



H&K Health Dose: February 7, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week

The U.S. Congress is in session, and floor votes are scheduled through Feb. 9, 2023, according to the [weekly schedule](#) from Majority Leader Steve Scalise (R-La.). The House is scheduled to take a two-week break from votes after this week, with a return planned on Feb. 27, 2023. The biggest action in the House chamber this week will be President Joe Biden's address to the nation with the annual State of the Union on Feb. 7, 2023. The address will likely focus on the economy and foreign affairs. Regarding healthcare, the president will highlight expanding healthcare for veterans, addressing the opioid epidemic, progress on cancer research and efforts to address the national mental health crisis. There may be references to Medicare prescription drug pricing reform (including a call for a universal insulin price cap); thwarting cuts to Medicare, Medicaid and Social Security; and any updates on the unwinding the COVID-19 public health emergency (PHE).

Also this week, there are two notable healthcare hearings. The House Energy and Commerce Committee will hold a joint hearing of the Subcommittee on Oversight and Investigations as well as the Subcommittee on Health titled, "[The Federal Response to COVID-19](#)," on Feb. 8, 2023. This will be the first of several hearings on the federal health agencies' pandemic response and the transition out of the current PHE. Witnesses scheduled to testify include U.S. Food and Drug Administration (FDA) Commissioner Robert Califf, Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, Senior National Institutes of Health (NIH) Official Lawrence Tabak and Assistant U.S. Department of Health and Human Services (HHS) Secretary for Preparedness and Response Dawn O'Connell.

On Feb. 9, 2023, the Senate Judiciary Committee [will revisit a package of five bills](#) that aim to increase competition to brand drugs.

President Biden to Release Budget on March 9

President Joe Biden has announced that his budget proposal for fiscal year 2024 is expected to be released on March 9, 2023. The budget will likely contain major investments in cancer research, the Advanced Research Projects Agency for Health (ARPA-H), the IRS, cybersecurity programs and military funding, among others. The budget will also emphasize Biden's support for entitlement programs like Medicare, setting the stage for imminent debt ceiling discussions. Biden has indicated his desire to protect Medicare and Medicaid from funding cuts as conservatives push to reduce the national deficit.

Energy and Commerce Committee Addresses the Use of QALYs

The House Committee on Energy and Commerce's Subcommittee on Health recently held a hearing on the illicit fentanyl poisoning crisis, a cybersecurity breach of suicide lifelines and quality-adjusted life year (QALY) measures. While a majority of the hearing was spent discussing solutions to the fentanyl crisis, members also discussed [H.R. 485](#), the Protecting Health Care for All Patients Act. The bill was introduced by Energy and Commerce Chairwoman Cathy McMorris Rodgers (R-Wash.). It would ban the use of QALYs and other similar metrics in the Medicare program to determine a person's accessibility to life-saving treatments and medicine. The bill would also prohibit the importation of price controls on medicine from countries that use QALYs like the United Kingdom.



The bill represents an overarching push to combat discrimination against people with chronic illnesses and disabilities. The hearing revealed that majority and minority members might share concerns regarding the use of QALYs and the effect usage has on the U.S. healthcare system.

Wyden Presses CMS for Details on Drug Pricing Law Implementation

This past week, Sen. Ron Wyden (D-Ore.), chairman of the U.S. Senate Committee on Finance, wrote a [letter](#) to the Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure, asking for an update on what progress has been made to implement the Medicare inflation rebate provisions such as price gouging penalties on drug companies. In the letter, Wyden asked for details on when and how these provisions will be implemented. Specifically, the letter requests a clear implementation timeline and information on how the inflation rebates will be calculated and collected. Additionally, Wyden has indicated that the Senate Finance Committee, which has broad health jurisdiction, will track these inflation rebate provisions to ensure they lower prices for seniors and increase accountability. His letter comes after the HHS reported more than 3,000 drug price increases during 2022.

COVID-19 Emergency Declarations End on May 11

The Office of Management and Budget (OMB) announced the national COVID-19 PHE will end on May 11, 2023. Currently, the national COVID-19 emergency and the PHE are slated to expire on March 1, 2023, and April 11, 2023, respectively. OMB said it intends to "extend the emergency declarations to May 11, and then end both emergencies on that date."

There are numerous implications to ending these emergency declarations, each of which gave the federal government flexibility to waive or modify certain requirements in a range of areas, including Medicare, Medicaid, the Children's Health Insurance Program (CHIP) and in private health insurance, as well as to allow for the authorization of medical countermeasures and to provide liability immunity to providers who administer services, among other things.

Notably, the end of these emergency declarations will result in a reorganized federal COVID-19 response that shifts much of the responsibility for vaccine and treatment distribution to the private sector. People without health insurance will be responsible for paying out-of-pocket for vaccines, tests and treatments, while insured individuals may see the cost of such products increase. Vaccines will remain free for Medicare, Medicaid and CHIP beneficiaries.

Other flexibilities and regulatory authorities instituted in response to the COVID-19 PHE would also end (unless Congress intervenes), though some measures have already been de-linked from the emergency declaration. For example, the Consolidated Appropriations Act of 2023 extends certain telehealth policies through 2024 and permits states to resume Medicaid redeterminations in April 2023. Other provisions, such as the Medicare coverage requirement waivers (like the three-day hospital stay requirement prior to a skilled nursing facility admission) and permission for patients to receive extended supplies of many drugs under the Medicare prescription drug benefit, were not extended in the year-end funding bill. Hospitals will also no longer receive the 20 percent increased Medicare payment for the treatment of COVID-19 patients.

CMS is feverishly working on providing resource updates regarding the unwinding of the PHE. The following materials reflect recent changes and are currently available on the [CMS emergencies page](#):

- Provider-specific fact sheets for information about COVID-19 PHE [waivers and flexibilities](#)
- [CMS 1135 Waiver / Flexibility Request and Inquiry Form](#)
- [Acute Hospital At Home](#)



Updates will continue to be provided and can be found on the [CMS emergencies page](#) for the most up-to-date information.

REGULATORY UPDATES

CMS Releases Advance Notice of Methodological Changes For 2024 MA, Part D Payment Policies

Last week, the CMS released its [Advanced Notice](#) of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. The Advanced Notice includes a 3.12 percent year-to-year reduction in plan payments as a result of proposed changes to the Risk Model. Despite this, CMS projects that plans will see a net 1.03 percent increase in payments overall in 2024. The notice additionally includes updates to key MA and Part D Star Ratings, potential new measure concepts and certain existing quality measures as a means to align a set of core measures across federal programs and with private payers.

FTC Signals Increased Enforcement for Unauthorized Health Data Sharing

Last week, the Federal Trade Commission (FTC) announced that it has brought its first-ever [enforcement action](#) under its Health Breach Notification Rule against a digital health platform. This follows the FTC's previous warning, in September 2021, that health apps must comply with the rule or face penalties. This action represents the first time the FTC has sought to enforce the 2009 [Health Breach Notification Rule](#). The 2009 regulation was crafted in collaboration with the HHS to fill in gaps in Health Insurance Portability and Accountability Act (HIPAA) standards. These actions can be seen as part of a broader trend toward more active regulation of third-party data sharing.

CMS Releases Guidance on Changes to Medicaid Continuous Enrollment Requirement

CMS recently released updated guidance regarding changes to the Medicaid continuous enrollment requirement under the Consolidated Appropriations Act of 2023. The Families First Coronavirus Response Act (FFCRA) previously required states to continue Medicaid coverage for most enrollees during the COVID-19 pandemic, with a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP). However, under the Consolidated Appropriations Act, the Medicaid continuous enrollment requirement will end on April 1, 2023, and the temporary FMAP increase will gradually phase down, ending on Dec. 31, 2023. The Consolidated Appropriations Act also imposes new reporting requirements for states and expands the enforcement authorities of CMS to ensure compliance with the new regulations.

340B Contract Pharmacy Limits

The first of three pending appeals on whether a pharmaceutical manufacturer can limit the distribution of covered 340B drugs to contract pharmacies resulted in a victory for pharmaceutical manufacturers. The companies sued the HHS after regulators ordered them to stop restricting sales of 340B drugs to contract pharmacies. The U.S. Court of Appeals for the Third Circuit resolved conflicting decisions among district courts within the Third Circuit by ruling that the 340B program did not require pharmaceutical manufacturers to distribute or deliver drugs purchased by 340B-covered entities to all contract pharmacies that the entity had partnered with. Two other circuits are considering the same issue on appeal.