



H&K Health Dose: March 28, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: House and Senate Discuss Prescription Drug Supply Chain and Lowering Costs

The U.S. House of Representatives and U.S. Senate are both in session this week, wrapping up legislative business before a two-week recess commences. The Senate Committee on Finance is hosting a hearing entitled "[Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers](#)" on March 30, 2023, featuring prescription drug experts, academics and economists, but no pharmacy benefit managers (PBMs). Meanwhile, the House Committee on Energy and Commerce is hosting a hearing entitled "[Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care](#)" on March 28, 2023.

The U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra will also continue testifying in front of various congressional committees on the [HHS budget](#). He is before the House Committee on Energy and Commerce and the House Committee on Ways and Means this week.

Senate Advances PBM Transparency Bill

On a mostly party-line vote, the Senate Committee on Commerce advanced the [PBM Transparency Act](#), bipartisan legislation that seeks to prevent PBMs from engaging in unfair practices such as spread pricing that drive up the cost of prescriptions for consumers. The PBM Transparency Act was introduced by Senate Commerce Chair Sen. Maria Cantwell (D-Wash.) and Chuck Grassley (R-Iowa). Several Republicans voted against party lines and supported the bill, despite GOP concerns regarding the power the bill gives the Federal Trade Commission (FTC) to enforce the bill. Both chambers will continue to focus on PBM reform, with the Senate Committee on Finance holding a hearing this week on the impact PBMs have on the health system and the House Committee on Energy and Commerce planning to hold their hearing.

House Committee on Energy and Commerce Fast Tracks QALYs Legislation

In a recent markup, the House Committee on Energy and Commerce advanced legislation that would ban the federal government's use of Quality Adjusted Life Years (QALYs) when evaluating the effectiveness of treatments and cures. The [Protecting Health Care for All Patients Act](#), championed by House Committee of Energy and Commerce Chair Cathy McMorris Rodgers (R-Wash.) and House Committee on Ways and Means Chair Jason Smith (R-Mo.), seeks to expand access to cures and prevent discrimination against Americans with disabilities and chronic illnesses. All House Committee on Energy and Commerce Democrats voted against the bill, suggesting it may struggle in the upper chamber should it clear the House. Members of the Democratic party have been supportive of banning the use of QALYs but indicated that this particular measure requires more negotiations to ensure the bill would not disrupt the implementation of drug price negotiations.

Lawmakers Take Issue with CBER's Clinical Holds

The top leaders of the House Committee on Energy and Commerce's Health Subcommittee, Reps. Brett Guthrie (R-Ky.) and Anna Eshoo (D-Calif.), recently sent a letter to the director of the U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) taking issue with the amount of clinical holds delaying an investigation for cell and gene therapies. The letter called on CBER to resolve issues through discussions with sponsors rather than through the issuance of a clinical hold to review novel products



expeditiously. With 40 percent of all clinical holds involving cell and gene therapy, lawmakers insinuated that CBER has been using holds as a means for the FDA to gain additional review time.

Senators Question Secretary Becerra on President Biden's Budget Proposal

Last week, the Senate Committee on Finance and the Senate Committee on Appropriations' Subcommittee on Labor, Health and Human Services, Education and Related Agencies received testimony from Secretary Becerra regarding President Joe Biden's fiscal year 2024 (FY24) budget proposal for the HHS. During questioning, members addressed funding levels for mental health and substance abuse, Medicare Advantage, telehealth, maternal health and Alzheimer's research, among other priorities. Members also questioned Secretary Becerra on the cost of prescription drugs, HHS' response to COVID-19 and the nation's healthcare workforce shortages. Secretary Becerra is scheduled to testify on the House side this week, marking the first time he will face the GOP-led committees.

REGULATORY UPDATES

No Surprises Act – CMS to Resume the Independent Dispute Resolution Process

On March 17, 2023, the Centers for Medicare & Medicaid Services (CMS) announced that under the No Surprises Act, certified independent dispute resolution (IDR) entities would resume issuing payment determinations for disputes involving items or services furnished on or after October 25, 2022.

In late February 2023, certified IDR entities were instructed to resume making payment determinations for payment disputes involving items or services furnished before October 25, 2022, as the relevant departments considered how to address a recent court decision involving the surprise billing regulations. Stakeholders noted concern with the potential pause, as IDR entities face a significant backlog of disputes.

The standards governing a certified IDR entity's consideration of information when making payment determinations in these disputes are provided in the August 2022 Requirements Related to Surprise Billing final rules, as revised by the recent U.S. District Court for the Eastern District of Texas order and opinion.

CMS notes that the necessary updates have been made to the federal IDR portal and process guidance documents to reflect the changes. Additional details are available on the [CMS website](#).

HRSA Announces Organ Procurement and Transplantation Modernization Initiative

The Health Resources and Services Administration (HRSA) [announced](#) an organ transplant modernization initiative that includes actions to strengthen accountability and transparency in the Organ Procurement and Transplantation Network (OPTN).

The initial phase of the initiative includes:

- **Making Data Available for Informed Decisions:** To support patients, clinicians, researchers and other stakeholders, HRSA is launching an initial data set of organ donation and transplantation data that will aim to improve decision-making in the organ donation process.
- **Securing Support for Modernization:** The [president's FY24 Budget](#) allocates approximately \$67 million to support the initiative; additional increases are expected.
- **Building HRSA Capacity for Modernization:** HRSA is using program management support services to further its overall approach of focusing on engaging more stakeholders in the process of modernization design and implementation.



- **Ongoing Consultation with USDS:** HRSA will continue to consult with the U.S. Digital Service (USDS) as it actively works to create a strategy for advancing OPTN information technology (IT) modernization.
- **Engaging Stakeholders:** HRSA will prioritize the critical needs affecting patients and clinicians by engaging with a diverse group of various stakeholders.
- **Collaborating with Industry:** In late spring of 2023, HRSA will host collaborative forums that promote participation from vendors and the IT community.
- **Soliciting Proposals for Modernization:** HRSA intends to issue requests for proposals (RFPs) for multiple contract awards to further support and improve the OPTN. HRSA will also increase the OPTN board of directors' autonomy through this expanded contracting process.

HRSA will keep stakeholders informed about the modernization initiative and provide regular progress updates on [its website](#).

CMS Continuous Enrollment Condition Unwinding

In March 2020, the Families First Coronavirus Response Act (FFCRA) established the "continuous enrollment condition," which provided states with extra federal Medicaid funding in exchange for maintaining enrollments for all Medicaid-enrolled individuals throughout the public health emergency (PHE). Many states implemented comparable policies that had a similar impact on the Children's Health Insurance Program (CHIP). Up until the passage of the Consolidated Appropriations Act 2023 (CAA 2023), the ending of the continuous enrollment condition was linked with the ending of the PHE. When the CAA 2023 was passed, the continuous enrollment condition end date was decoupled from the ending of the PHE and will now end on March 31, 2023.

Accordingly, five states are set to begin removing Medicaid and CHIP beneficiaries from the rolls in a few days. A couple other states have a 90-day redetermination process and will disenroll people in May 2023, while other states will start processing their renewals in April 2023.

Meanwhile, the Biden Administration continues to hold monthly webinars to answer stakeholders' questions about the redetermination process and beneficiary protections. The last call was held last week, where CMS noted that there would be an "unwinding" Special Enrollment Period (SEP) due to the unprecedented nature of the unwinding. Consumers in Federally Facilitated Marketplace (FFM) states who lose Medicaid or CHIP coverage between March 31, 2023, and July 31, 2024, can submit an updated application and receive a 60-day SEP window to enroll in coverage. State-Based Marketplaces have their own option to offer the unwinding SEP. A complete list of CMS resources may be found [on the Medicaid website](#).