



## H&K Health Dose: May 23, 2023

A weekly dose of healthcare policy news

### LEGISLATIVE UPDATES

#### **This Week: June 1, 2023 Debt Limit Deadline Creeps Closer**

House Speaker Kevin McCarthy (R-Calif.) met with President Joe Biden on May 22, 2023, and had a "productive discussion," but they have not yet reached a deal on raising the U.S. debt ceiling. Notably, President Biden and Speaker McCarthy are facing an upcoming deadline known as the X-date as the two continue their debate to increase the federal debt ceiling. The X-date – the day the U.S. government says it can no longer fulfill all its financial obligations – is rapidly approaching, according to Treasury Secretary Janet Yellen. Yellen contends that "it is highly likely" the U.S. Department of the Treasury won't be able to pay all the bills in early June, potentially "as soon as June 1." The debt ceiling is a limit set by Congress on the amount of borrowing the Treasury can do, currently \$31.4 trillion. Breaching the debt limit is not the same as having a government shutdown. Because Congress in the past has always lifted the debt ceiling before the Treasury has run out of money, no one knows for sure what will happen if Congress doesn't act this time – what the Treasury and the Federal Reserve will do and how financial markets will react. If the debt limit is reached, the Treasury would likely consider prioritizing paying certain bills and delaying payments to others, generating concerns about which programs or services may be at risk. Experts warn that Medicare and Medicaid payments to providers and managed care companies might be delayed, as is possible for public health programs. Unless or until Yellen provides more information on the department's plans, all ideas on potential responses and repercussions of reaching the debt limit are speculative.

#### **House Energy and Commerce Subcommittee Advances Healthcare Bills for Full Committee Consideration**

Last week, the House Committee on Energy and Commerce's Subcommittee on Health [advanced](#) a slate of bipartisan healthcare bills to the full committee, addressing issues from price transparency, industry consolidation, health workforce, changes to Medicaid disproportionate share hospital reductions, Medicare site-neutral payment, the 340B Drug Pricing Program and pharmacy benefit management arrangements, among other issues.

Of note, the panel rolled 10 bills it had originally planned to consider separately into an amendment for a sweeping price transparency bill (HR 3281), the Transparent PRICE Act. This package includes many transparency provisions; pharmacy benefit managers (PBMs) oversight; a two-year reprieve from pending Medicaid disproportionate share hospital payment cuts; and reauthorizations necessary for continued funding for community health centers, the National Health Service Corps (NHSC), teaching health centers that operate the graduate medical education program and the special diabetes programs. The package is financed by eliminating remaining funds in the Medicaid Improvement Fund and by including a site-neutral policy impacting payment for physician-administered drugs. The committee advanced the newly combined Transparent PRICE Act with the support of all members present.

Notably, other site-neutral payment policies were not advanced, although Committee Chair Cathy McMorris Rodgers (R-Wash.) raised an amendment more broadly addressing site-neutral policies. She later withdrew the amendment after noting that although the policy needs more work, she intends to bring it back up. "Lowering health care costs is a top priority of mine," McMorris said. "And I am committed to additional work on these policies with the Ranking Member [Frank] Pallone and members of this committee to follow up on these important steps we are taking today."



The Energy and Commerce Committee will conduct a full committee markup on May 24, 2023, that will include some of the bills the subcommittee advanced, including:

- Securing the U.S. Organ Procurement and Transplantation Network (OPTN) Act
- Protecting Access to Treatments and Increasing Extremely Needed Transparency Act (PATIENT Act)
- Medicaid VBPs for Patients (MVP) Act
- Providers and Payers COMPETE Act
- Fairness for Patient Medications Act
- Animal Drug User Fee Amendment
- A bill to amend title III of the Public Health Service Act to ensure transparency and oversight of the 340B drug discount program

## **Senate HELP Chairman to Propose Health Care Package**

The Senate Committee on Health, Education, Labor and Pensions (HELP) Chair Bernie Sanders (I-Vt.) recently announced a plan to provide \$130 billion for community health centers and \$60 billion in funding to grow the workforce over the next five years. This push comes after the committee conducted hearings on community health centers and healthcare workforce shortages earlier in the year. Sanders' response represents a massive infusion of new healthcare funding, which likely will draw pushback from Republicans amid the House Republicans' effort to slash spending levels.

While Sanders' package is unlikely to progress, there might be an appetite for legislation to support community health centers. The House Energy and Commerce Committee was scheduled to mark up the [Strengthening Community Care Act](#) last week, but the committee has not yet advanced the bill. That bill would extend current community health center funding levels through 2028, but it does not include the funding increases seen in Sanders' proposal. Without reauthorization, funding for community health centers will expire in September 2023.

## **House Appropriations Committee Postpones Consideration of FDA Funding Bill**

The House Committee on Appropriations' Subcommittee on Agriculture, Rural Development, Food and Drug Administration recently marked up the fiscal year (FY) 2024 funding bill. The full committee was scheduled to convene and consider the appropriations bill on May 24, 2023. The bill provides \$6.6 billion in funding for FY 2024. Notably, the bill does not include a rider preventing pharmaceutical prescriptions to be shared electronically. The rider has been included in the U.S. Food and Drug Administration (FDA) funding bill since 2015.

Appropriations Committee Chair Kay Granger (R-Texas) announced that markups scheduled for this week would be postponed given "recent developments in the negotiations between Speaker McCarthy and the president, and in order to give the speaker maximum flexibility as talks continue.

## **House Lawmakers Reintroduce the Telemental Health Services Act**

Senior members of the House Energy and Commerce Committee Reps. Bill Johnson (R-Ohio) and Doris Matsui (D-Calif.) recently reintroduced the Telemental Health Care Access Act. This bill would permanently remove the requirement that doctors see Medicare beneficiaries in person within six months of being treated virtually for mental and behavioral health concerns. The appropriations package for FY 2023 included provisions of the bill and delayed the in-person requirement for telemental services through 2024.



## Delaware Senator to Retire at the End of Current Term

Sen. Tom Carper (D-Del.), a member of the Senate Committee on Finance's Subcommittee on Health Care, announced that he will not seek reelection. The four-term senator, who was instrumental in crafting and passing the Affordable Care Act, will retire at the end of the year, ending a political career that has spanned almost 50 years.

## REGULATORY UPDATES

### ARPA-H Announces Inaugural Program Targeting Bone Regrowth

The Advanced Research Projects Agency for Health (ARPA-H) announced the launch of its first program last week. The Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO) aims to develop breakthroughs that would allow the human body to repair its own joints. The project is led by one of ARPA-H's first program managers, [Ross Uhrich](#), a surgeon and former naval officer. ARPA-H officials noted that osteoarthritis is most common among women, with a high prevalence among Black and Hispanic populations. Research teams interested in NITRO can find more information [on the System for Award Management \(SAM\) website](#).

### GAO Releases New Report on Noncompete Agreements

The U.S. Government Accountability Office (GAO) released a new [report](#) detailing its investigation into non-compete agreements (NCAs), including those in the healthcare and social assistance employment sector. In its report, GAO estimated that 18 percent of workers were subject to NCAs at the time the study was conducted, and 38 percent of workers have been subject to an NCA at some point in their career. More than half of the 446 private sector employers responding to GAO's survey reported that at least some of their workers had NCAs. The report was requested by Sens. Ron Wyden (D-Ore.), Elizabeth Warren (D-Mass.), Tim Kaine (D-Va.), Christopher Murphy (D-Conn.), Marco Rubio (R-Fla.) and Todd Young (R-Ind.).

### FTC Aims to Broaden Regulation of Health Data Privacy Online

On May 18, 2023, the Federal Trade Commission (FTC) [released](#) a notice of proposed rulemaking seeking comment on proposed changes to the Health Breach Notification Rule (HBNR). The proposed regulations aim to clarify how the rule applies to health apps and other digital health tools that do not fall under the Health Insurance Portability and Accountability Act (HIPAA), the federal health privacy law that governs data protection by health plans and providers. The proposed changes to the rule follow a 2021 statement the FTC issued affirming that health apps and connected device companies are in fact subject to the HBNR. The policy statement raised considerations about what the FTC considers a data breach to be, what entities can be defined as healthcare providers under the HBNR and how federal lawmakers can keep pace with the fast-moving tech industry that has disrupted how consumers manage their health.

After reviewing public comments stemming from the 2021 policy statement, the FTC has proposed the following changes:

- Introducing new definitions to clarify the HBNR's application to health apps; this involves modifying the definition of "[personal health record] PHR identifiable health information" and introducing new definitions for "health care provider" and "health care services or supplies"
- Specifying that a "breach of security" includes unauthorized acquisition of identifiable health information resulting from a data security breach or unauthorized disclosure
- Modifying the definition of "PHR related entity" to align with the rule's scope, emphasizing that only entities accessing or sending unsecured PHR identifiable health information to a personal health record qualify



- Providing clarity on how a PHR collects personal health data from multiple sources
- Authorizing the use of email and other means to provide breach notices to consumers
- Improving the rule's readability to promote compliance

The public will have 60 days after the notice is published in the *Federal Register* to submit comments on the proposed changes.