



H&K Health Dose: February 14, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. Senate worked over the weekend and passed a \$95 billion foreign aid package for Israel, Taiwan and Ukraine. House Speaker Mike Johnson (R-La.) will decide next steps in the U.S. House of Representatives. Notably, congressional leadership is focused on this emergency funding and not on the details of the fiscal year (FY) 2024 government funding packages, whose March 1, 2024, and March 8, 2024, deadlines are approaching. Because the March 8 bill is the vehicle for a health package, an agreement must be reached on government funding in order for any significant health legislation to be attached.

House Vote on QALY Legislation

The House approved the Protecting Health Care for All Patients Act (H.R. 485) on Feb. 7, 2024, with a slim majority of 211 votes in favor and 208 against. This legislation aims to prevent federal health programs such as Medicare and Medicaid from utilizing metrics like the quality-adjusted life year (QALY) to gauge the value of medical treatments. Currently, federal law prohibits the U.S. Department of Health and Human Services (HHS) from using QALY or similar measures that undervalue individuals with disabilities when determining coverage or incentives within Medicare. However, this restriction doesn't extend to other agencies or state-level decisions regarding Medicaid or the Children's Health Insurance Program (CHIP). Many of those programs use cost-effectiveness research when negotiating the placement of drugs on health plans' coverage lists and discounts with drug manufacturers. H.R. 485 expands these prohibitions to additional health programs, including Medicare prescription drug plans, Medicaid, CHIP, as well as health programs under the U.S. Department of Defense (DOD), U.S. Department of Veterans Affairs (VA) and the Federal Employee Health Benefits (FEHB) Program. Furthermore, it prevents federal agencies and states from waiving these restrictions under any waiver or demonstration authority such as experimental changes to state Medicaid programs starting in 2025.

While supporters of H.R. 485 argue that QALYs discriminate against people with disabilities, congressional Democrats have voiced concerns that the bill's language is too vague and could impact a broader set of comparative effectiveness analysis used in federal drug price negotiations.

Legislators Continue to Seek Feedback on 304B Drug Pricing Discussion Draft

As discussed in the Feb. 6, 2024, edition of Health Dose, members of the Senate 340B Bipartisan Working Group – Sens. John Thune (R-S.D.), Debbie Stabenow (D-Mich.), Shelley Moore Capito (R-W.Va.), Tammy Baldwin (D-Wis.), Jerry Moran (R-Kan.) and Benjamin Cardin (D-Md.) – released a [discussion draft](#) of legislation on reforms to the 340B drug pricing program. The group is accepting [stakeholder input](#) on the draft from stakeholders [via email](#) through April 1, 2024.

CBO Releases Budget and Economic Outlook, Omits Expected Drug Spending Projections

In a new analysis, the Congressional Budget Office (CBO) estimates that [spending on Medicare](#) will increase by about \$65 billion in 2024 due to larger payments to Medicare Advantage and Part D payments, while Medicaid expenditures will decrease by \$58 billion due to a high number of post-pandemic redeterminations.

Outlays for major healthcare programs are also predicted to increase as a percentage of Gross Domestic Product (GDP) from 2024 through 2034. The CBO projects increases in Medicare from 3.21 percent to 4.2 percent of GDP and temporary decreases in Medicaid before reaching 2.2 percent of GDP in 2034.



Though analysis of the Inflation Reduction Act's (IRA) cost savings and effects on drug innovation was expected as part of a broader economic update, the CBO omitted the topic. The omission indicates that the CBO is continuing to assess new data on the IRA's impact on pharmaceutical innovation.

This Week: House E&C Committee Subcommittee on Health Legislative Hearing on 19 Bills

The House Committee on Energy and Commerce (E&C) Subcommittee on Health will convene for a legislative hearing on Feb. 14, 2024, "[Legislative Proposals to Support Patients and Caregivers](#)," to consider 19 bills. Many of the bills would reauthorize health and public health programs, including the Lifespan Respite Care Program and the Dr. Lorna Breen Health Care Provider Protection Act, which provides funding for grants to support mental health education and awareness campaigns for healthcare workers.

Last Week: Committee Hearings on Drug Shortages; Drug Pricing; AI

The House Committee on Ways and Means (W&M) held a hearing to discuss domestic, chronic drug shortages on Feb. 7, 2024. Members discussed potential tax and trade policies intended to reduce overreliance on China and India in the drug supply chain, incentivizing long-term contracts with drug manufacturers and Medicare payment policies, including proposals to implement certain financial incentives for hospitals that maintain buffer stock inventories. Many of the policies discussed mirror those proposed by the Senate Committee on Finance in a white paper released last month, "[Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs](#)."

At a Senate Committee on Health, Education, Labor and Pensions (HELP) hearing on Feb. 9, 2024, legislators and witnesses honed in on patent reform as a mechanism to control drug pricing, arguing that drug manufacturing companies manipulate the current patent system to delay and prevent competition from low-cost generic and biosimilar alternatives. Members also discussed the role of pharmaceutical benefit managers (PBMs), with Sen. Tim Kaine (D-Va.) referencing the [Pharmacy Benefit Manager Reform Act \(S. 1339\)](#) – a bipartisan legislative package addressing PBM reform that has been stalled since it was approved by the committee in May 2023. Sen. Kaine shared that, based on a recent conversation with HELP Committee Chair Bernie Sanders (I-Vt.), the bill may come up for a floor vote in the near future with an amendment to include a delinking provision.

Congressional interest in artificial intelligence (AI) also continued last week at the committee level with the Senate Finance Committee convening for a hearing, "AI and Health Care: Promise and Pitfalls." At the hearing, members were optimistic about the potential for AI to help curb costs in the health sector while also expressing concerns about AI potentially exacerbating improper denials or delays in care associated with prior authorization. Last fall, Finance Committee Chair Ron Wyden (D-Ore.) and Ranking Member Mike Crapo (R-Idaho) [sent a letter](#) to the HHS requesting information regarding "current authorities and planned efforts by HHS and its sub-agencies...related to artificial intelligence (AI) tools, including predictive algorithms, rules-based automated systems, and more advanced AI systems, such as generative AI."

Last Week: House Oversight Committee Advances PBM Legislation

The House Committee on Oversight and Accountability approved a PBM reform bill on Feb. 6, 2024, the [Delinking Revenue from Unfair Gouging \(DRUG\) Act \(H.R. 6283\)](#). This legislation, introduced by Reps. Mariannette Miller-Meeks (R-Iowa) and Nanette Barragan (D-Calif.), would implement a number of PBM reforms to Medicare Part D and private employer-sponsored health plans:

- Implement de-linking policies, requiring PBMs to only charge a flat fee (bona fide service fee) for a drug's placement
- Prohibit "spread pricing," when a PBM charges the health plan more than they paid for a medicine



- Prevent PBMs from paying affiliated pharmacies more than competing pharmacies for the same services
- Ban "patient steering" practices, whereby a PBM encourages or requires patients to use its affiliated pharmacies
- Impose potential civil monetary penalties of \$10,000 for each day of a PBM's violation

Congressional Retirements

House E&C Committee Chair Cathy McMorris Rodgers (R-Wash.) announced on Feb. 8, 2024, her intent to retire from Congress at the end of her term. Rep. Rodgers has served in Congress for 10 terms and served as the E&C Committee Chair since 2023. She is also a former Republican Conference Vice Chair.

Rep. Rodgers' retirement announcement is the most recent of several Republican members of the committee. In addition to Reps. Jeff Duncan (R-S.C.), John Curtis (R-Utah), Greg Pence (R-Ind.) and Kelly Armstrong (R-N.D.), two committee members serving on the GOP Doctors Caucus – Reps. Michael Burgess (R-Texas) and Larry Bucshon (R-Ind.) – have also announced their intent to retire. Among other members, Rep. Brett Guthrie (R-Ky.) – current chair of the E&C Committee Subcommittee on Health – will likely be a contender for the leadership position.

Two other House Republicans also announced their intent not to seek re-election last week. Rep. Matt Rosendale (R-Mont.) will be running for the Senate seat currently held by Sen. Jon Tester (D-Mont.), and Rep. Mike Gallagher (R-Wis.) will step down at the end of the year after four terms in Congress.

Additionally, a special election to fill the seat left vacant when legislators voted to expel former Rep. George Santos (R-N.Y.) from Congress last December will take place on Feb. 13, 2024.

Rep. Victoria Spartz (R-Ind.) has reversed her decision to retire from Congress and will run for reelection in November 2024.

Additionally, former Maryland Gov. Larry Hogan (R-Md.) announced that he plans to run for the Maryland Senate seat currently held by retiring Sen. Ben Cardin (D-Md.).

A full list of House members retiring or seeking other office is [available online](#).

REGULATORY UPDATES

CMS Adjusts 2024 Hospital Outpatient Prospective Payment Rates

The Centers for Medicare & Medicaid Services (CMS) released an interim final rule on Feb. 13, 2024, that finalizes several payment rate adjustments to the 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center final rule originally [published last October](#). The agency noted that these changes would cause "minor" reductions; most of the adjustments listed in the rule were less than a \$1 reduction. Also clarified in the rule was that rural emergency health providers can preview their health quality reporting program data before its published, rather than review only available over the 30-day pre-publication period. Specific adjustments include an increase in Medicare reimbursements for hyperbaric oxygen therapy from \$75.61 to \$135.89, and an adjustment to payment rate of kidney histotripsy procedures. CMS summarized that "... (they) are not altering our payment methodologies or policies, but rather, (they) are simply correctly implementing the policies that (CMS) previously proposed, requested comment on, and subsequently finalized."

CMS 2024 Health Equity Award: Call for Nominations

CMS has announced the Call for Nominations for the 2024 CMS Health Equity Award. Nominations are now open to organizations working to advance health equity, showing others how to reduce disparities in healthcare access,



quality and outcomes. Nominations are due March 13, 2024. To apply, [email this form](#) to the CMS Office of Minority Health at OMH@cms.hhs.gov. CMS will announce the winner at the 2024 CMS Health Equity Conference May 29-30, 2024.

Types of eligible organizations include:

- public and private organizations at state, local, county and tribal levels
- non-governmental organizations, nonprofits, businesses, academic organizations and those impacting health outcomes
- organizations that impact health outcomes, philanthropic organizations, and tribal organizations who align themselves with or promote the CMS Framework for Health Equity and the CMS Strategic Plan's pillar for Health Equity

Eligible organizations must:

- demonstrate that they have reduced disparities in healthcare quality, access or outcomes in the communities and populations they serve
- serve at least one of the following populations: racial and ethnic minorities, people with disabilities, sexual and gender minorities, rural populations and other individuals impacted by persistent poverty and inequality

For more information visit CMS' [Health Equity Award webpage](#).

HRSA Issues Organ Transplantation RFPs

The Health Resources and Services Administration (HRSA) [recently released](#) updates related to its [Organ Procurement and Transplantation Network \(OPTN\) Modernization Initiative](#). The solicitations build on the HRSA OPTN Modernization Initiative announced in March 2023. To support the initiative, Congress enacted legislation in September 2023 authorizing HRSA to expand competition for OPTN contracts and transform the system. While the legislation gave HRSA additional flexibility, Congress has not yet appropriated the additional funding necessary to accomplish HRSA's modernization goals.

The most recent actions announced by HRSA include the following:

- releasing a contract solicitation to create an independent OPTN board of directors, including supporting a special election to seat a new board within six months of contract award
- issuing a multi-vendor contract solicitation to support broad competition and best-in-class vendors for critical OPTN functions to better serve the needs of patients, families and their care teams
- launching the discovery and development phase of the transition to a modernized OPTN information technology (IT) matching system that leverages industry-leading IT standards and practices
- actions to address "pre-waitlist" inequities in the organ waitlist process and reduce variations in referrals to transplant and in organ procurement practices, including standardizing and updating data reporting on referrals, time-to-patient assessment, time-to-organ procurement and other data to allow for greater accountability across geography and populations and facilitate improved system performance

CMS Updates Ground Ambulance Data Collection System User Guide; Announces Webinar

Starting January 1, 2024, selected ground ambulance organizations in Year 3 and Year 4 are required to report cost, utilization, revenue and other information to CMS. Organizations that fail to report may be subject to a 10 percent payment reduction. In order for organizations to prepare for reporting, CMS has published a User Guide and will be hosting an office hour session on Feb. 29, 2024, from 2:00 – 3:00 p.m. ET. CMS notes that the webinar is most



relevant to selected ground ambulance organizations in Year 3 and Year 4 of the Ground Ambulance Data Collection System (GADCS) as they are set to begin reporting data to CMS in 2024. Registration for the webinar is [available online](#).

CMS Releases 2021 Medicare Current Beneficiary Survey (MCBS) Chartbook

CMS released its annual update to the [Medicare Current Beneficiary Survey \(MCBS\) Chartbook](#) on Feb. 6, 2024, with data for 2021. The MCBS Chartbook is designed to provide the public with a new interactive collection of charts and tables based on estimates from the MCBS.

MACPAC Policy Brief Released

The Medicaid and CHIP Payment and Access Commission (MACPAC) announced the availability of a new policy brief, "[High-Cost Drugs and the Medicaid Program: MACPAC Evidence and Recommendations](#)," on Feb. 6, 2024. The brief refers to prior recommendations made in [2021](#) and [2023](#) on drug pricing.

Three Medicaid Rules Pending at OMB, Race to Finish Before CRA Begins

Three final rules that address Medicaid eligibility processes and include new reporting requirements on managed care organizations are pending at the White House Office of Management and Budget (OMB), following the schedule set by HHS' Fall 2023 Regulatory Agenda and putting the rules on track to be finalized by the spring.

CMS Posts Transcripts from 10 Patient-Focused Listening Sessions for the Medicare Drug Price Negotiation Program

Transcripts are [now available](#) from 10 patient-focused listening sessions, one for each of the selected drugs part of the IRA's Medicare Drug Price Negotiation Program. The listening sessions took place between Oct. 30, 2023, and Nov. 15, 2023, and included feedback from patients, caregivers, consumer and patient organizations, and other interested parties for this first cycle of drug pricing negotiations.

SAMHSA and ONC Announce the Behavioral Health Information Technology (IT) Initiative

The Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of the National Coordinator for Health Information Technology (ONC) will work together to invest more than [\\$20 million](#) in SAMHSA funding over the next three years to advance health information technology (IT) in behavioral healthcare and practice settings. The project supports the [HHS Roadmap for Behavioral Health Integration](#) and is consistent with the President Joe Biden's [call to action](#) to prevent, treat and provide long-term recovery support for mental illness and substance use disorders.

SAMHSA and OCR Release 42 CFR Part 2 Final Rule

The rule modifies the confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR Part 2. With this final rule, HHS implements the confidentiality provisions of Section 3221 of the [Coronavirus Aid, Relief and Economic Security \(CARES\) Act](#), which requires the HHS to align certain aspects of Part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules and the Health Information Technology for Economic and Clinical Health Act (HITECH). Finalized policies impact areas such as patient consent, disclosures, penalties, breach notifications, patient notice and safe harbor. For details, see the [Fact Sheet](#) or see the [unpublished PDF](#).