety of issues related to Essential Health Benefits (EHB) under the Affordable Care Act (ACA).

**Background:** EHB is a central component of the ACA’s reforms to make comprehensive coverage more widely available by identifying the 10 benefit categories that are “essential” to individual and small group comprehensive health insurance. EHBs are also used by employer plans to calculate eligible member cost sharing that is applied to a member’s deductible and out-of-pocket limit. The Obama administration gave states the authority to choose the EHB-benchmark plan that serves as a reference plan for the products offered in the state and is intended to equal the scope of benefits under a “typical employer plan.”

**Why this matters:** The RFI notes that the benchmark plan as described in coverage documents is not always detailed, creating ambiguity and variance in the specific features of the benefits, including the amount, duration and scope of benefits. As time has passed, with the exception of some mental health and substance use disorder benefits that a handful of states have enhanced in their EHB designs, the EHB-benchmark plans have not kept pace with benefits that are supported by evolving clinical practice (e.g., silver diamine fluoride, doula and midwife services). The RFI also requests feedback about the existing flexibilities issuers have to substitute within an EHB category (with the exception of prescription drugs), and even across EHB categories—flexibilities that have not been adopted, to CMS’s knowledge. With respect to the EHB category of prescription drugs, the RFI considers whether CMS should switch the current drug classification system of the USP Guidelines to the USP Drug Classification (DC) system which is updated annually.

Comments on the RFI are due January 31.

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## **CMS Updates Guidance to States on Engaging Managed Care Plans to Maximize Continuity of Coverage**

The Centers for Medicare & Medicaid Services (CMS) released an updated guidance document outlining strategies for states to engage their Medicaid managed care plans to maximize continuity of coverage for enrollees after eligibility redeterminations resume. The updated deck provides new examples and scenarios of ways health plans can engage with states and beneficiaries to support continuity of coverage during the unwinding of the public health emergency. [Read More](#)

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## **Nearly 16 Million People Have Signed Up for Affordable Health Coverage in ACA Marketplaces Since Start of Open Enrollment Period**

The Biden administration announced about 15.9 million people have selected an Affordable Care Act (ACA) Marketplace health plan nationwide since the start of the 2023 Marketplace Open Enrollment Period (OEP) on November 1. This represents activity through January 7, 2023 (Week 10) for the 33 Marketplaces using [HealthCare.gov](https://www.healthcare.gov) and through December 31, 2022 (Week 9) for the 18 State-based Marketplaces (SBMs) in 17 states and the District of Columbia that are using their own eligibility and enrollment platforms. An enrollment snapshot fact sheet can be found [here](#). Additionally, 2023 enrollment was 16% higher in exchange plans than in 2022.

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### **FTC Proposes Rule to Ban Non-Compete Clauses**

The Federal Trade Commission [proposed a new rule](#) that would ban U.S. employers from imposing non-compete clauses on their workers. According to the FTC, non-compete clauses are a widespread and often exploitative practice that suppresses wages, hampers innovation, and blocks entrepreneurs from starting new businesses. By stopping this practice, the agency estimates that the new proposed rule could increase wages by nearly \$300 billion per year and expand career opportunities for about 30 million Americans.

In a [statement](#), the agency said the rule would apply to employees, independent contractors, and anyone who works for an employer. The rule also would rescind non-compete agreements currently in effect. The proposed rule would not apply to other types of employment restrictions, such as non-disclosure agreements.

The agency said its new rule would make it illegal for an employer to:

- Enter into or attempt to enter into a non-compete with a worker
- Maintain a non-compete agreement with a worker
- Represent to a worker that the worker is subject to a non-compete

**The agency will seek public comment on the proposed rule through March 10, 2023.**

**Why this matters:** Initial comment from the hospital industry regarding the proposed rule is that government should not dictate contractual agreements between an employer and prospective employee, and opposes policies and regulations that would override these agreements. Both the Hospital and Healthsystem Association of Pennsylvania (HAP) and the American Hospital Association (AHA) will be coordinating to develop and submit comments on this important proposed rule.

Additional information about the [proposed rule](#) is available to review [online](#).

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### **Hospitals Disappointed as Federal District Court Places HHS in Charge of 340B Repayment**

A federal court on January 10, 2023 [decided to allow](#) the U.S. Department of Health and Human Services (HHS) to propose an appropriate remedy for its past underpayments to hospitals participating in the 340B Drug Pricing Program.

**Background:** After a [unanimous victory](#) for hospitals in the U.S. Supreme Court last summer, the D.C. court ordered HHS to halt its unlawful 340B cuts for the remainder of 2022. In the [outpatient prospective payment system \(OPPS\) final rule](#) for calendar year (CY) 2023, the agency said it would defer any proposal of a remedy for CYs 2018–2021 until sometime before its CY 2024 payment rule, and in subsequent legal filings, the agency stated that it intends to announce a final remedy before the 2024

OPPS rulemaking cycle is complete next fall. Hospitals were hopeful that the court would require the agency to act much quicker.

American Hospital Association (AHA) General Counsel and Secretary Melinda Hatton [said](#), “For more than five years, the Department of Health and Human Services has unlawfully withheld vital funding from 340B hospitals that helps them provide a range of important benefits to their patients and communities. We are disappointed that the district court elected to extend this delay by remanding this case back to the department to determine the appropriate remedy.”

**Why this matters:** In June, the US Supreme Court ruled unanimously that it was illegal for the Trump administration to cut payment rates for drugs acquired through the 340B program, and ordered it to pay back billions to hospitals.

But 340B hospitals are still waiting for the payments to be returned to them. Hospitals had asked the U.S. District Court for the District of Columbia to vacate the rules and dictate terms of repayment to the HHS.

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## **CMS Awards 200 New Medicare-funded Residency Slots to Hospitals**

The Centers for Medicare & Medicaid Services (CMS) last week awarded the first 200 of 1,000 Medicare-funded physician residency slots to enhance the health care workforce and support positions in hospitals serving underserved communities.

The [Fiscal Year \(FY\) 2022 Inpatient Prospective Payment System \(IPPS\) final rule](#) established policies to implement 1,000 new Medicare-funded physician residency slots to qualifying hospitals, phasing in 200 slots per year over five years. About 75 percent of the new positions will be for primary care and mental health specialties, the agency said.

CMS said it prioritized hospitals with training programs in geographic areas demonstrating the greatest need for additional providers.

The application period for the second round of 200 residency positions will open during January 2023 and close on March 31, 2023. Additional information about the CMS announcement is available [online](#).

**Why this matters:** These graduate medical education residency slot awards will help address access to care challenges and workforce shortages in the highest need areas.

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## **State Issues**

### **New York**

Legislative

#### **Pharmacy Legislation in Committee**

The following bills related to pharmacy are on committee agendas this week and are expected to advance:

- **Drug price increase notice (S.599)** — Requires drug manufacturers to provide at least 60 days’ notice of their intention to raise the cost of a drug more than 10%.

- **Insulin copay cap (S.504)** — Caps copayments for a 30-day supply of insulin medication at \$30.
  - **Anti-step therapy (S.1276/A.901 )**— Restricts health plans' use of step therapy protocols.-
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## **Governor outlines Health Care Priorities in State of the State Address**

In her State of the State address, Gov. Hochul highlighted several health care initiatives she aims to accomplish in the 2023 legislative session. Included are drug price transparency, expanded access to primary care and mental health services, enhanced Essential Plan coverage, and establishment of a commission to transform the health care system. Not in the speech, but in written material, is mention of creation of a health guaranty fund and increased oversight to improve hospital discharge planning.

More details will be forthcoming in the Governor's proposed budget, set to be released on Feb. 1.

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## Regulatory

### **Medicaid Redeterminations to Start in April**

The Department of Health notified plans that it will restart the process of Medicaid renewals on April 1, 2023, with a process that will take 14 months to complete. Renewal dates will align with members' pre-established renewal dates prior to the start of the PHE for the members who were previously Medicaid eligible. For members who first became eligible for Medicaid during the PHE, the renewal date will be the same month that they became enrolled. In upstate, local districts will begin sending notices to members at the end of April for June 2023 end dates.

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## **State Issues**

### **Pennsylvania**

Legislative

### **Shapiro's Health Cabinet Takes Shape**

Governor Josh Shapiro last week announced nominations for five key health leadership positions in his administrative cabinet.

Shapiro said his nominees brought decades of public health experience to their roles and would help ensure Pennsylvanians had "access to quality, affordable health care and a social safety net that is there for them in times of need."

### **Dr. Valerie Arkoosh - Secretary of the Department of Human Services**

Dr. Valerie Arkoosh served as Professor of Clinical Anesthesiology and Clinical Obstetrics and Gynecology at the Perelman School of Medicine of the University of Pennsylvania. Dr. Valerie Arkoosh also served as Chair of Montgomery County Board of Commissioners since 2016.

### **Dr. Debra L. Bogen - Secretary of Health**

Dr. Debra Bogen served as Director of the Allegheny County Health Department since 2020. Prior to her appointment, Dr. Debra Bogen was a member of the Pittsburgh region medical and research community for more than two decades. She held a primary academic appointment as Professor of Pediatrics at the University of Pittsburgh, and secondary appointments in psychiatry and clinical and translational science. Dr. Debra Bogen also served as the Vice Chair of Education for the Department of Pediatrics at UPMC Children's Hospital of Pittsburgh.

### **Dr. Latika Davis-Jones - Secretary of Drug and Alcohol Programs**

Dr. Latika Davis-Jones served as Senior Director of Behavioral Health at Highmark Wholecare. She has focused on the physical and behavioral health needs of vulnerable populations for the past 25 years. Prior to joining Highmark Wholecare, Dr. Latika Davis-Jones was responsible for the organization, implementation, and coordination of drug and alcohol services at the Allegheny County Department of Human Services.

### **Jason Kavulich - Secretary of Aging**

Jason Kavulich served as the Lackawanna County Area Agency on Aging Director since 2016. Jason Kavulich had worked as a case worker and manager at Lackawanna County's Office of Youth and Family Services for 17 before being named county Area Agency on Aging Director.

### **Michael Humphreys - Insurance Commissioner**

Michael Humphreys currently serves as Acting Insurance Commissioner since 2022, appointed under the Wolf Administration. Prior to being appointed, Michael Humphreys served as the Chief of Staff for the Insurance Department since 2019. Before joining the Insurance Department, Michael Humphreys served as Assistant Commissioner for Insurance at the Tennessee Department of Commerce and Insurance (TDCI). Michael Humphreys previously worked for the National Council of Insurance Legislators (NCOIL), serving as the legislative organization's Director of State-Federal Relations from 2007 until 2012.

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## **State Issues**

### **West Virginia**

Legislative

### **West Virginia Legislative Session Begins; Health Care Bills Introduced**

The 2023 Regular Session of the West Virginia Legislature convened on Wednesday, January 11 for its 60-day term ending Saturday, March 11 at midnight. Following the November General Election, Republicans have now completely flipped the political script in the state from the Democrats in less than two decades ago by holding "ultra" majorities of 88-12 in the House of Delegates and 31-3 in the State Senate.

There has already been an unprecedented level of legislative activity in the health issues space over just the first three days of the 2023 legislative session. Close to 700 bills have already been introduced and the Senate has already taken action on the complex and controversial issues associated with the reorganization of the Department of Health and Human Resources and the financing of the Public Employee Insurance Agency.

**Prior Authorization:** In addition, a draft bill was circulated proposing dramatic modifications to the statutes affecting prior authorizations by health plans—an initiative being strongly pushed by the West Virginia Hospital Association and Senate Majority Leader, Dr. Tom Takubo. House Health Chair Amy Summers introduced her version of the prior authorization bill (HB 2535) and it is solely referred to her committee—meaning it could be on a fast track to the floor of the House.

**Prescription Drug Pricing Bills:** And, as expected since both were major issues in 2022, proposals to eliminate the so-called practice of “white bagging” with regard to certain specialty pharmacy products (**HB 2429**) and to lower to current insulin and related device costs to match the recent changes in Medicare (**HB 2430**) were both introduced on the first day and can be expected to receive prompt attention in the House of Delegates.

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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