



H&K Health Dose: May 2, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: The House is in Recess and the Senate Continues Business

The U.S. House of Representatives is in recess while the U.S. Senate continues on with legislative business. The Senate Committee on Health, Education, Labor, and Pensions (HELP) has a [hearing](#) scheduled for May 4, 2023, on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). PAHPA's current expiration date is September 30, 2023. Additionally, the Senate Committee on Finance is holding a [hearing](#) on mental health provider networks on May 3, 2023.

On May 1, 2023, Sen. Ben Cardin (D-Md.), a senior member of the Senate Finance Committee's Subcommittee on Health Care, announced that he will be retiring after this term and will not seek reelection.

Senate HELP Considers Bills on Increasing Access and Competition But Punts to Next Week

On May 2, 2023, the Senate HELP Committee was set to [consider](#) several bipartisan bills focused on improving access to generic medication, increasing competition for rare disease medications and reforming pharmacy benefit managers (PBMs). The bills to be considered include the Ensuring Timely Access to Generics Act, Expanding Access to Low-Cost Generics Act, Retaining Access and Restoring Exclusivity (RARE) Act and the Pharmacy Benefit Manager Transparency Act. However, the committee postponed the markup after several members called foul on Chair Bernie Sanders (I-Vt.) allowing certain amendments to be considered despite previous arrangements with Ranking Member Bill Cassidy (R-La.) to the contrary. While many of the amendments were bipartisan in nature, the negative characterization of the committee's procedural posture led to a recess being called.

The legislation considered by the committee could be included in a larger drug-pricing package that Senate Majority Leader Chuck Schumer (D-N.Y.) wants to bring to floor in the coming weeks. The markup will pick back up on May 11, 2023.

House Energy and Commerce Holds Hearing on Transparency

The House Committee on Energy and Commerce's Subcommittee on Health held a [legislative hearing](#), "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care," on April 26, 2023. In the hearing, discussion centered around the urgent need for increased transparency in healthcare. Representatives also discussed the need to disincentivize hospital consolidation by promoting competition, frustrations with PBMs and the need for the Centers for Medicare & Medicaid Services (CMS) to approve a new Alzheimer's medication. Programs such as 340B for hospitals were supported.

The hearing marked the first appearance of CMS Administrator Chiquita Brooks-LaSure before Congress since confirmation. During member questioning, Brooks-LaSure contended that CMS would strengthen its hospital price transparency rules and called on Congress to grant additional authority to CMS on price transparency.



House Ways and Means Oversight Hearing on Tax-Exempt Hospitals

On April 25, 2023, the House Committee on Ways and Means' Subcommittee on Oversight held a hearing on tax-exempt hospitals and the community benefit standard. The hearing considered the benefits provided by nonprofit hospitals to American communities in contrast to the cost of their tax-exempt status to American taxpayers. In particular, the discussion focused on how the IRS determines tax-exempt status, including the community benefit standard and whether the current reporting requirements (i.e., "Schedule H") are sufficient.

Lawmakers heard testimony from a panel of four witnesses, including a representative from the Government Accountability Office (GAO), academics and a representative from the American Hospital Association (AHA). Witnesses spoke to the immense value that tax-exempt status afforded to these nonprofit hospitals; however, some also noted the "variability" across different hospitals in meeting the community benefit standard, recommending several reforms.

House Appropriations Committee on Oversight and Accountability Hearing on the Provider Relief Fund (PRF) and Workforce Shortages

On April 26, 2023, the House Committee on Appropriations' Subcommittee on Departments of Labor, Health and Human Services, Education, and Related Agencies held a hearing, "Provider Relief Fund and Healthcare Workforce Shortages." The hearing featured testimony from Carole Johnson, administrator of the Health Resources and Services Administration (HRSA). Administrator Johnson overviewed HRSA's efforts to expand the current healthcare workforce and also stressed funding innovative healthcare training models to support behavioral health, healthcare coverage and care in home and community settings. The hearing largely focused on workforce shortages; however, Republican members also raised questions about waste and improper use of funds in the Provider Relief Fund (PRF), and Democrats expressed overall concerns that Republican budget cuts would limit access to healthcare.

Dueling Insulin Bills Compete for Attention in the Senate

Co-chairs of the Senate Diabetes Caucus, Sens. Jeanne Shaheen (D-N.H.) and Susan Collins (R-Maine), recently reintroduced their bipartisan insulin bill, the [Improving Needed Safeguards for Users of Lifesaving Insulin Now \(INSULIN\) Act](#). The bill seeks to comprehensively address the costs of insulin by removing barriers to access, capping out-of-pocket costs, fostering competition and extending patient protections. Their bill comes after Sens. Raphael Warnock (D-Ga.) and John Kennedy (R-La.) introduced their [own bill](#) aimed at lowering insulin costs. The bill seeks to cap out-of-pocket costs for insulin at \$35 per month for those who are uninsured as well as those with private insurance. The Inflation Reduction Act (IRA) included a similar cap on insulin costs for Medicare beneficiaries, but Republicans blocked inclusion of the private insurance cap. While both bills cap the cost of insulin at \$35 per month, the Shaheen-Collins bill is much broader.

The pairs of Senators are jockeying to have their bills prioritized by leadership as the Senate HELP Committee focuses its attention on drug pricing and lowering costs. Next week, the Senate HELP Committee is scheduled to conduct a hearing on insulin. At the hearing, senators will hear testimony from the CEOs of the three largest PBMs with a focus on insulin prices. The hearing comes after several drug manufacturers have announced plans to cut the cost of insulin for consumers. Neither Chair Bernie Sanders (I-Vt.) nor Senate Majority Leader Chuck Schumer (D-N.Y.) have demonstrated a preference between the two bills. However, Schumer has indicated that he would like to bring a legislative package on drug pricing to the floor this month. Kennedy stated, "It seems to me the short way home is to let all four of us come together with Sen. Schumer and work something out in one bill."



Senate Democrats Call for an Expansion of the Inflation Reduction Act

Last week, more than 20 Democratic senators – led by Sens. Amy Klobachar (D-Minn.) and Peter Welch (D-Vt.) – introduced [legislation](#) to strengthen the drug pricing reform in the IRA. Specifically, the Strengthening Medicare and Reducing Taxpayer (SMART) Prices Act would allow prescription drugs and biologics to be eligible for negotiation five years after approval by the U.S. Food and Drug Administration (FDA) and increase the overall amount by which Medicare can lower prices through negotiation. Additionally, the SMART Prices Act would also lower Medicare Part B drug prices through negotiation two years earlier than under current law and increase the overall number of drugs that U.S. Department of Health and Human Services (HHS) can negotiate starting in 2026. The bill is unlikely to move in the Republican-controlled House.

House Appropriations Schedule Announced

The House Appropriations Committee will begin conducting markups of fiscal year (FY) 2024 spending bills later this month. According to a letter from Chair Kay Granger (R-Texas) to panel members, the first subcommittee markups will be scheduled for May 17 and 18, with the first full committee markups tentatively planned for May 23, 24 and 25. The remaining subcommittee markups will be held June 7 and 8, with the full committee completing consideration of the measures June 13, 14 and 15.

REGULATORY UPDATES

CMS Issues Proposed Medicaid Rules

On April 27, 2023, CMS issued two proposed rules for the Medicaid Program: [Ensuring Access to Medicaid Services](#) and [Medicaid and Children's Health Insurance Program \(CHIP\) Managed Care Access, Finance, and Quality](#). Together, these proposed rules are designed to establish consistent access standards via greater transparency and new and updated reporting requirements for states and Medicaid managed care plans. Of particular note under the CHIP rule are the changes that the rule makes to the Medical Loss Ration (MLR) regulations applicable to Medicaid Managed Care Organizations (MCOs). The rule attempts to realign the Medicaid and CHIP MLR regulations with those in existence for Qualified Health Plans and Medicare Advantage organizations. The rule accomplishes this by making changes to 1) the provider incentive arrangement standards, 2) the quality improvement activity reporting and 3) the expense allocation methodology reporting. It also would require secret shopper surveys and an annual payment analysis for certain services. The rule includes requirements for the use of state directed payments and increased reporting requirements for states that use such a system.

The second rule, [Ensuring Access to Medicaid Services](#), addresses the use of advisory committees in the Medicaid care process. The rule also establishes a Beneficiary Advisory Group, which it sees as a vehicle for Medicaid beneficiaries, their families and related advocacy groups to provide feedback to the state on the effectiveness and coverage provided by the Medicaid program in that state. Comments are due on both rules by July 3, 2023.