



H&K Health Dose: May 16, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Debt Limit Looms as Negotiations Continue

U.S. Department of the Treasury Secretary Janet Yellen previously announced that the government could run out of money to fund government operations "potentially as early as June 1" unless Congress acts to address the issue. Secretary Yellen is expected to make another announcement on the debt limit deadline this week. President Joe Biden and congressional leadership are scheduled to meet on May 16, 2023. However, the clock is ticking toward June 1, 2023, with limited time in session for Congress and the president scheduled to leave the country later this week.

The House Committee on Energy and Commerce is set to [mark up](#) 17 bills on May 17, 2023. Additionally, the House Committee on Ways and Means will be holding a [hearing](#) on healthcare transparency on May 16, 2023, followed by an additional [subcommittee hearing](#) regarding anticompetitive and consolidated healthcare markets on May 17, 2023. The Senate Committee on Finance is also hosting a [hearing](#) on May 17, 2023, to examine ways to improve healthcare access in rural communities.

Energy and Commerce Committee to Mark Up 17 Bills

The House Energy and Commerce Committee has scheduled for May 17, 2023, a health subcommittee [markup](#) of 17 pieces of legislation, ranging from bills on pharmacy benefit managers (PBMs) and drug price transparency to 340B drug discount program reform. A full committee markup is expected on May 24, 2023.

This comes after the House Energy and Commerce Committee held a bipartisan [subcommittee hearing](#), "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care," on April 26, 2023. That hearing centered around many of the bills being marked up on May 17, 2023, all of which focus on transparency and competition. Notably, legislative proposals to tweak site-neutral payment policy were discussed during the hearing but were not slated for the markup on May 17, 2023. Committee staff has indicated that they are still working on site-neutral payment reform.

Senate Committee on HELP Advances PBM and Generic Drug Package

Last week, the Senate Committee on Health, Education, Labor and Pensions (HELP) passed a bipartisan package of bills on PBM reform and generic drug competition after postponing the initial legislative hearing due to disagreement over amendments at the beginning of the month. The committee passed the following bills, which now await a vote on the Senate floor:

- [S. 1067](#): The Ensuring Timely Access to Generics Act seeks to increase generic drug competition through increased oversight of the U.S. Food and Drug Administration's (FDA) citizen petition process.
- [S. 1114](#): The Expanding Access to Low-Cost Generics Act aims to prevent generic "parking" by allowing generic companies that are not first filers the ability to receive 180-day market exclusivity if the first filer does not come to the market after a specified time-frame.
- [S. 1214](#): The Retaining Access and Restoring Exclusivity (RARE) Act specifies that the seven-year orphan drug market exclusivity period for rare disease drugs would ban the approval of other drugs for the same use or indication rather than the same disease or condition.
- [S. 1339](#): The PBM Reform Act would ban spread pricing and expand oversight mechanisms for PBM operations.



Chair Bernie Sanders (I-Vt.) indicated that there will be future opportunities for consideration of drug pricing proposals that were not taken up during the markup.

Senate HELP Committee Hosts Roundtable on Healthcare Workforce

Additionally, the Senate HELP Committee recently held a roundtable on improving health workforce diversity and addressing workforce shortages. Committee Chair Bernie Sanders (I-Vt.) invited participants from Historically Black Colleges and Universities (HBCUs) to speak to specific challenges and ways to address the workforce shortage. Participants voiced support for the [Resident Physician Shortage Reduction Act](#), a bipartisan bill introduced by Reps. Terri Sewell (D-Ala.) and Brian Fitzpatrick (R-Pa.) earlier in the year. The bill would expand the number of Medicare-supported medical residency positions by 14,000 over seven years. Additionally, participants advocated for Congress to appropriate \$5 billion for academic health sciences centers at historically Black graduate institutions to support research and development infrastructure.

House Republicans Call for Oversight of CMS's Innovation Center

The House Committee on Ways and Means' Subcommittee on Health convened a [hearing](#) last week to consider policies that inhibit innovation and patient access. During the hearing, Republicans called for increased oversight of the Center for Medicare & Medicaid Innovation (Innovation Center), criticizing a recent Innovation Center proposal to reduce Medicare reimbursement for drugs cleared via the FDA's accelerated approval process. The agency believes the policy would incentivize manufacturers to complete confirmatory trials in a timelier manner, but Chair Jason Smith (R-Mo.) argued that it would slow innovation and reduce access to life-saving therapies. Rep. Vern Buchanan (R-Fla.) has proposed introducing legislation on the issue.

House Energy and Commerce Committee Begins Work on PAHPA Reauthorization

The House Energy and Commerce Committee's Subcommittee on Health recently held a [hearing](#) on preparing for future public health security threats. The hearing kicked off the legislative process for reauthorizing the Pandemic and All Hazards Preparedness Act (PAHPA), which is set to expire on September 30, 2023. Reps. Richard Hudson (R-N.C.) and Anna Eshoo (D-Calif.) indicated that their request for information issued back in February received more than 250 responses from stakeholders.

REGULATORY UPDATES

CMS Releases Latest Unwinding Guidance

In [guidance](#) released on May 12, 2023, Centers for Medicare & Medicaid Services (CMS) notes that states cannot touch their Medicaid premiums schedule until January 1, 2024, unless it's for new eligibility groups, to reduce premium amounts or to exempt new populations from premiums. Otherwise, the Biden Administration encourages states to submit a state plan amendment to reduce premium amounts or exempt additional populations from premium requirements. The guidance also explains when states must attempt to recontact a beneficiary due to returned mail and lets Medicaid agencies share beneficiary information with providers so they can encourage their patients to renew coverage. CMS also affirms that state Medicaid and Children's Health Insurance Program (CHIP) agencies can share beneficiaries' information with their providers as long as it's to encourage their patient to complete a renewal. States can also authorize certain Medicaid and CHIP providers to help their patients complete a renewal.

COVID-19 PHE Declaration Ends

May 11, 2023, marked the expiration of the COVID-19 public health emergency (PHE), which was officially declared on January 31, 2020. CMS [issued](#) an updated fact sheet detailing which pandemic-era policies will



and will not change with the end of the PHE. This update includes five new questions (14-18) on Medicare telehealth flexibilities. CMS is also maintaining and updating the [COVID-19 resource page](#), which includes fact sheets on various issues related to the end of the PHE.

Additionally, CMS on May 12, 2023 – a day after the public health emergency ended – shifted direction and agreed to let hospital-employed physical therapists, occupational therapists, speech-language pathologists, diabetes self-management training and medical nutrition therapy providers continue billing CMS for telehealth services as they have during the pandemic through the end of the calendar year 2023.

GAO Reports on 340B and Public Health Preparedness

The U.S. Government Accountability Office (GAO) [released a report](#) on the 340B drug pricing program. The information from GAO was requested by House Energy and Commerce Committee Chair Cathy Rodgers (R-Wash.). The report covers a variety of topics, including 1) Health Resources and Services Administration's (HRSA) 340B disproportionate share hospitals (DSH) percentage eligibility exception process, 2) characteristics of excepted hospitals, 3) the amount of 340B drug purchases and discounts that excepted hospitals indicated they had in 2020 and 2021, 4) the extent to which excepted hospitals indicated they provided discounts on 340B drugs to low-income, uninsured patients in 2022 and 5) results of HRSA's previous audits and other oversight activities to assess 340B Program compliance by excepted hospitals. GAO found that of the 53 hospitals with their exception request approved, 35 were located in rural areas and 31 had fewer than 100 beds. The report also found that excepted hospitals had varying explanations for why they requested an exception for the DSH percentage requirement, with many highlighting the impact of COVID-19 on their operations.

GAO also published a report, [Public Health Preparedness: Critical Need to Address Deficiencies in HHS' Leadership and Coordination of Emergencies](#), which assessed HHS' ability to lead and coordinate the nation's preparedness for and response to PHEs.

GAO concluded that HHS fell short in the following five areas:

1. Establishing clear roles and responsibilities
2. Collecting and analyzing complete and consistent data
3. Providing clear and consistent communication
4. Establishing transparency and accountability
5. Understanding key partners' capabilities and limitations