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H&K Health Dose: September 24, 2024

A weekly dose of healthcare policy news

The U.S. House of Representatives and U.S. Senate are in Washington, D.C., for one more week before leaving until after election day. Congress must pass a spending measure by the Sept. 30, 2024, fiscal year (FY) deadline at the end of the week to avert a government shutdown. Last week, House Speaker Mike Johnson (R-La.) failed to get House Republicans' six-month continuing resolution (CR) – which included the controversial Safeguard American Voter Eligibility (SAVE) Act – across the finish line.

Over the weekend, legislators reached an agreement on a bipartisan compromise measure (H.R. 9747), described by Speaker Johnson as a "clean, three-month CR" to extend funding for essential programs through Dec. 20, 2024; the text and a section-by-section summary are available online. Of particular interest, Title II of the bill covers Health Extenders, including funding for No Surprises Act implementation. Notably, Section 202 addresses the "Extension of Authority to Issue Priority Review Vouchers to Encourage Treatments for Rare Pediatric Diseases," while Section 221 focuses on "Revising Phase-In of Medicare Clinical Laboratory Test Payment Changes." Should H.R. 9747 be brought up under suspension of the rules, the vote is projected to occur on Sept. 25, 2024, at around 5:30 p.m. ET. Senate Majority Leader Chuck Schumer (D-N.Y.) has taken steps to prepare a legislative vehicle for the Senate to lead on advancing a clean CR, should the House fail to do so.

Congressional committees are busy this week with several healthcare-related hearings. These hearings focus on a range of topics, including the cost of diabetes and obesity prescription drugs, artificial intelligence (AI) and women's reproductive health.

LEGISLATIVE UPDATES

House Passes Slate of Healthcare-Related Legislation

The House of Representatives passed a number of healthcare-related bills last week, positioning them for possible inclusion in an end-of-year package. The Autism CARES Act (H.R. 7213) passed by a 402-13 vote.

The following bills were passed by voice votes:

- Leveraging Integrity and Verification of Eligibility for (LIVE) Beneficiaries Act (H.R. 8084)
- Chronic Disease Flexible Coverage Act (H.R. 3800)
- Telehealth Enhancement for Mental Health (TELEMH) Act (H.R. 7858)
- Accelerating Kids' Access to Care Act (H.R. 4758)
- Dennis John Benigno Traumatic Brain Injury Program Reauthorization Act (H.R. 7208)
- Medicaid Program Improvement Act (H.R. 8111)
- Medicare and Medicaid Fraud Prevention Act (H.R. 8089)
- Supporting Patient Education And Knowledge (SPEAK) Act (H.R. 6033)
- BOLD Infrastructure for Alzheimer's Reauthorization Act (H.R. 7218)
- Supporting and Improving Rural EMS Needs (SIREN) Reauthorization Act (S. 265)
- Poison Control Centers Reauthorization Act (S. 4351)
- DeOndra Dixon INCLUDE Project Act (H.R. 7406)
- Vietnam Veterans Liver Fluke Cancer Study Act (H.R. 4424)
- H.R. 6160, to reauthorize a lifespan respite care program
- H.R. 8112, to require certain additional provider screening under the Medicaid program

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E&C Marks Up Telehealth Extension and Other Health Bills

The House Committee on Energy and Commerce (E&C) held a markup last week to consider 16 pieces of legislation. Among the measures passed by the panel was a bill (H.R. 7623) to extend COVID-19-era telehealth flexibilities for two years. The Telehealth Modernization Act extends flexibilities – including those related to geographic and originating site restrictions, practitioners eligible to furnish telehealth services, telehealth services for federally qualified health centers and rural health clinics, and the furnishing of audio-only telehealth services – through Dec. 31, 2026. Such flexibilities are currently scheduled to expire on Dec. 31, 2024. The package is offset by provisions to reform the pharmacy benefit manager industry. The bill passed by a vote of 41-0. The other healthcare-related bills considered by the committee include:

- H.R. 8107, Ensuring Access to Medicaid Buy-in Programs Act, advanced by a vote of 43-0
- H.R. 8108, to add a Medicaid state plan requirement with respect to the determination of residency of certain individuals serving in the Armed Forces, advanced by a vote of 42-0
- H.R. 3433, Give Kids a Chance Act, advanced by a vote of 43-0. H.R. 7155, United States-Abraham Accords Cooperation and Security Act, was included in the amendment in the nature of a substitute to H.R. 3433
- H.R. 7188, Shandra Eisenga Human Cell and Tissue Product Safety Act, advanced by a vote of 40-0
- H.R. 3227, Ensuring Seniors' Access to Quality Care Act, advanced by a vote of 20-18
- H.R. 9067, Building America's Health Care Workforce Act, advanced by a vote of 23-17

Senate HELP Committee Ranking Member Requests Information from Two Largest Contract Pharmacies

Senate Committee on Health, Education, Labor and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) sent letters to two drugmakers "requesting information to understand how these companies generate revenue from 340B, and how, or if, that revenue results in direct benefits for patients." Since launching his investigation in September 2023, Sen. Cassidy has sent letters to numerous participants in the 340B program, including letters to two hospital-covered entities, two community health center covered entities and two contract pharmacies.

Democrats Show Support for Extending ACA APTC Subsidies

Sen. Jeanne Shaheen (D-N.H.) and Rep. Lauren Underwood (D-III.) gathered 190 members of the U.S. Congress to write to congressional leadership urging timely action to extend the Affordable Care Act's (ACA) enhanced advance premium tax credit (APTC) subsidies. The press release and each letter are available online. While action is unlikely this year, as the subsidies don't expire until the end of 2025, this letter underscores the importance that many members of Congress place on this issue.

REGULATORY UPDATES

MACPAC Holds September 2024 Public Meeting

The Medicaid and CHIP Payment and Access Commission (MACPAC) agenda included sessions on recently published final rules, home- and community-based services, the Program of All-Inclusive Care for the Elderly Model, youth behavioral health residential services, managed care external quality review, justice-involved youth and the hospital payment index technical expert panel. Slides and a transcript will be posted online.

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Long-Anticipated MDRP Rule Released by CMS

Since the publishing of the Medicaid Drug Rebate Program (MDRP) proposed rule in May 2023, interested parties have been anticipating what this final rule would contain. The Centers for Medicare & Medicaid Services (CMS) chose not to finalize several of the most contentious elements from its May 2023 Proposed Rule, including Best Price stacking, a drug pricing survey and the definition of "manufacturer." However, CMS did finalize several significant changes to the MDRP. The finalized regulations are scheduled to take effect on Nov. 19, 2024, though some provisions related to managed care programs will have delayed effective dates. The Final Rule and Fact Sheet are available online. A summary of the Final Rule accompanies this Health Dose, as an email attachment.

CMS Releases Updated Medicaid Guidance

On Sept. 20, 2024, CMS issued guidance that aims to improve states' compliance with Medicaid and CHIP renewal requirements. According to the guidance, states have until the end of 2024 to assess compliance with federal renewal requirements and send CMS their assessments. States that aren't meeting current federal Medicaid eligibility requirements have until Dec. 31, 2026, to correct their deficiencies.

JUDICIARY

DOJ Petitions Supreme Court on Preventative Care

The U.S. Department of Justice (DOJ) filed a petition requesting that the U.S. Supreme Court review and reverse a lower court decision that considered the Affordable Care Act's preventative care coverage mandate. DOJ holds the position that the U.S. Department of Health and Human Services (HHS) supervises the United States Preventative Services Task Force, rendering the provision valid. DOJ asserts that should the judges disagree with that argument, the Supreme Court should rectify the constitutional inadequacy as it has in previous, arguably similar cases.