



H&K Health Dose: February 14, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week the HELP Committee and Senate Commerce Will Hold Hearings

The U.S. House of Representatives is in recess the next two weeks. The U.S. Senate is scheduled to be on recess next week, but committee work continues. This week, the Senate Committee on Health, Education, Labor and Pensions (HELP) will hold its first hearing to examine health workforce shortages. The Senate Committee on Commerce, Science, and Transportation hearing will convene a full committee hearing on accountability to pharmacy benefit managers (PBMs).

The Final PHE Renewal

The U.S. Department of Health and Human Services (HHS) [renewed](#) the COVID-19 public health emergency (PHE) for 90 days on Feb. 10, 2023, and told [states](#) to expect the PHE and certain flexibilities to end May 11, 2023. This is consistent with the Biden Administration's [plan](#) to end the COVID-19 national and public health emergencies on May 11, 2023. The announcement has already begun a flurry of activity from the administration to address and clarify how to transition temporary policy changes that were put in place during the PHE and are set to expire with it. Centers for Medicare & Medicaid Services (CMS) [has already updated](#) more than a dozen provider-specific fact sheets, providing guidance and information on certain waiver end dates to physicians, hospitals, long-term care facilities, inpatient rehabilitation facilities, federally qualified health centers, laboratories and Medicare Advantage and Part D plans, among others.

President Joe Biden Delivers State of the Union

The House and Senate met in a joint session of Congress the evening of Feb. 7, 2023, to receive President Joe Biden's [State of the Union address](#). The State of the Union covered a handful of healthcare priorities. Of note, President Biden touted preventing millions of dollars in surprise bills and addressing non-competes. He also intends to crack down on the misuse of COVID-19 relief funds and high prescription drug costs. During his address, he urged Congress to make permanent the healthcare premium tax credits that will expire after 2025 without congressional action and touted this year's record enrollment numbers under the Affordable Care Act (ACA). Other noteworthy items include calls for improving mental health services and access, preventing veteran suicides and reigniting the cancer moonshot. Although the president called on Congress to support his priorities, the reality is that, with a split Congress, it remains to be seen how productive this session will be. The president's full remarks, as prepared for delivery, can be reviewed on the [White House website](#).

Senate Judiciary Committee Advances Bipartisan Bills to Lower Prescription Drug Costs

On Feb. 9, 2023, the Senate Committee on the Judiciary reported five bills that are designed to lower prescription drug prices. The bills are:

- **S. 79, Interagency Patent Coordination and Improvement Act of 2023**, to establish an interagency task force between the U.S. Patent and Trademark Office (USPTO) and the U.S. Food and Drug Administration (FDA) for purposes of sharing information and providing technical assistance with respect to patents
- **S. 113, Prescription Pricing for the People Act of 2023**, as amended, to require the Federal Trade Commission (FTC) to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations



- **S. 142, Preserving Access to Affordable Generics and Biosimilars Act**, as amended, to prohibit brand-name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products
- **S. 148, Stop Significant and Time-Wasting Abuse Limiting Legitimate Innovation of New Generics Act (Stop STALLING Act)**, as amended, to enable the FTC to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and to facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns
- **S. 150, Affordable Prescriptions for Patients Act of 2023**, to amend the FTC Act to prohibit product hopping

Senate Finance Health Subcommittee Chair Announced

Senate Committee on Finance Chairman Ron Wyden (D-Ore.) recently announced that Sen. Ben Cardin (D-Md.) will chair the Committee's Subcommittee on Health Care. Sen. Cardin is a strong supporter of increasing telehealth access, expanding Medicare benefits and improving preventative care. Sen. Steve Daines (R-Mont.) will continue to serve as the subcommittee's Ranking Member for the 118th Congress.

Other Senators tapped to serve on the subcommittee are as follows:

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| ■ Debbie Stabenow (D-Mich.) | ■ Chuck Grassley (R-La.) |
| ■ Bob Menendez (D-N.J.) | ■ John Thune (R-S.D.) |
| ■ Tom Carper (D-Del.) | ■ Tim Scott (R-S.C.) |
| ■ Bob Casey (D-Pa.) | ■ Bill Cassidy (R-La.) |
| ■ Mark Warner (D-Va.) | ■ James Lankford (R-Okla.) |
| ■ Sheldon Whitehouse (D-R.I.) | ■ Todd Young (R-Ind.) |
| ■ Maggie Hassan (D-N.H.) | ■ John Barrasso (R-Wyo.) |
| ■ Catherine Cortez Masto (D-Nev.) | ■ Ron Johnson (R-Wis.) |
| ■ Elizabeth Warren (D-Mass.) | ■ Marsha Blackburn (R-Tenn.) |

REGULATORY UPDATES

Court Vacates Provisions of No Surprises Act Final Rule

Last week, a federal judge for the U.S. District Court for the Eastern District of Texas dealt providers a win when he ruled that part of the independent resolution (IDR) process established under the No Surprises Act (NSA) should be vacated. The judge ruled in favor of a state medical group's motion for summary judgment challenging part of an interim final rule the HHS, U.S. Department of Labor and the U.S. Department of the Treasury released about the qualifying payment amount (QPA).

The lawsuit challenged the requirement that IDR entities use the closest out-of-network rate to the QPA when arbitrating a payment dispute. The QPA is the health plan or issuer's median contracted rate recognized by the plan on Jan. 31, 2019, for the same or similar item or service, in the same geographic region, adjusted for inflation. The QPA must be calculated by specialty. This is one of a number of lawsuits challenging various aspects of the implementation of the NSA, and it is not the first time the courts have sided with providers. The departments have not yet filed a notice of appeal or amended their sub-regulatory guidance to align with the district court's order.



CMS and OIG Issue Guidance on Inflation Reduction Act (IRA)

Last week, the Office of Inspector General (OIG) issued a technical assistance brief regarding the implementation of the inflation-based rebates that manufacturers must pay for Part B drugs whose prices increase faster than inflation. Specifically, the [brief](#) summarizes the administrative challenges that CMS may face in implementing the Part B rebate provisions and also identifies potential solutions to mitigate the challenges. In addition, CMS continues to update its dedicated [Inflation Reduction Act \(IRA\) website](#) with program guidance, frequently asked questions and timelines designed to guide the pharmaceutical industry through the significant regulatory changes occurring over the next few years.