



H&K Health Dose: September 19, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Pivotal Week on Spending

The state of government funding remains in limbo as Congress barrels towards the Sept. 30, 2023, funding deadline. Twelve days out from a government shutdown, Congressional leaders are scrambling to find a path forward. Over the weekend, Republicans in the U.S. House of Representatives released their [bill text](#) to keep the government running through Oct. 31, 2023, fund border security and temporarily cut domestic spending by 8 percent. This was a deal brokered by several members of the House Freedom Caucus and Main Street Republicans Caucus. However, there are already a handful of Republicans who have vowed to vote against the continuing resolution (CR), jeopardizing its passage. Due to the many conservative priorities included in the bill, even if it passes the House, it is a non-starter on the U.S. Senate side, where senators are likely to support passage of a clean CR. Speaker Kevin McCarthy (R-Calif.) has indicated he plans to bring the bill to the floor for a vote on Sept. 21, 2023. However, on Sep. 19, 2023, House Republicans opposed the GOP-led annual defense appropriations bill, which indicates trouble for McCarthy should he bring the CR to a vote. Meanwhile, the Senate is looking to pass its minibus package of the Agriculture, Rural Development, Food and Drug Administration (Agriculture-FDA), the Military Construction, Veterans Affairs and Related Agencies Appropriations (Military Construction-VA), and Transportation, Housing and Urban Development and Related Agencies Transportation-HUD) bills this week.

A number of health-related hearings will be held this week: House Committee on Ways and Means will conduct a hearing on implementation of the No Surprises Act; Senate Committee on Finance will conduct a hearing on home healthcare; House Committee on Energy and Commerce's Subcommittee on Health will conduct a hearing on Medicare innovation; and House Committee on Oversight and Accountability will conduct a hearing on pharmacy benefit managers (PBMs), among others.

Sanders, Marshall Release Health Care Workforce Package

Senate Committee on Health, Education, Labor and Pensions (HELP) Chair Bernie Sanders (I-Vt.) and panel member Roger Marshall (R-Kan.) have reached an agreement on a healthcare workforce package that would provide a significant funding increase for the nation's community health centers. The [legislation](#) would reauthorize funding for a number of healthcare workforce programs that are due to expire on Sept. 30, 2023, including community health centers, the National Health Service Corps (NHSC) and the Teaching Health Center Graduate Medical Education (THCGME) program, among others.

The bill also includes several miscellaneous health policy provisions, including banning anticompetitive terms in facility and insurance contracts; requiring identification numbers for off-campus outpatient departments; and prohibiting the billing of facility fees for any telehealth service, including evaluation and management (E/M), as well as for any E/M service provided in the emergency department except for current procedural terminology codes 99281-99285. In addition, it includes a U.S. Government Accountability Office (GAO) report on the effectiveness of the NHSC at attracting healthcare professionals to health professional shortage areas (HPSAs). A summary of the bill's provisions can be found [online](#).

The HELP Committee will take up the bill during a [markup](#) scheduled for Sept. 21, 2023. Notably, the legislation does not have the support of HELP Committee Ranking Member Bill Cassidy (R-La.), who argues that the bill "lacks full Hyde [Amendment] protections and drastically increases spending without a plan to pay for it." Cassidy has expressed support for the package being advanced in the House, which contains lower funding amounts.



House Floor Schedule on Health Bills Fluctuating

House leadership announced on Sept. 18, 2023, that the [Lower Costs, More Transparency Act](#) was scheduled to receive a vote on the House floor. The sweeping healthcare package, focused on transparency, was introduced by early September by House Committee on Energy and Commerce Chair Cathy McMorris Rodgers (R-Wash.), Ranking Member Frank Pallone Jr. (D-N.J.), House Committee on Ways and Means Chair Jason Smith (R-Mo.), and House Committee on Education and the Workforce Committee Chair Virginia Foxx (R-N.C.). The bill incorporates bipartisan policy provisions that have advanced from the three committees. Key provisions in the bill include:

- Codify and enhance hospital price transparency requirements
- Health insurance and health plan price transparency requirements
- Site-neutral payments related to ambulatory payment classification (APC) groups for drug administration performed at off-campus outpatient departments
- PBMs and drug pricing reform, including requirements for group plan sponsors and a ban on Medicaid spread pricing
- Extension of community health center funding and the Special Diabetes Program
- Elimination of Medicaid disproportionate share hospital cuts for fiscal years (FYs) 2024-2025

The bill will need a two-thirds majority of the House to pass under suspension of the rules. House leadership pulled the measure hours before it was scheduled to be voted on, citing a desire to focus on government funding instead. However, it is also unclear if the healthcare package would garner enough support to be the heightened threshold needed for passage.

Another well-watched health bill is awaiting floor time: the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ([SUPPORT Act](#)) reauthorization, sponsored by House Committee on Energy and Commerce Subcommittee on Health Chair Brett Guthrie (R-Ky.), could be considered as soon as this week. The legislation would review congressional authorization of opioid recovery centers and training for providers who treat people with substance use disorder. Senate HELP Ranking Member Bill Cassidy (R-La.) has also introduced a reauthorization bill in the Senate, although the measure has not yet made its way through the committee.

Sanders Agrees to Confirmation Hearing for NIH Nominee

Senate HELP Committee Chair Bernie Sanders (I-Vt.) has committed to holding a confirmation hearing next month on the nomination of Dr. Monica Bertagnolli to serve as director of the National Institutes of Health (NIH). Sanders' statement followed an announcement by the Biden Administration that it had secured an [agreement](#) from a biotech company to limit the list price of a next-generation monoclonal antibody treatment for COVID-19 to equal to or less than the price in other major countries. Sanders had previously pledged to oppose all administration health nominees until the White House took unilateral action to cut drug prices.

House Committee on Energy and Commerce Holds Drug Shortage Hearing

House Committee on Energy and Commerce Subcommittee on Health convened a [legislative hearing](#) on preventing and responding to drug shortages. During the hearing, members discussed several bills seeking to address issues across the pharmaceutical supply chain, including:

- [H.R. ____](#), Stop Drug Shortages Act: Rep. Cathy McMorris Rodgers (R-Wash.)
- [H.R. 3008](#), Drug Shortage Prevention Act of 2023: Rep. Sara Jacobs (D-Calif.)



- [H.R. 3810](#), Drug Origin Transparency Act of 2023: Rep. Anna Eshoo (D-Calif.)
- [H.R. 3793](#), Ensuring Access to Lifesaving Drugs Act of 2023: Rep. Elissa Slotkin (D-Mich.)
- [H.R. 167](#), Patient Access to Urgent-Use Pharmacy Compounding Act of 2023: Rep. Morgan Griffith (R-Va.)

The hearing comes after Republicans and Democrats butted heads regarding whether to include drug shortage measures as a part of the Pandemic and All-Hazards Preparedness Act (PAPHA). Democrats were unsuccessful at convincing Republican counterparts to include drug and medical shortages in the committee's PAHPA bill. McMorris Rodgers has indicated she is willing to working towards a bipartisan drug shortage package, but an obvious path forward did not emerge during the legislative hearing. With government funding, a series of authorities set to expire and a looming threat of a shutdown, it will likely be difficult for the drug shortage issue to catch momentum.

Ways and Means Committee "Member Day" Meeting

Last week, the House Committee on Ways and Means hosted "Member Day," an annual hearing open to all members of the House to speak on legislative ideas, solutions or opinions on topics within the jurisdiction of the committee.

Healthcare issues raised during the hearing included revising the Medicare rule requiring a three-day inpatient stay for skilled nursing coverage (H.R. 5138) and ensuring that prior authorization decisions are made by physicians (H.R. 5213). Additionally, representatives raised concerns about high prescription drug prices and the role of PBMs in driving up costs, along with the need for legislation to ensure fair reimbursement for patients' medications (H.R. 2880). Focusing on lowering patient expenses, representatives also discussed how the government should promote competition in healthcare by removing obstacles for new providers and eliminating the inpatient-only service list (H.R. 2862).

Senators Express Concern Over DEA's Proposed Telemedicine Rule

Senate Select Committee on Intelligence Chair Mark Warner (D-Va.), Senate Minority Whip John Thune (R-S.D.) and others sent a [letter](#) to the Drug Enforcement Administration (DEA) expressing support for the agency's new engagement of a potential special registration for telehealth but sharing serious concerns over the agency's proposed rules on the future of prescribing controlled substances via telehealth. The bipartisan letter conveys concern that the DEA's proposed rules would drastically affect patient care and states: "Although we appreciate the limited flexibilities proposed by the rule, they are insufficient to meet the health care needs of our constituents and the needs of the providers who care for them."

REGULATORY UPDATES

White House Cancer Moonshot Advances \$240 Million Investment

President Joe Biden and First Lady Jill Biden convened a meeting of the Cancer Cabinet on Sept. 13, 2023, to [announce](#) new actions to advance the mission of the White House Cancer Moonshot.

- The Advanced Research Projects Agency for Health (ARPA-H) is partnering with the NIH, National Cancer Institute (NCI) and other agencies to develop a biomedical data fabric toolbox to advance progress in cancer research.
- ARPA-H's nationwide health innovation network, ARPANET-H, will be deployed to accelerate clinical trials for patients with cancer and other diseases.



- The National Aeronautics and Space Administration's (NASA) division for Biological and Physical Sciences, in partnership with the International Space Station (ISS) National Laboratory, will fund projects to advance cancer research and technology while in orbit on the ISS.
- The U.S. Department of Veterans Affairs (VA) has partnered with the NCI to develop a two-way exchange process to collect more data on cancer's effect on patients treated at VA facilities.
- The VA is also expanding its [National TeleOncology](#) program to more than 30 sites. The program makes highly specialized cancer care, such as virtual tumor boards, more easily available to veterans, especially those living in rural areas.

The announcement also included a number of new commitments from external groups.

DEA Telemedicine Listening Session

Under the COVID-19 public health emergency (PHE), flexibilities were created to permit the prescribing of controlled substances through telemedicine without an in-person visit. Earlier this year, the DEA issued a proposal to roll back the flexibilities ahead of the PHE's May 11, 2023, expiration and received strong opposition from stakeholders and Congress. The DEA then extended the pandemic flexibilities through Nov. 11, 2023, to reconsider its proposal and review input.

The DEA convened stakeholders on Sept. 12 and 13, 2023, for two days of meetings on the topic. Stakeholders provided input on reimbursement models, data collection in prescribing, and clinical guidelines and prescribing controls. Many presenters during the sessions expressed concerns that the previous regulations proposed in March 2023 could restrict access to controlled substances for conditions such as mental health, palliative care and substance use disorder treatment, underscoring the importance of flexible telehealth prescribing to guarantee patients' access to essential medications.

During these listening sessions, the agency announced that there would be an additional written comment period this fall for its telemedicine prescribing rules proposal, signaling it may again need to extend pandemic rules beyond the current Nov. 11, 2023, expiration date. The temporary rule extending COVID-19 telemedicine flexibilities for the prescription of controlled medicines can be found [online](#).